ANNUAL REPORT **2019**

KEDRION
BIOPHARMA

STATEMENT ON THE NOVEL CORONAVIRUS

This edition of our Annual Report goes to press at a time of great trial and distress in Italy and around the world. We have focused our energies – and continue to do so – on keeping our families, our employees and our communities safe, while ensuring that Kedrion Biopharma maintains its mission and obligation to provide vital therapies to those who need them. Please be safe.

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LETTER FROM PAOLO MARCUCCI

2019 WAS A YEAR OF GROWTH AND CHALLENGE. IN MEETING THOSE CHALLENGES, KEDRION BIOPHARMA EXCEEDED ITS RESULTS FROM THE PREVIOUS YEAR AND ESTABLISHED A POSITION FROM WHICH WE CAN LOOK TO 2020 WITH OPTIMISM AND PROMISE.

Dear Friends

In 2019 our revenues topped 800 million Euro, a nearly 18% increase over the previous year. While we continue to search for market expansion, our ability to focus has resulted in 90% of our revenues flowing from 13 countries. The US remains our most important market, generating 352 million Euro in revenue. Italy accounted for 159 million Euro and the rest of Europe for 95 million Euro. We see significant potential in markets in Latin America and the Middle East, especially Turkey. Revenue from the rest of the world area totaled some 202 million Euro.

A significant milestone was achieved in 2019, with the return of our Melville plant to renewed operation. Several regulatory hurdles have been cleared, allowing for consistently increasing levels of production. With all approvals in place we will be in a position to ramp up toward full potential.

2019 also saw the completion of new Quality Control and Research and Development laboratories within the S. Antimo plant, in Italy, with no interruption in production activities. This represented a relevant milestone in a 10 million Euro investment project involving the entire manufacturing site.

Our strategy to ensure ourselves continued availability of plasma has led us to become self-sufficient in this precious resource. We collect plasma in 29 centers in the United States and Hungary through KEDPLASMA. Collection has increased by 10% in the US and 6% in Hungary, totaling 957k liters in 2019. Plasma sales exceeded 209 million Euro, a 35% increase over 2018.

Kedrion's commitment to providing relief from conditions requiring hyper-immune plasma-derived therapies remains strong, especially with regard to Rh disease and Rabies. In 2018, we led a worldwide effort to celebrate the 50th anniversary of the discover of the first successful prophylactic against Rh disease. As a central part of these celebrations, we helped organize a global movement to eradicate this devastating threat to the lives of babies, which still affects half the pregnant women around the world. We continued this campaign in 2019, and supported the establishment of WIRhE, the Worldwide Initiative for Rh disease Eradication, headquartered at Columbia University Medical Center.

Our post-exposure prophylactic for Rabies, introduced in 2018, has garnered a remarkable 20% of the US market in 2019. This is a reflection of a product marketed by an energetic and creative sales force, one that focusses on education and collaboration with providers and patients.

While the market for treatment of Hemophilia A was disrupted by the welcome introduction of an effective monoclonal therapy, it is clear that there will continue to be a significant need and demand for plasma-derived Factor VIII – especially in areas where the new drugs are not available or affordable. We are committed to continuing to provide effective treatment to Hemophilia patients however we can, wherever they are.

Our work in the research and development of new plasma-derived therapies continues. We are ready to begin clinical trials of KIg10, our 10% Intravenous Immunoglobulin for Primary Immunodeficiency Disease (PID) patients after recruiting the requisite number of test subjects at an accelerated pace.

Our plasma-derived Plasminogen, another therapy in the development stage, is a promising treatment for the rare condition, Ligneous Conjunctivitis, which presents most often in childhood and can lead to blindness. Pending regulatory approval our Kedrion human Plasminogen has been available under Compassionate Use/Expanded Access programs and its use is now reimbursable by the National Public Health System in Italy.

Perhaps the most significant achievement of 2019 was the attraction of major investment from FSI SGR SpA, the largest Italian investment fund dedicated to growth of Italian companies. FSI has long been committed to the support of quality companies and their investment in Kedrion is a welcome vote of confidence. What's more, our existing investment partner, CDP Equity, has chosen to maintain its own stake by means of an additional pro-quota capital increase of Euro 16.7 million. These investments will allow us to not only achieve our plans and goals but to go beyond in pursuit of new opportunities.

While the Marcucci Family will continue to hold majority control, and I will maintain my role as Chairman, a new CEO will be appointed to take on the responsibility of day-to-day operations of the Company. This will give me the opportunity to focus on strategy, business development and the future growth and success of Kedrion in the long-term.

Confident capital investments from new and old shareholders, increased efficiencies, identification of new opportunities, and expanded capacities – especially in the US market – will enable us to obtain sustainable results, never forgetting that ultimately the objective of our work is to meet even more patients' needs worldwide.

Paolo Marcucci,
Kedrion Chairman and CEO

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COMPANY OVERVIEW

THE BASICS

Kedrion Biopharma is a biopharmaceutical company that collects and fractionates plasma to produce and distribute worldwide plasma-derived products for the prevention and treatment of rare and debilitating diseases and conditions such as Hemophilia, Primary Immunodeficiencies and Rh sensitization.

From its roots in Tuscany, Italy, where it is still headquartered, Kedrion has grown and expanded into a global influence in the plasma-derived sector. It is now the fifth most important provider of plasma-derived products around the world, serving health needs in some 100 countries.

As a long-time partner with the Italian National Health System, Kedrion Biopharma has advocated and supported the goal of national self-sufficiency in the production of crucial plasma-derived products in Italy. The company offers its unique expertise and experience to work with other countries toward pursuing this goal.

BEYOND THE BASICS

Kedrion Biopharma's motivating metaphor is a bridge. Indeed, when it comes to its fundamental activity - collecting plasma, turning it into medicines and therapies to treat serious and rare conditions and distributing them to caregivers and patients - Kedrion ***is*** a bridge. But even beyond that, Kedrion Biopharma brings people and resources together to help others around the world. We are committed to patients who are seeking a way across the troubled waters of rare disease and threatening conditions.

*Including Castelvecchio Pascoli plant (Lucca, Italy) completion impending
**Source: Marketing Research Bureau "The Worldwide Plasma Protein Market 2017" and publicly available information
As of December 31st, 2019

Headquarters in Italy with subsidiaries in Europe, USA, Latin America and Asia

5* manufacturing plants in 3 countries

29 plasma collection centers worldwide

5th world player and 1st in Italy in terms of revenues in the field of plasma-derived products**

Partner in the self-sufficiency program in Italy

Commercial presence in approximately 100 countries

2019 turnover: 808.2 million Euro

Annual growth rate since 2012: 11.5%

People annual increase since 2011: 8.5%

BioSC, the first GLP certified laboratory in Italy for pathogen safety

12 voluntary standards and certifications in manufacturing, human resources, environment

OUR PEOPLE – BRIDGE BUILDERS

Kedrion is about people helping people. To meet our mission of providing the best possible help to those suffering from rare and serious conditions, we know it is essential that we provide the best possible care and attention to our valued employees. An important part of this is in designing meaningful education and training programs and encouraging professional and skill growth at all levels.

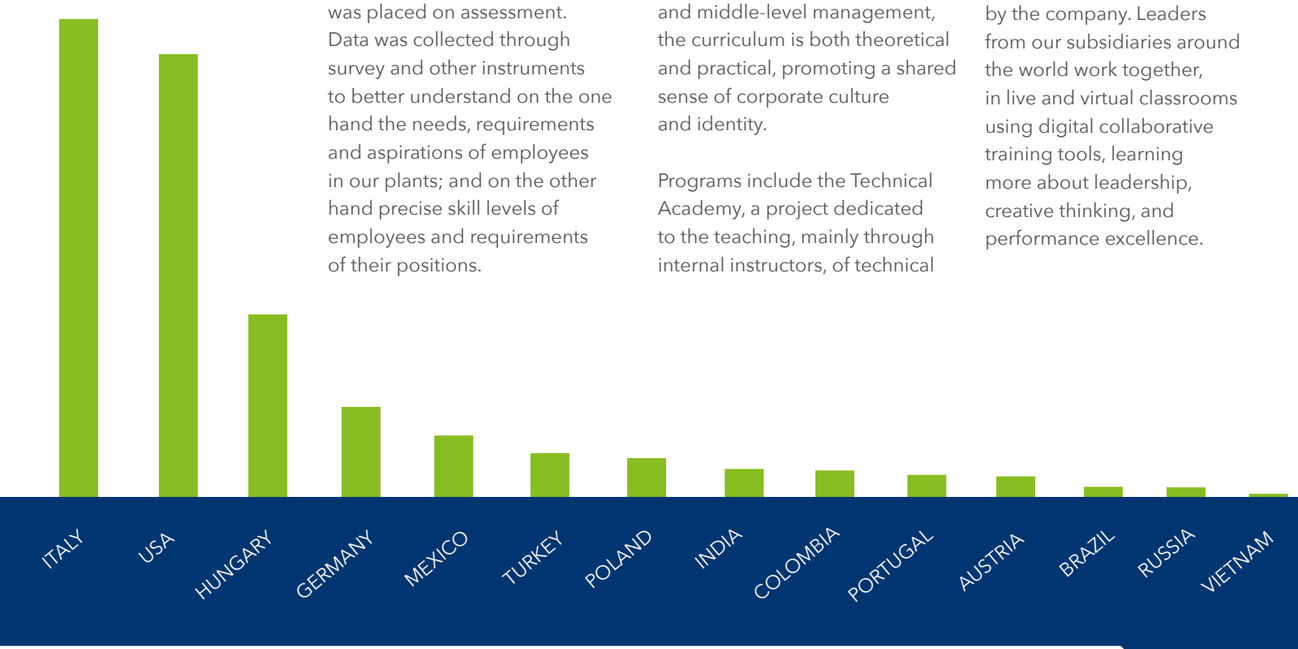
A significant emphasis in 2019 was placed on assessment. Data was collected through survey and other instruments to better understand on the one hand the needs, requirements and aspirations of employees in our plants; and on the other hand precise skill levels of employees and requirements of their positions.

These data will allow us to design more effective training programs throughout the company.

At the management level, Kedrion has established a unique program within our Scuola Kedrion, a collaborative project with Fondazione Campus in Lucca, Italy. Many of the courses and curricula of the school, which has been in operation for more than ten years, are aimed at key people in the company coming from all our global locations. Serving top and middle-level management, the curriculum is both theoretical and practical, promoting a shared sense of corporate culture and identity.

Programs include the Technical Academy, a project dedicated to the teaching, mainly through internal instructors, of technical knowledge and skills related to the production of plasma-derivatives.

Especially important among the school's activities is the Kedrion Management Development Program (KMDP). The program was inaugurated in 2017 and has trained some 50 managers, supporting them on their development path addressing best practices, management tools and the Leadership Model implemented by the company. Leaders from our subsidiaries around the world work together, in live and virtual classrooms using digital collaborative training tools, learning more about leadership, creative thinking, and performance excellence.

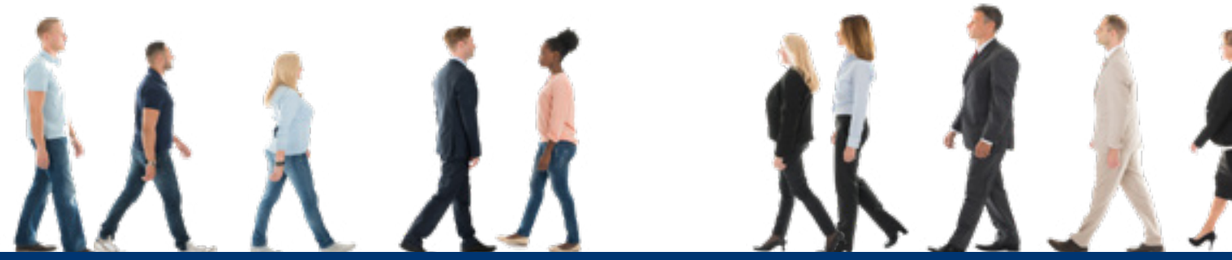


SUPPORTING GROWTH

A very effective and impactful element of the KMDP offers participants the opportunity to join in a mentoring relationship with a senior manager. Mentors can provide mentees very individual advice on career and development goals. Mentees can pursue knowledge and experience particular to their aims and interests.

> It requires much reflection and humility to place yourself before a mentee. Even though I have many years of personal and professional experience... I think that it is important to have respect for the person sitting in front of you. I always try to get my colleague to speak so that I can grasp the essence of the help I can offer. Often just talking and articulating your thoughts to a person (to the mentor) who does not know your story helps a lot. I always try to sincerely "offer a little bit of me" by sharing my failures and successes, both professional and personal, where I come from, and describing the facts that led me to become what I am today.
>
> **Sandra Rimorini,** Chief Quality & Regulatory Officer

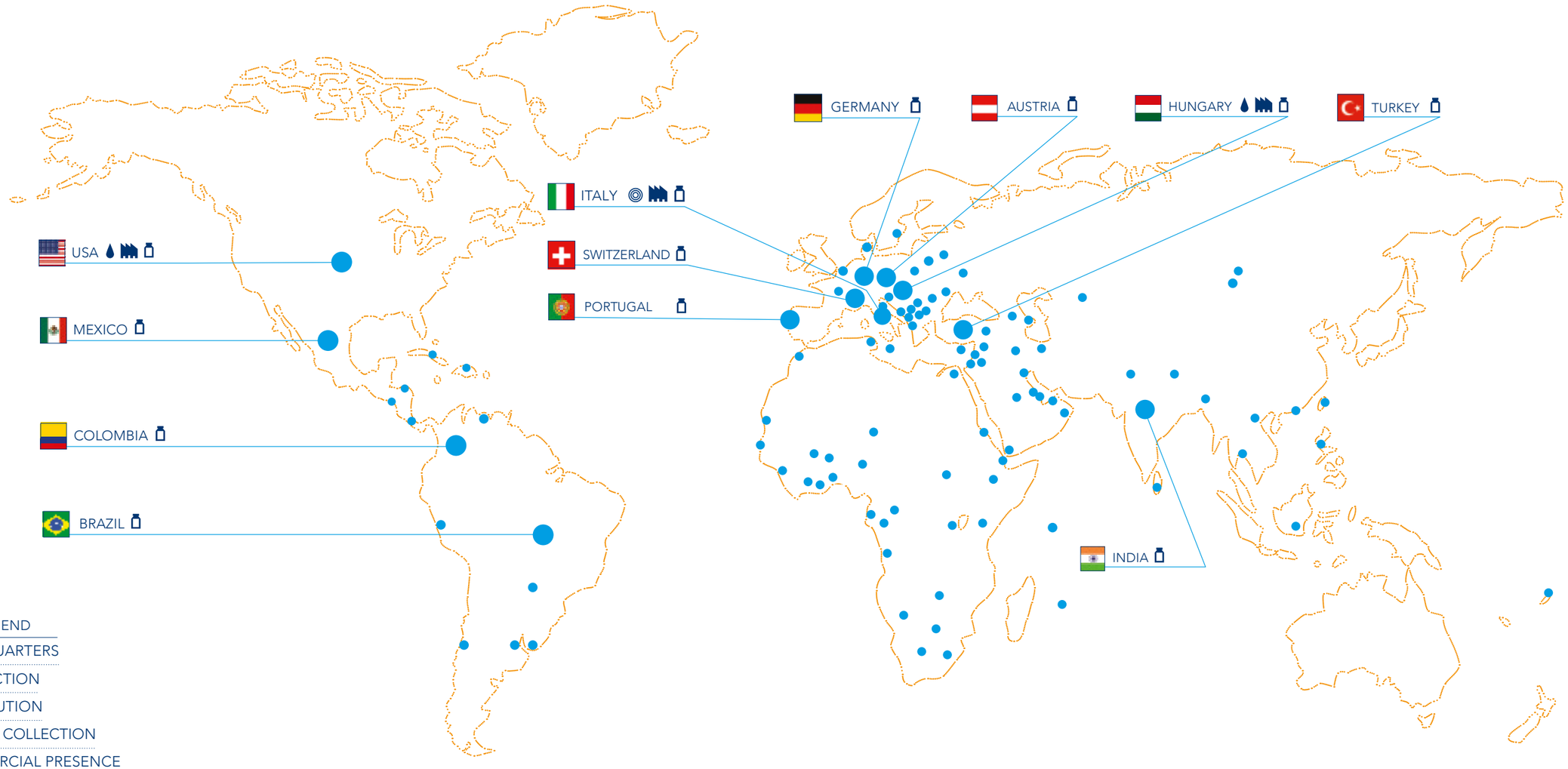
> Having a mentor during the lifelong path of learning is always something special. Participating in trainings and attaining up-to-date information is always easier and more interesting having an experienced colleague by my side. (A mentor)... pays me active attention, asks questions and by asking questions drive(s) me to ask the right questions at the right time and this way helps me to take one step further... (The mentor) gives me feedback, provides ideas and vision and by doing so acts as a personal guide on the road. And finally such interaction becomes inspiring for both. The one always ready to take an extra mile will always appreciate having such an opportunity.
>
> **Akos Toth,**
> Administration and Controlling Director, HUMAN BioPlazma, Hungary



2,656
PEOPLE IN THE WORLD

As of December 31st, 2019

OUR WORLD



MAP LEGEND

- HEADQUARTERS
- PRODUCTION
- DISTRIBUTION
- PLASMA COLLECTION
- COMMERCIAL PRESENCE

As of December 2019

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WHAT WE OFFER

PRODUCTS

1 RARE DISEASES

HEMATOLOGY / HEMOPHILIA
EMOCLOT / HUMACLOT / PLASMACLOT / EMOWIL / KLOTT* / KOĀTE***
Factor VIII/Von Willebrand Factor concentrate

NUWIQ**
Recombinant Factor VIII

WILFACTIN**
Von Willebrand Factor concentrate

AIMAFIX / KEDRIFIX / IXED*
Factor IX concentrate

EMOSINT
DDAVP Desmopressin

IMMUNOLOGY / NEUROLOGY
Ig VENA / HUMAGLOBIN Liquid / KEDRIGAMMA / VENITAL*
Standard i.v. Immunoglobulin 5%

GAMMAKED***
Standard i.v. Immunoglobulin 10%

NAXIGLO / KEYCUTE*
Standard s.c. Immunoglobulin

2 MOTHER AND CHILD HEALTH

RhoGAM / ImmunoRHO / KeyRho / MICRhoGAM
Anti-D i.m. Immunoglobulin

IMMUNOHBs 180 IU
Anti-Hepatitis B i.m. Immunoglobulin

3 INTENSIVE CARE & TRANSPLANTATION

UMAN ALBUMIN / UMAN SERUM / KALBI / HUMAN ALBUMIN / KEDRIALB / ALBITAL* / KEDBUMIN*** / ALBUKED*** / ALBUMINA LFB**
Human Albumin solution

KEDRAB***
Human Rabies Immunoglobulin

VENBIG / KEYVENB
Anti-Hepatitis B i.v. Immunoglobulin

IMMUNOHBs / UMAN BIG / KEDHBs*
Anti-Hepatitis B i.m. Immunoglobulin

TETANUS GAMMA / TETIG
Anti-Tetanus i.m. Immunoglobulin

UMAN COMPLEX / KEDCOM*
PRONATIV**
Prothrombin Complex concentrate

AT III KEDRION / ATKED*
Antithrombin concentrate

KOLFIB / SILKETAL*
Fibrin sealant

K FLEBO
Potassium aspartate

4 TRANSFUSION MEDICINE

CERUS INTERCEPT**
Plasma and platelets pathogen inactivation

PLASMASAFE / PLASMAGRADE*
Pharmaceutical grade plasma

SERVICES

1 PLASMA PROCESSING FOR NATIONAL SELF-SUFFICIENCY PROGRAMS (ITALY AND ABROAD)

2 TECHNOLOGY TRANSFER

3 VIRUS AND PRION CLEARANCE STUDIES (BioSC)

*Products for the Italian Self-Sufficiency Program **Products in license ***Products only available for the US market
As of March 2020

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2019
STEP BY STEP

JANUARY

CLINICAL STUDY FOR KIg10 GETS UNDERWAY IN THE UNITED STATES

The US Food and Drug Administration (FDA) approved the company's application for Investigational New Drug (IND) status to begin the clinical study for our 10% Immunoglobulin (KIg10). This allows us to begin work on the clinical study to demonstrate the efficacy and safety of this product in the treatment of adult patients with Primary Immunodeficiency Diseases (PID).

FEBRUARY

FDA AUTHORIZES THE RESUMPTION OF PRODUCTION ACTIVITIES AT THE MELVILLE (USA) PLANT

All the intermediates produced in the Melville plant - Cryo Paste, Fraction II+III and Fraction V - were approved by the Food and Drug Administration (FDA), allowing Kedrion to resume production activities at its US site.
This is a decisive step forward on the path towards the plant's full integration into the company's global industrial system.

NARRATIVE MEDICINE AT THE CENTER OF EPATEAM "TRANSPLANT STORIES" MEETING

"Narrative medicine" emphasizes listening to patient stories as an important therapeutic tool that can transform the healing relationship. Practitioners encourage a dialog that begins with listening to the patient who is experiencing the treatment path first-hand.

The role of story in transplant medicine was the focus of a meeting organized with the support of Kedrion by EPATEAM, a networking project dedicated to liver transplantation, on the occasion of the first anniversary of the launching of the Epateam.org digital platform. Dr. Rita Charon, Director of the Program in Narrative Medicine at the Columbia University College of Physicians and Surgeons, spoke to the assembled group of researchers, healthcare professionals and patients and shared her research.

MARCH

TUSCANY PHARMA VALLEY IS LAUNCHED, KEDRION AMONG THE FOUNDING COMPANIES

Toscana Pharma Valley is the first network of leading pharmaceutical industry companies in the Tuscany Region. Kedrion is one of the promoters of this innovative network that makes collaboration and integration a strategic lever for both industrial growth and for the development of local communities.

APRIL

16th INTERNATIONAL CONGRESS ON HEMOPHILIA – ANTALYA, TURKEY

During the celebration of World Hemophilia Day, Kedrion participated in the Antalya conference, collaborating with its Turkish business partner ONKO to promote awareness of prevention and eradication strategies for inhibitors. The role of plasma-derived Factor VIII in the treatment of Hemophilia A was presented during the scientific symposium.

MAY

FOCUS ON TECHNICAL AND SCIENTIFIC EXPERTISE AT BOLOGNANA

The "Technical Skills Framework" pilot project was launched at the Bolognana production site in Italy. With the goal of strengthening Kedrion's assets of technical-scientific knowledge and taking full advantage of the expertise of our specialists, this initiative aims to identify and evaluate all the technical skills throughout the company, in order to design specific programs for training, development and continuous improvement.

JUNE

ENVIRONMENTAL SUSTAINABILITY: EPD CERTIFICATION® EXTENDED TO ALL PRODUCTS MADE IN BOLOGNANA

The voluntary international EPD® certification (Environmental Product Declaration) was extended to all products manufactured at our plant in Bolognana, Italy (Factor VIII, Albumin and Immunoglobulin). In 2016 Kedrion was the first company in the world in the plasma-derivatives industry to obtain this certification, which provides transparent, verified and comparative information on the environmental impact of the entire life cycle of a product or service.

PERIPHERAL NERVE SOCIETY (PNS) ANNUAL GLOBAL MEETING

Kedrion participated in the 2019 PNS Meeting in Genoa, Italy, during which the company organized a scientific symposium aimed at exploring potential new therapeutic frontiers in the treatment of Peripheral Neuropathies induced by chemotherapy drugs.

TWO-DAY HEMOPHILIA CONFERENCE ORGANIZED BY KEDRION IN TRIESTE, ITALY

The current state of Hemophilia treatment and the key role of Factor VIII; patients at the center of the therapeutic pathway; the global challenge of access to treatment: these themes were the focus of the Congress on " Hemophilia care: Building Confidence" a wide-ranging medical and scientific event organized entirely by Kedrion. The unique meeting brought together clinicians, donor and patient associations, and prestigious international guests in Trieste, Italy.

JULY

KEDRION WINS "LEGAL MANAGEMENT OF THE YEAR" AWARD

Kedrion won the Industry Life Sciences award for "Best Legal Management" at the 2019 TopLegal Corporate Counsel & Finance Awards. The company won this prestigious award due to the positive outcome of the antitrust case that acquitted our company after the AGCM investigation, following participation in the consortium of Emilia Romagna Region call for tenders.

OPEN INNOVATION: KEDRION SUPPORTS RESEARCH PROJECT FOR THE TREATMENT OF HEMOPHILIA A

The University of Pisa, in collaboration with Kedrion Biopharma announces the winning project of the "Proof-of-Concept" (PoC) call intended to finance cutting-edge technologies from innovative idea to working prototype. The winner: INFOREC biotechnology project, "Engineering and production of recombinant Factor VIII, with long half-life and high coagulating activity".

AUGUST

SUBJECT ENROLLMENT COMPLETED FOR PEDIATRIC CLINICAL STUDY OF KEDRAB®

Kedrion completed the enrollment process for research subjects in the clinical study to demonstrate the efficacy, immunogenicity and safety of our Human Rabies Immunoglobulin (HRIg) in children with suspected exposure to Rabies virus. The goal is to obtain approval by the Food and Drug Administration (FDA) of pediatric indication for use in Rabies post-exposure prophylaxis (PEP).

SEPTEMBER

FIRST INVESTMENT PHASE COMPLETED AT SANT'ANTIMO, ITALY PLANT

The dedication of a new building to house Quality Control and Research & Development laboratories at the Campania site follows the earlier completion of a building for Management and Administrative Offices. The new structures are centerpieces of an extensive 10 million Euro investment plan for the Sant'Antimo plant.

KEDRION RENEWS ITS COMMITMENT TO THE FIGHT AGAINST HEMOLYTIC DISEASE OF THE FETUS AND NEWBORN (HDFN)

The Second Annual International Symposium for the Eradication of HDFN was held on September 28, in the beautiful setting of the Istituto degli Innocenti in Florence (Italy). It was the occasion for the official launch of WIRhE (the Worldwide Initiative for Rh disease Eradication), a new non-profit entity, established in New York under the auspices of Columbia University. Kedrion supported the event with an unrestricted grant.

"GUELFO MARCUCCI" PRIZES AWARDED

Two young scientists, Valentina Rubino from the University of Basilicata and Francesca Stufano of IRCCS Ca' Granda Policlinico in Milan, were awarded the 2019 Guelfo Marcucci scholarships. The prizes, part of the Research Awards presented by the Carlo Erba Foundation in Milan, were established by Kedrion in memory of company founder, Guelfo Marcucci, to recognize young scientists for original research in non-oncological hematology.

KEDRION SUPPORTS HUNGARIAN NEUROLOGICAL COMMUNITY

With the aim of staying current with the latest research and developments in the field, Kedrion supported the annual Hungarian Neuroimmunology Congress, held in the town of Visegrad. Prof. Giovanni Antonini, of La Sapienza University of Rome (Italy), was invited by Kedrion to speak on the diagnosis and treatment of Dysimmune Neuropathies.

OCTOBER

RESULTS OF CLINICAL STUDY ON KEDRAB® PUBLISHED IN *HUMAN VACCINES & IMMUNOTHERAPEUTICS*

The results of a clinical study on KEDRAB®, the new Human Rabies Immunoglobulin (HRIg) developed by Kedrion in collaboration with the Israeli company, Kamada, are published in the pages of the prestigious scientific journal ***Human Vaccines & Immunotherapeutics***. This was a comparative phase 2/3 study to demonstrate the safety and efficacy of KEDRAB® compared to an already approved HRig. Based on the results of this phase 2/3 trial and two phase 1 trials, the Biologic License Application was granted by the FDA to Kedrion for distribution of KEDRAB® in the US.

TUSCANY PHARMA VALLEY PROJECT ADVANCES

A seminar dedicated to the Tuscany Pharma Valley project, was held during Connext, a Confindustria event in Florence. The project brings Tuscan pharmaceutical companies together with the Region of Tuscany to collaborate, grow and innovate through mutual exchange of expertise and experience. Kedrion is one of the leaders of this model project.

KEDRION LEADS DISCUSSION ON THE USE AND VALUE OF FACTOR VIII IN LATIN AMERICA

The current and future role of Factor VIII-based replacement therapy in the treatment of Hemophilia A was the central theme of a symposium organized by Kedrion at the International Congress of the CLAHT Group (Latin America Cooperative Group on Haemostasis and Thrombosis) in San José, Costa Rica. The congress was attended by leading Latin American experts in the field and was an important opportunity in this geographical area to demonstrate Kedrion's commitment to collaborate and dialogue with researchers, practitioners and the community of patients with Hemophilia.

NOVEMBER

KEDRION JOINS IPOPI AT THE 2019 IPIC CONGRESS IN MADRID, SPAIN

The importance of early diagnosis and the key role played by research and continuous updating in the field of Immunology. These were the most-discussed topics at the 2019 International Primary Immunodeficiencies Congress (IPIC 2019) of the International Patient Organization for Primary Immunodeficiencies (IPOPI) in Madrid, Spain. Kedrion has a strong and long-standing collaboration with IPOPI and participated in this Congress.

DISCUSSING VIRAL INACTIVATION IN FLORENCE, ITALY

At the Risk Management Forum in Florence, the first results of the Health Technology Assessment, conducted by AdRes - Health Economics and Outcomes Research – and commissioned by Kedrion, were presented. The study seeks to estimate the economic value of platelet concentrate inactivation in Italy with the INTERCEPT Blood System®, a medical device produced by CERUS Corporation and distributed exclusively in Italy by our company.

KEDRION CONTRIBUTES TO GROWTH IN THE ITALIAN PHARMACEUTICAL SECTOR

The latest update of the Nomisma report "Industry 2030. The Italian pharmaceutical industry and its champions to the challenge of the new manufacturing paradigm" was presented in Rome on November 19. It noted that the "FAB 13", thirteen medium-large companies, including Kedrion Biopharma, belonging to Farmindustria, recorded approximately 11.6 billion in aggregate revenues in 2018, an increase of 4% over 2017, and a 3.3% increase in the number of employees.

PATIENT ENROLLMENT COMPLETED FOR KIg10 STUDY

Kedrion achieved its enrollment goal for the Phase 3 clinical study to demonstrate the efficacy and safety of KIg10, our 10% Immunoglobulin for treatment of adults with Primary Immunodeficiency.

The completion of the enrollment process, accomplished one month earlier than scheduled, represents a significant step forward toward the eventual availability of this important therapy.

A BRIDGE TO OUR COMMUNITIES

Motivated by a deep sense of ethical and civic responsibility, we aspire to promote a culture of social and environmental sustainability, trust and reciprocity.
Through our daily work, we strive to improve the lives of all those with whom we work and those who live in the communities that host us in Italy and in the rest of the world.
In 2019, we continued our commitment to support the medical-scientific community in research and ongoing training, while at the same time, aspiring to be an exemplary global citizen, we offered our contribution to many voluntary activities and projects.

For example, in Italy, among the various initiatives promoted in this area, we have supported:

- **The Robert F. Kennedy Non-Profit Foundation of Italy** (event support)
- **The Carlo Erba Foundation - 2019 Guelfo Marcucci Awards** (two scholarships intended for young researchers)
- **Alumni Association - Ghislieri Foundation** (Ghislieri Award support)
- **Treedom** (support for a sustainable development project that involves the creation of a company forest consisting of 500 trees planted by local farmers in Guatemela, Honduras, Colombia and Kenya)
- **The Paracelsus Foundation** (support for institutional activities)
- **The Luigi Villa Foundation** (support for research activities in the areas of Hemostasis and Thrombosis)
- **The University of Palermo - DICHIRONS Department** (contribution to a scholarship in Hematology studies)
- **The University of Milan** (medical/scientific training)
- **The University of Tor Vergata** (contribution for medical-scientific education - Master's degree program)
- **The Fonesa Foundation** (support for a rehabilitation project aimed at patients with Hemophilia)
- **The Careggi Non-Profit Foundation** (activity support)
- **Doctors with Africa CUAMM NGO** (support for the 2019 "Mothers and Children First" Annual Meeting)
- **LILT - The Italian League for the Fight Against Cancer** (support for the Pink Ribbon Campaign)
- **The Olimpiadi del Cuore Non-Profit Association** (event support)
- **Local charitable and voluntary associations in the province of Lucca**

KEDRION BIOPHARMA | CARES

In the United States, where for several years the company has been promoting spontaneous volunteer activities in support of local communities with the ***Kedrion Cares*** program, Kedrion and KEDPLASMA employees have contributed to and/or participated in (among others):

- **The Jersey Cares Non-Profit Organization**
- **CFA - The Center for Food ACTION Non-Profit Organization**
- **The Camilla House Charity Organization**
- **The Long Island Cares Charity**
- **The Susan G. Komen Foundation**
- **The One Warm Coat Non-Profit Organization**
- **The Options for Community Living Charity Organization**
- **The Feeding Children Everywhere Non-Profit Organization**
- **The Child Enrichment Inc. Non-Profit Organization**
- **The Blessings in Backpack Non-Profit Organization**
- **The Immune Deficiency Foundation**
- **The Hemophilia Federation of America**
- **GBS/CIDP Foundation International**

Similarly in Hungary we have contributed to and supported activities with (among others) the following organizations:

- **The Foundation for Children with Leukemia**
- **The "Our Blood is Our Life" Hematological Diseases Foundation**
- **The "Ferenc Csolnoky" Hospital of Veszprém, Hungary**
- **The Association for Immunological and Rheumatological Rehabilitation**
- **The Nephrology Foundation of Szeged, Hungary**
- **The Therapeutic Apheresis Center at the Semmelweis University Clinic of Internal Medicine, Budapest**
- **The Hungarian GBS/CIDP Patient Foundation**
- **The Santa Barbara Hospital Foundation**
- **The Hungarian Hemophilia Society**
- **The Eötvös Loránd University Student Foundation, Budapest**
- **The "Károly Tormay" Polyclinic Hospital Medical Center, Gödöllő**
- **The "Tibor Jánossy" Obstetrics and Gynecology Foundation**
- **The "Aprónép" Pedriatric Patient Care Foundation**

IN FOCUS

HEMOPHILIA
JOINING OUR COMMUNITIES

Kedrion Biopharma's long established commitment in the field of coagulation disorders remains firm. Treatment of Hemophilia, an inherited bleeding disorder, is currently undergoing dramatic transformations with the introduction of new and promising therapies. But it is clear that, despite these therapeutic advances, replacement therapy will remain an important part of the treatment options – especially in areas where newer products are unavailable or unaffordable.

Our response to this is to renew our commitment to Hemophilia patients and the Hemophilia community, to encourage and support the education of patients and their families, and the sharing of information among patient associations, the healthcare sector, scientific researchers and academia. Only through a full and educated understanding of the various therapeutic needs and paths can the Hemophilia community in any given situation make the best possible informed decisions for personalized therapy. Only through such understanding and communication can we best contribute to improving access to treatment and guarantee a better quality of life to those suffering from these rare disorders.

With this conviction in mind, Kedrion organized a major medical/scientific congress in Trieste, Italy on June 27 – 28, 2019, to discuss ""Hemophilia Care: Building Confidence" ("Emofilia. La certezza della cura"). The event was unique in bringing together not only clinical experts, healthcare institutions and industry representatives, but plasma donor associations, patient associations, and patients themselves to engage in a broad-ranging scientific program and discussion of treatment options, treatment access and personalized care.

In Turkey, we attended and supported the 16th International Hemophilia Congress held in Antalya, during which we led a symposium on inhibitor prevention and eradication strategies, highlighting the role of plasma-derived Factor VIII. Later in the year, we presented the same topic at a series of educational medical sessions in the country (the first two of which were held in Istanbul and Izmir).

EIGHT

In 2019, we continued to grant our unconditional support to "EIGHT", the first global educational initiative entirely dedicated to encourage the international medical community to reflect on the role of Factor VIII in Hemophilia treatment. Replacement therapy continues to be the consensus mainstay of Hemophilia, and will likely continue to be for some time, especially for the treatment of acute bleeds or for Immune Tolerance Induction (ITI), for which there are no alternatives to replacement factors.
An EIGHT website, launched in 2019, provides information online. Learn more at www.eightfactor.com.

Educational events are more important where there is less general awareness – especially among Hemophilia patients – about treatment options and developments.
The situation in Latin American countries, though clearly not uniform, is a case in point. Despite remarkable advancements in treatment and overall progress in Hemophilia care, new and old challenges continue to plague the bleeding disorders community in Latin America: access to diagnosis, access to therapy, and the burden of infusions - especially in patients on prophylaxis regimen.
Such themes were at the heart of the 2019 International Congress of Grupo CLAHT in San José, Costa Rica (October 10-12). At this most important regional Hemophilia medical event, Kedrion led a symposium with a lively debate, addressing the current and future role of Factor VIII-based replacement therapy in the treatment of Hemophilia. Invited speakers included Dr. Miguel Escobar (Texas, USA) and Dr. Carlos Ramírez (Bogotá, Colombia).

> Despite new therapies coming in, replacement factors still have a role in the treatment of Hemophilia. On one side, we have been using them for more than fifty years, and even today they are irreplaceable for certain categories of patients. On the other, it is ethically very important to be able to provide every person with the same healthcare options, and every patient with adequate treatment, and I'm not sure we are ready for all this innovation, which has costs not every country is able to bear, at least not for everyone.
>
> **Dr. Carlos Ramírez**,
> Hematologist
> at Clínica Colsanitas
> in Bogotá, Colombia

Our 2019 activities in Latin America were focused especially on Colombia, where we promoted educational medical meetings with the support of Dr. Carmen Escuriola - one of the most important international expert in this field, and in Mexico, where we met and consulted with a wide range of experts, clinicians, healthcare institutions, and patient associations, as well as with patients and their families.

CASE STUDY: MEXICO

The per capita consumption of Coagulation Factor VIII in most of Latin America falls well below the level of treatment recommended by international guidelines, that is 4 IUs for every 1,000 inhabitants.
In Mexico, the shortfall is dramatic. Here, at best, preventive treatment is a very recent achievement, albeit reserved exclusively for patients registered with the IMSS or ISSSTE (the two social security institutes), and in any case for children under the age of ten and other particularly serious cases; and still today it remains a mirage for the vast majority of patients.

> In this Country there are 5,000 people with Hemophilia but only half of these receive adequate health care; the average consumption per capita of Factor VIII is 1.4 IUs and 30% of the population has no access whatsoever to coagulation factors. Even today people are dying from Hemophilia, due mainly to the scarce availability of the product and the poor infrastructures outside the biggest cities; and even where treatment is available, knowledge is poor and the level of education is low, both in doctors and patients. There is still a lot of work to be done so that all those suffering from coagulation disorders, regardless of age or their socio-economic situation, may have access to quality treatment.
>
> **Dr. Adolfina Bergés García,**
> Pediatric Hematologist and Medical Advisor
> to the Federation of Hemophilia
> of the Mexican Republic

RENÉ

René is 35 and lives in Monterrey, Nuevo León. His mother, María de la Luz, learned of her son's condition in 1985, when René was only 6 months old: "While playing with his brothers, he started to get bruises which would not heal. Doctors carried out many tests, and in the end told me, 'your son is a hemophiliac and he will spend more time in hospital than at home.' My world fell apart, I thought that I wouldn't make it: I drew strength from the meetings promoted by the Federation of Hemophilia, where I would see other mothers with two or three children suffering from Hemophilia and think that I only had the one."

René picks up the story: "When I was a child, coagulation factors were not available: we used cryoprecipitate, when necessary, and often I would have to be admitted to hospital urgently, with heavy consequences such as those to my legs and ankles. When I was about 13 years old, they started to send Factor VIII, but it was not enough, and we would use it only in emergencies. For me prophylaxis has represented the before and after of a normal life: I began 3 years ago and, although I have very low factor levels, I manage with two infusions per week. The improvement has been incredible."

Today René is a guitar player in a progressive metal band called Neural FX, and has performed throughout his country, as well as in the USA and Europe. This clearly shows the value of increasing awareness, accessibility to factor, and the benefits of prophylaxis.

GABRIEL

Gabriel, who lives with his family in Guadalupe, has also experienced the transition from emergency treatment only, to a prophylactic regimen.
"I can say that I had a normal childhood, in spite of the illness. After all, my level of Factor IX is 3%, and so in my case we're talking about moderate Hemophilia B. I didn't have a problem until I was about 8 or 9 years old when I had to treat a bad tooth: the bleeding didn't stop, not even after two or three days, and at that time – it was the end of the 1970s – no one really knew this disease. After various tests, the doctor told my mother that she should take me to the Mexican Children's Hospital. There I was diagnosed with Hemophilia. I spent my whole adolescence going back and forth to the Children's Hospital."

Today Gabriel and his wife, Silvia, have two children, Germán aged 22 and Aydee aged 21. Aydee told us:

"From when I was a child, even though I didn't really know what Hemophilia was, I knew that my father could injure himself easily and that he had to be careful, and that he would have to go to hospital often. When I was about ten years old my parents began to explain to me that I was a healthy carrier of the same disease. It frightened me a lot to see my father infusing his treatment on his own, but after he underwent a hip operation I began to get closer to him and to his condition; nowadays I help him with his infusions and I get him to explain all the necessary steps: it is my way of overcoming my fear because I am aware that in the future my sons will probably be hemophiliacs and I need to know how to carry out these steps correctly.

Gabriel continues: "Up until a year ago as an employee of the Ministry of Health, I was eligible to receive health care from the ISSSTE, which guaranteed treatment... but only for injuries, traumas or hemorrhagic events. With all the consequences that this has on the level of articulation. Just over a year ago I moved to a private company, so now I am registered with the IMSS and I have had access to prophylactic treatment: for me this means having infusions every three days and, up until now, no real emergency, and the quality of life has improved immensely."

WIRhE
CONNECTING THE WORLD TO PROTECT MOTHERS AND BABIES

Several years ago, we joined with academics, health-care professionals and commercial partners to raise awareness about a widespread, serious, and ongoing health threat that was either not recognized or ignored. Hemolytic disease of the fetus and newborn (HDFN), also known as Rh disease, is a life-threatening condition that arises when a woman's blood type is incompatible with that of her fetus. Rh disease has been essentially eliminated in more wealthy countries for nearly 50 years, thanks to a simple and inexpensive, plasma-derived Immunoglobulin treatment. Kedrion has been a leader in this field: its "Anti-D Immunoglobulin" is the most well-known and widely used HDFN prophylactic in the world.

When we learned from the work of researchers in Stanford University and Toronto's Hospital for Sick Kids that Rh disease was still a major problem in less economically developed countries – indeed, that half the women in the world still had no access to treatment – we resolved to do something about it. It soon became clear that the problem was not a simple matter of access, but of awareness, infrastructure, cultural barriers... a host of obstacles.

In 2018, as part of a celebration of the 50th anniversary of the licensing of the first treatment for Rh disease, Kedrion supported a series of meetings and conferences around the world, culminating in the First Annual International Symposium for the Eradication of Rh Disease, hosted by and at Columbia University Medical Center in New York City, where the first Rh disease prophylaxis was developed in 1968. The meeting, as its title suggests, was not merely a celebration, but a call to action to raise awareness and develop strategies to deal with this global tragedy.
In 2019, these efforts came together in a meeting among a core group of experts and academics, including representatives from Kedrion, hosted by the Centro Nazionale Sangue in Rome. There it was decided to launch a new formal global organization to take on the challenge of eliminating Rh disease everywhere around the world.

An international event was planned to launch this new organization. The Second International Symposium for the Eradication of Rh Disease took place in Florence, Italy on 28 September 2019. Its name would be the Worldwide Initiative for Rh disease Eradication – WIRhE. Its mission: "connecting the world to protect mothers and babies".

Kedrion supported the event with an unrestricted grant.

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A GLOBAL CHALLENGE. IN FLORENCE, A GLOBAL RESPONSE.

Meeting in the historic halls of the “Istituto degli Innocenti” in Florence, Italy, distinguished participants from more than 20 countries, representing some fifteen scientific, academic, government and non-government organizations, discussed strategies to “fill the gap” between the need for HDFN prophylaxis around the world and its availability. More than half the women in the world who are at risk still do not have access to Rh Immunoglobulin – fifty years after it was developed to prevent hemolytic disease of the fetus and newborn, which it accomplished quickly in the North America, Europe, and Australia.

The Second International Symposium for the Eradication of Rh Disease marked the launch of WIRhE, the Worldwide Initiative for Rh disease Eradication under the leadership of Dr. Steven Spitalnik, Professor of Pathology and Cell Biology and Co-Director of the Laboratory of Transfusion Biology at Columbia University Medical Center in New York City. The symposium was hosted by the PREIS School (Permanent International and European School in Perinatal, Neonatal and Reproductive Medicine), which is located in Florence and chaired by Dr. Gian Carlo Di Renzo, founder and director of PREIS and Dr. Spitalnik.

Among the notable participants were representatives from, the International Federation of Gynecology and Obstetrics (FIGO); the Hospital for Sick Kids in Toronto, the Rhesus Solution Initiative, Nigeria; the Russian Society of Ob/Gyn; Philippine Obstetrics and Gynecologic Society (POGS), Manila; Government of Punjab, Pakistan; Department of Obstetrics and Gynecology, Peking University First Hospital, China; Médecins Sans Frontières (MSF).

Dr. Di Renzo, Dr. Spitalnik and Dr. Gerard Visser of FIGO and Emeritus professor of Obstetrics at University of Utrecht, provided an overview of the history, the current state and the anticipated future of the Rh disease problem. Representatives from Colombia, Brazil, China, Argentina, Philippines, Turkey, Pakistan, Israel, Canada and the UK reported on the state of Rh disease and its prevention in their respective countries. CEO Paolo Marcucci aslo addressed the symposium and confirmed Kedrion’s commitment to support WIRhE and its global objectives.

“Having people come from all over the world share their ideas, their problems, their issues and be enthusiastic about working together was just fantastic. And having the meeting in the Ospedale degli Innocenti, a hospital for young children, to be talking about how to protect young children..., it was just the perfect venue.
I was particularly impressed by the representative from one country because he, he answered the questions that we asked and he said, we have no data; we have no intervention, we don’t do anything. Help us, basically. And he wasn’t embarrassed to tell us that. I think he felt that this was a safe environment. And he wants help in interaction on what to do, which is all we’re hoping for. So it was great.

Dr. Steven Spitalnik,
Executive Director of WIRhE

Some people like the representatives from China, the Nigeria representative... were in the end almost touched that an initiative like this can help. In countries in which there are barriers or difficulties or there are economic (challenges), the WIRhE initiative has ideas, how to work them out. And I think this, they understand very well, because, I have to say that the quality and the commitment has been palpable everywhere.

Dr. Gian Carlo Di Renzo,
founder and director of PREIS, Hon. Secretary-General Emeritus, FIGO

The last two days, the most important to me was that it was a gathering of people from 20 different countries with completely different backgrounds and they all had the same goal: to eradicate this disease. Here it looks as if the professional world agrees, and if people agree you can make large steps.

Dr. Gerard Visser,
Emeritus professor of Obstetrics at University of Utrecht

This conference is very exciting for me and my colleagues. I want to thank the international organization for inviting me to join WIRhE. I think we must take action in China to eradicate the Rh disease.

Dr. Huixia Yang,
Peking University First Hospital, Beijing, China

Dr. Huixia Yang hopes now to conduct broader surveys in China to get a more clear picture of the incidence of Rh negative blood type in various ethnic groups. The occurrence of Rh disease was likely artificially lowered by the earlier policy of limiting families to one child, so there is an expectation that a rising incidence is on the horizon.
At this time China has little access to the Anti-D prophylaxis.

We're very happy to be part of this movement, this global initiative to really eradicate a very preventable disease. As a maternal-fetal specialist, I see a lot of complicated pregnancies actually. And sometimes it's heartbreaking, but there are some diseases that you cannot really do anything about, like some forms of congenital anomalies and that's not easy to accept. But for a baby to die because of something that can easily be prevented, that is very, very heartbreaking. And to see a mother experience loss several times without knowing why, and then realizing that it's her poverty: lack of 10,000 pesos that caused her babies to die and to see her suffer emotionally because of that. It's heartbreaking for the physician as well. So we hope that we can prevent stories like that and just get stories of success.
So we're very excited that we are now part of this initiative.

Dr. Maynila Domingo,
Clinical Associate Professor of Obstetrics and Gynecology, University of the Philippines

DONORS FOR A SPECIAL CAUSE

Anti-D Immunoglobulin is produced from special plasma that is rich in Anti-D (Rh) antibodies.
It is collected from donors who have been sensitized to the Rh protein.
All of the plasma used to make the Kedrion products that prevent Rh sensitization around the world is collected from such donors in a single center - KEDPLASMA's Somerset Labs near Buffalo, NY, USA.

I donate because I've been blessed with a unique blood type, because I'm physically capable and because I simply love life. I want to help others experience the simple joy of living, or at the very least, give them the opportunity to. I chose plasma over whole blood donation because I could do it more frequently and effectively "give more", from my perspective. Lastly, I feel fortunate to be useful. Thanks for asking.
Jane Lepper

The reason I donate my plasma is because I wouldn't have my three beautiful children if someone else hadn't donated their plasma for me. During my pregnancies, I learned about the program and vowed to come to the center as soon as I was past menopause and will continue to donate as long as I am able.
Kathleen Grimm

My daughter needed Anti-D prophylaxis when she became pregnant. It saved my wonderful grand children. I had never heard of a mother's blood attacking a fetus. She said you should become a donor. It has been three years now and she had to have more of your product to save another grandchild. That is why I come.
Joel Ridge

I donate because I'm contributing to a most worthy cause – the saving of lives of babies. When I was training as a nurse, Anti-D prophylaxis had just come out and I thought it was the most amazing worndeful invention.
And now I'm actually participating.
Nancy Glover

JOHN GORMAN LECTURESHIP IN TRANSFUSION MEDICINE

The Florence symposium was also the occasion of the 4*th John Gorman Lectureship in Transfusion Medicine*. John Gorman was one of the researchers responsible for the development of the Rh Immunoglobulin prophylactic at Columbia in 1968. As a part of the activities celebrating the 50th anniversary of this breakthrough, Kedrion Biopharma pledged to Columbia University Medical Center support for this important annual lectureship to continue in perpetuity. For 2019, the Lectureship was presented by Professor Giuseppe Remuzzi, world-renowned scientist, director of the Mario Negri Institute for Pharmacological Research (IRCCS) and member of the National Council of Health.
In introductory remarks, Kedrion CEO Paolo Marcucci noted, "We are honored and privileged to support the John Gorman Lectureship. Dr. Gorman and his colleagues provided the world with a solution to a terrible challenge to maternal and infant health."

NEUROLOGY

CONNECTING COMMUNITIES: AN ONGOING COMMITMENT

Kedrion's 2019 activities in the field of Neurology exemplify our continuing commitment to partnering with international medical and scientific communities. We have a long history of collaboration with the Peripheral Nerve Society (PNS), and with many of its affiliates such as the Italian ASNP (Association of Peripheral Nervous System Diseases) and the GBS-CIDP (Guillain-Barré Syndrome - Chronic Inflammatory Demyelinating Polyneuropathy) Foundation International.

"I first came into contact with Kedrion in 2002, when the company started supporting research on the Peripheral Nerve, and promoting initiatives and projects aimed at establishing - for the first time in Italy - a proper medical-scientific community working in this field. Today, thanks also to Kedrion's contribution, our Italian community is strong and highly regarded internationally.

Prof. Dario Cocito,
Department of Neurosciences,
Ospedale Molinette,
Torino (Italy)

"Kedrion has played a positive role in the development of the entire PNS, and of the ASNP in particular, by offering a constant and continuous support to promote research-oriented initiatives and their application in the field of Neuropathies."

Prof. Angelo Schenone,
Department of Neurosciences,
IRCCS AOU San Martino,
Genova (Italy)

For more than 20 years now, Kedrion has encouraged and supported events and initiatives around the world, offering specialists the opportunity to exchange information and discuss experiences with in-country colleagues as well as through international networking. This allows for shared and expanded knowledge of diagnostics, clinical practice and therapeutic approaches.

On June 22-25 more than a thousand experts from around the world gathered in Genoa, Italy to attend the annual PNS Meeting. This most important international event dedicated to Peripheral Nervous System disorders was inaugurated 25 years earlier just 20 miles away, in Rapallo, Italy. During the 2019 conference, a Kedrion-supported scientific symposium was dedicated to exploring new potential therapeutic options using standard intravenous Immunoglubulins (IVIg) in the treatment of Chemotherapy-Induced Peripheral Neuropathies (CIPN), one of the most important subjects of interest in clinical studies carried out in recent years.

DISENTANGLING THE DIAGNOSIS

In many cases, Neurology is a particularly intricate matter where it is necessary to gradually clear the field in order to reach a diagnosis, and then to follow on with the appropriate therapy.
This is especially true for Peripheral Nerve diseases, such as Guillain-Barré Syndrome, Multifocal Motor Neuropathy and CIDP (Chronic Inflammatory Demyelinating Polyneuropathy).

Cristina is 17 years old and lives in Anzio, near Rome, Italy.

"I have been playing volley since I was three. My parents are both volleyball coaches in their spare time, so for me it went without saying! Shortly after moving up to the Under 16 Team – this was in 2017, when I was in the 9th Grade – I started having some physical problems: I could barely jump, I ran poorly, I wasn't even fast, everyone thought I 'sucked at sports'.
I started going to a gym that was run by friends of the family, who are also physiotherapists, and they soon realized that something was wrong."

Her father Giovanni continues: "Out of the blue, in the space of just one or two months, Cristina's difficulties became much more severe, and her mother and I found it difficult to cope during the period of uncertainty that followed. In fact, it took almost a year to reach some form of diagnosis: a year of holding our breath, during which time Cristina underwent a long series of medical tests, and which we feared would result in the diagnosis of some severe degenerative diseases. Considering that the first theory had been Type 3 Spinal Muscular Atrophy (SMA), you can imagine how we felt every time there was a result that didn't confirm our fears... We're talking about it calmly now, but until a year ago, we couldn't even mention it."

"We were worried about Cristina's future: as an adolescent, already going through that difficult phase in life, where having to deal with any physical problem has such an impact, her concerns were affecting her here and now, her daily life. For example, what if I have to do something with my friends, and can't cope physically? Her fear was: what if they make fun of me? Will they understand me? And it was a good thing that she didn't worry about what would have happened if she was diagnosed with a severely disabling disease. She always wanted to go to the volley games and practices, even though she couldn't do what the others were able to do, and she never gave up."

IVIG AND CIDP

Immunoglobulins are widely used to treat serious autoimmune disorders affecting the Peripheral Nervous System. Peripheral Neuropathies result from damage or disease to the nerves carrying messages from the brain and spinal cord to the rest of the body. Damage to these nerves interrupts communication between the brain and other parts of the body, impairing muscle movement, preventing normal sensation in the arms and legs, and causing pain.
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) is a rare disorder of the peripheral nerves characterized by increasing sensory loss and weakness associated with loss of reflexes. Initially, people with CIDP may simply be aware that it takes more effort to do the things they used to do, but over several months the symptoms may progress to the point that they may no longer be able to perform simple daily activities such as climbing stairs, walking without assistance, or lifting objects overhead. Its estimated prevalence ranges from 0.8 to 8.4 per 100,000 people. The cause of CIDP remains unknown.

Then, at the end of 2017, came a breakthrough: Cristina was visited for the first time by Neurologist Giovanni Antonini, Head of the Neuropathology Department of the Sant'Andrea Hospital in Rome.

As Cristina comments, "I was fortunate to have met Prof. Antonini. At first, he didn't know what the problem was either, but basing himself on experience and intuition, he decided to try treating me with Immunoglobulins; this completely changed my life. Before the treatment started, my mother would get me up from a very low sofa that we have at home, because I couldn't get up myself. Therefore, we said that I would know I was getting better the day I was able to get up from that sofa by myself. After the first infusion, I tried and I did it. It was a great moment."

Prof. Antonini told us: "From a medical point of view, this story underlines the importance of knowing the patient's medical history which, over and above the clinical evaluation, is essential and invites us always to consider that a case may be atypical. Such as Cristina's, who had an above average level of physical activity, and had always been playing competitive sports, until she began to lose her strength at a certain point: in my opinion her condition did not fall within a congenital disease framework, which exists from birth and gradually begins to manifest itself, and then progressively worsens. When I saw her for the first time, I thought it was worth considering that this was an acquired disease, and I decided to treat her with Immunoglobulins, which have the significant characteristic of never being a risk for the patient. Moreover, in the case of CIDP, response to therapy is one of the criteria considered as a support for the diagnosis. Fortunately, we were successful. Can we talk about recovery? We're all confident about how to begin treatment, but we never know how long the treatment should last, or how to end. The protocol recommends slow tapering, progressively increasing the time between infusions, hoping that no complications arise between treatment cycles, and that Cristina will actually be cured."

Beginning with cycles of five days a month, Cristina's therapy was gradually decreased and now is four days every three months.

"My daughter's case has had a successful outcome," Giovanni concludes. "At least, we now understand that a therapy is available for many types of rare and severe diseases, a therapy that allows the patient to enjoy a completely 'normal' quality of life, even physically. Cristina feels relieved, and we are relieved too: we know that a disease is in progress, and we can't say that it has been cured, because this might take several years, but we do know that there is a protocol and that the therapy works, and we also hope that this type of therapy can be improved for the future. Cristina is less worried now, and that's the most important thing."

VIRAL INACTIVATION
SAFETY FIRST

Since 2017, Kedrion has been the exclusive distributor in Italy of the INTERCEPT Blood System®, a medical device produced by CERUS Corporation, the only company in the field of blood transfusion to earn both the CE Mark and the FDA approval for pathogen reduction of both platelet and plasma components.
In the last two years, we have devoted considerable resources and energy to the dissemination of knowledge and the use of this device throughout Italy, driven by the conviction that the introduction of the viral inactivation process for plasma and platelet concentrates represents a significant step forward for transfusions in Italy - both as a further measure to prevent any contamination by pathogens and as a potential solution to the threat posed by the appearance of new emerging viruses.

The INTERCEPT Blood System® is a pioneering technology that has been adopted in routine transfusion activities by more than thirty countries worldwide.

> In Switzerland, the nationwide adoption of this device for pathogen inactivation in platelets has been in force since 2011. This was a joint decision by the Swiss health authority and the national hemovigilance system to prevent the risk of bacterial contamination. A decade later, we are very satisfied with this choice: the hemovigilance data shows that there have been no more cases of sepsis or other platelet transfusion infections. Moreover, we have recorded a 66% reduction in acute transfusion reactions, both in terms of number and severity.
>
> **Dr. Laura Infanti,**
> Regional Transfusion Service,
> Swiss Red Cross
> Hematology Service, University
> Hospital of Basel, Switzerland

DEDICATED TO SAFETY

Year after year, Kedrion continues to reinforce and extend its expertise in the field of transfusion medicine, with the ultimate goal of guaranteeing the highest safety standards, both for its products and for the people for whom these products are intended.
This commitment was manifested in 2010, when the Biological Safety Center (BioSC), located at the Bolognana plant in Italy, was established. This is the first laboratory in Italy to have obtained the GLP (Good Laboratory Practices) Certification from the Italian Ministry of Health for the study of the inactivation and removal of pathogens in biological and biotechnological products. The BioSC mission is to respond to new and growing safety needs in the field of biological contamination through research, innovation and the continuous improvement of the services Kedrion offers. Over the years, the Biological Safety Center has become a point of excellence and reference in the field of viral validation studies, both in Italy and internationally.

Kedrion's portfolio also includes a virus-inactivated plasma, commonly known as Plasma S/D, produced at the plant in Sant'Antimo, Italy. This is a fresh frozen plasma of pharmaceutical grade with a high degree of safety because it has undergone treatment with solvent and detergent in order to destroy or inactivate any viruses.

In 2019, Kedrion commissioned a Health Technology Assessment (HTA) from AdRes - Health Economics and Outcomes Research - in order to estimate the economic value of the nationwide inactivation of platelet concentrates in Italy with INTERCEPT. The preliminary data from the study has already been presented at the XIX SIdEM National Congress (Italian Society of Hemapheresis and Cellular Manipulation) in Rimini, and the final results will be presented at the Risk Management Forum in Florence during 2020.

> "In my opinion, any pharmacoeconomic analysis on the possible adoption of this device must be integrated and balanced by a careful multidisciplinary process that consistently addresses all social and ethical aspects related to an assessment involving the Italian National Health System as a whole.
> By making this technology available, Kedrion has taken on the duty to raise the public's awareness of an especially important issue, which is the possible implementation of these safety measures.
> A task that the company is carrying out with a great sense of responsibility.
>
> **Dr. Mario Eandi,**
> former Professor
> of Clinical Pharmacology,
> University of Torino (Italy)

In the meantime, several Italian Regions have already adopted this device - and others are preparing to do so to manage any epidemiological emergencies caused by new viruses.

RABIES
PREVENTION IS THE ONLY WAY

Rabies is a viral disease that is rare, but it is nearly always fatal. It is typically transmitted through contact with a rabid wild or domestic animal – usually from saliva through a bite. Worldwide, dogs are the most common source of the disease in humans, but in the United States, where pets are generally vaccinated against Rabies, the virus is most commonly found in skunks, raccoons, foxes and bats.

Post Exposure Prophylaxis (PEP) should be provided as soon after exposure as possible and consists of thorough wound washing, administration of Human Rabies Immune Globulin (HRIG) at the bite site, and initiation of a vaccine series administered in the arm or thigh distal from the HRIG site at days 0, 3, 7 and 14. The HRIG provides immediate antibodies to fight the Rabies virus until the vaccine can induce the body to produce its own antibodies. Kedrion Biopharma joined the fight against Rabies in 2018, when it partnered with Kamada Ltd, an Israeli pharmaceutical company that produces HRIG from Hyperimmune Anti-Rabies plasma collected by KEDPLASMA.

This partnership has resulted in remarkable success: Kedrion's Human Rabies Immune Globulin has already garnered nearly 20% of the US market.

To what can we ascribe this notable achievement? In a word – or two words: education and innovation. A primary expression of our commitment to bridging communities is to establish relationships with the people and communities we serve. This means especially an active and open dialogue with healthcare professionals, researchers, caregivers, educators.

Our marketing and sales personnel are deeply knowledgeable about our products and regularly share their expertise in formal and informal professional meetings such as with Rabies in the Americas (RITA) an annual "meeting (that) provides an opportunity for researchers, health professionals, international, national and local managers of Rabies programs, wildlife biologists, laboratory personnel and other people interested in advancing knowledge of Rabies surveillance, prevention and control, to meet each other, to share their successes and also to discuss the challenges to be met."

Despite its name, the conference now draws participants from more than 20 countries around the world. Our Rabies IG Brand Director, Peter Costa, is on the Steering Committee for RITA and is a nationally and globally recognized expert in Rabies control.

Beginning in 2019, Kedrion has begun developing a first-of-its-kind delivery program that would make HRIG available quickly to hospitals and clinics where and when it is needed. Many healthcare sites do not maintain a sufficient supply of HRIG; Kedrion aims at developing a program that could provide HRIG within three or four hours of notice. In several pilot program areas, we are confident we can make delivery within one hour. With Rabies, time is crucial.

At this time, no HRIG is approved for pediatric care. At the end of 2019, Kedrion enrolled the last of 30 patients, 17 years of age and under, in a study that will lead to a pediatric certification for a HRIG. Kedrion is building bridges to the future in the fight against Rabies.

THE BRIDGE

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I donate plasma to simply help someone. I may be offering a lifeline to a friend in my community or someone miles away from here. No matter who it is or where they are, I know that I'm making a difference by donating my lifesaving plasma and to me, that is the most rewarding aspect.

James
KEDPLASMA USA donor in Hickory, NC, USA

I donate because I have a few friends that had cancer and are now in remission because of the medications made from plasma. When they found out that I donate they cried because I was part of saving their life.

Leslie
KEDPLASMA USA donor in Hickory, NC, USA

FROM PLASMA...

Donors. We all depend on them: patients and their families, caregivers, all of us at Kedrion who are committed to providing a bridge to those who must find safe passage over troubled waters. We are so grateful that such generous people exist. Who are they? They are your neighbor, your co-worker, your relative... they are you. They are the best in all of us. They allow us to maintain hope in the face of the most difficult challenges of life.

Why do they give? Yes, in one way or another they are compensated for their time and effort, but these nominal sums cannot explain their generosity. Of all the ways they might earn a little money, they chose to do something that directly helps others. There is a basic generosity, a selflessness, a "bigheartedness" that is at the core of their actions. We thank them especially for the opportunity to connect their donations to the people who most need them.

USA

Kedrion Biopharma is the only producer of plasma-derived therapies to be "self-sufficient" in its plasma supply. We do not procure plasma from other collectors. To maintain this status, we aim to ensure an ever-increasing supply of plasma. In 2019, we added 6 new collection centers, a 66% increase, bringing the total number of centers run by KEDPLASMA USA to 21 and expanding our geographic presence to eleven states. We are expecting to add another 6 collection centers in the US in 2020. "KEDPLASMA USA prides itself on being the industry leader in donor customer service," notes Helen Nasser, Managing Director of KEDPLASMA USA, "setting itself apart by focusing on the donor experience. The goal is to ensure that the donor's positive experience and safety is visible in each one of our centers."

HUNGARY

The Hungarian plasma collection market is robust but competitive with more than 30 collection centers in a population of some 10 million. Kedrion Biopharma operates 7 centers. Attracting donors is a matter of providing better services and a more welcoming experience. Compensation for plasma donation in Hungary is allowed, but capped by law. "It's a small world to attract donors," notes Plasma Business General Manager, Paolo Melloni. "Having said that, our donors are very happy because they really feel the ownership that they are doing something good. Gabriella Komlódi, Managing Director of HUMAN BioPlazma, Responsible for Plasma Collection , started a club (the "Heroes' Club"), ... of the donors where you get to several different levels, kind of a platinum, gold, ... VIP status as a donor... they are very proud of it, it's important. So, Hungary is doing very well consistently with the market situation of fierce competition."

I have been working in a hospital for 35 years having an administrative job and I have been donating plasma for already 10 years.
Working in the healthcare, I can see exactly that more and more people are in need of plasma-derived therapies. As I am in excellent health I am glad to donate plasma, it is inspiring and a very good feeling for me to help patients that way.
In our family, help is provided on family basis: my husband is also a plasma donor being already beyond the 400th donation.

Erzsébet Erős Simay,
donor at the Debrecen Malompark Plasma Center (Hungary)

KEDPLASMA GOES PAPERLESS. SOMERSET BECOMES FULLY AUTOMATED

Each of the KEDPLASMA donor centers, went paperless during 2019. A landmark innovation in the generation and maintenance of digital donor charts will result in significant increases in efficiencies and productivity. And a secondary bonus will be substantial savings of paper as well as the space formerly needed to store paper files.

Our collection center in Buffalo, New York, Somerset Labs, collects hyper-immune plasma specifically for the production of Anti-D Immunoglobulin for the prevention of Rh sensitization and subsequent hemolytic disease of the fetus and newborn. This condition results from a mismatch between the Rh blood types of a mother and her fetus and can result in the death or severe damage to the fetus. We made major strides in technology in Somerset by creating full automation and adding them to the paperless environment.

DONORS AND PATIENTS MEET AND LEARN

During International Plasma Awareness Week (IPAW, 7-11 October), donors selected from the "Heroes' Club" at each of our centers in Hungary met with a group of patients from the "For GBS/CIDP Patients Hungary Foundation". These are the kinds of people for which plasma donations can be crucial. It was a real learning experience for both groups and the education continued when they all toured the Kedrion Biopharma Gödöllő plant. This facility represents a major part of the bridge between donor and patient, plasma and medicine, distress and relief.

This was an especially meaningful opportunity for donors and plant workers not only to put a face on the people their donations and their work help, but to hear some of their life stories. Péter Szűcs, for example, is a GBS patient whose condition was so serious before treatment that "I was paralyzed from the neck down. The diagnosis: GBS-AMAN syndrome. After nine months of continuous physical therapy, I could return home. Since then, my development has been steady; now I can walk with a walking aid. Thanks for being alive; if you weren't, I may not be here either."

Adrienn Cilárik is founder and President of the "For GBS/CIPD Patients Hungary Foundation". She is also a patient and was part of the delegation meeting at Gödöllő. "I told my story on a blog that prompted the GBS/CIDP International Foundation to invite me to become their volunteer liaison in Hungary. As of 2019, I carry out my tasks as the President of the "For GBS/CIDP Patients Hungary Foundation". I have been representing GBS/CIDP patients already for 6 years, participating at professional conferences and giving lectures."

ITALIAN DONORS

Kedrion has a long and deep relationship with Italian donors. They are the foundation of the Italian Blood System, donating generously, without remuneration, to help others.

Italian donors are organized in associations, the largest of which is the Associazione Volontari Italiani del Sangue (AVIS), the Association of Voluntary Italian Blood Donors, a charitable organization bringing together more than a million volunteer blood donors across Italy.

Kedrion Biopharma has an extended history of supporting AVIS. For example, in 2019 we celebrated our fifth year sponsoring Scuola Nazionale di Formazione AVIS, an educational program developed by Kedrion with AVIS Nazionale and the Fondazione Campus Lucca. The curriculum of this advanced program is designed to prepare new generations of young leaders for the Italian donor community.

Marking this milestone, we organized a reunion of graduates at the Azienda Ospedaliero-Universitaria Meyer, the world-famous Meyer children's hospital in Florence. Among the Reunion activities was a workshop dedicated to how plasma donations help people not only through established derived medicines, but can also be used in research on new drugs, such as our current development of Plasminogen.

In addition, we have initiated and supported study to help understand donor motivation – why they give and what psychosocial and organizational variables affect their decisions regarding donation.

The research has been conducted by the IMT School for Advanced Studies in Lucca in association with AVIS. Data has been collected using a dedicated web-based application called "Asky". Respondents remain anonymous and are asked about their reasons for donating as well as details about their social settings. The goal of these studies is to design programs that will encourage participation and involvement in plasma donation in Italy.

In November, as part of the innovative IMT research, Kedrion and KEDPLASMA opened the doors of the Gödöllő, Hungary plant and the Budapest 2 collection center to a delegation of donors from AVIS Nazionale, AVIS Toscana and AVIS Abruzzo. The visit was prompted by the need, at the conclusion of the study, to explore and examine the differences and similarities between the Italian Blood System, based on voluntary, informed and unpaid donations, and the Hungarian Blood System, which provides compensation for donations. This was a unique opportunity for donors from two donation models – one voluntary and unremunerated, the other compensated – exchange views and experiences. The IMT researchers were able to explore altruistic, psychosocial and organizational motivations and variables.
The visit was also an opportunity for donors to meet the people who helped turn their donations into life-enhancing medicines and for plant workers to meet the people at one end of the bridge on which they worked.

Final results of the study will be presented in 2020.

> This neuro-scientific study is without doubt a new and important tool to better understand the motivations that lead people to donate plasma. In fact, through knowledge of the donor's perception, we can find new ways and incentives to involve donors, to increase their awareness and active participation and to support the donor loyalty process. Being able to understand through neuroscience what drives one person to donate in comparison to others can also help us to identify new tools and new strategies to address the issue of donations and to continue to draw more citizens closer to the donor community.
>
> **Gianpietro Briola**,
> President of AVIS Nazionale

Kedrion continues to provide opportunities for donors, patients, students, and other representatives of relevant institutions to visit our production sites to learn more about the incredible journey across the bridge they all stand on from plasma to medicine.

> I believe that donors, as well as patients who receive plasma-derived therapies, are not yet fully aware of the deep and inseparable connection that exists between them. The donor and patient communities are both part of the same chain of solidarity and, as President of the AIP, I can only hope and commit myself to multiplying the opportunities for meeting and collaboration. As a patient, I believe that there are no words to express the immeasurable value of donating. Donating is an ethical and civic gesture that arises from goodwill and spontaneity, and which cannot be taken for granted by people like me who are leading normal lives, thanks to plasma-derived therapies.
>
> **Alessandro Segato**,
> President of Associazione Immunodeficienze Primitive (AIP) - Primary Immunodeficiency Association

FROM PLASMA TO PRODUCT...

The journey from donor to patient, from donation to medicine is at the heart of our mission and the core of our operations. Plasma is rich in many proteins such as clotting factors, Immunoglobulins and Albumin and it is these proteins that are the basis for the therapeutic products we produce. For plasma to become a life-changing therapy, many highly complex steps are taken.

Before any production process, collected plasma is stored under closely controlled conditions for at least 60 days. This is a safety precaution, allowing any batches that have been found in any way compromised to be removed and destroyed. Once this isolation period is completed, the plasma goes to one of our facilities where it is "fractionated". This is the process that separates the plasma into "intermediate pastes", which are mixtures of the various proteins that are the basis of medicinal derivatives.
The term "intermediate" refers to the fact that this is not yet the final end product, which requires further processing onsite or at different plants. Fractionation and further processing includes purification steps that ensure a pure and safe product; filling of vials or syringes; packaging; labeling and monitored storage. All of these steps satisfy the very strict national and international regulations under which we operate as a global producer.

Kedrion Biopharma has three plants capable of all of these complex processes: one in Melville, New York, USA; one in Bolognana, Tuscany, Italy; and one in Gödöllő, Budapest, Hungary.

Our Melville plant has undergone an extensive overhaul and was able to support some essential processes, producing intermediates in 2019, while awaiting approval for full operations from Italian, European and US regulatory agencies. Some of these have been awarded and some are pending. We look forward to bringing Melville fully online, when we anticipate producing intermediate for our 10% Immunoglobulin in development (KIg10) as well as the full production, from plasma to final product of RhoGAM® Anti-D Immunoglobulin.

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In Bolognana a continued program of standardization and statistical analysis of our processes resulted in 2019 yields that are the highest ever. The Gödöllő plant in Hungary has experienced some market-based disruptions resulting in a larger personnel turnover than normal. Kedrion has responded with a strong plan to emphasize standardization in production processes as well as an enhanced culture of Kedrion quality. It was at the Gödöllő plant that the clinical batches for trials of our new 10% Immunoglobulin were produced.

In addition to our full production plants, we have also two plants that do not fractionate, but are capable of the very complex and highly regulated procedures of purification. These are in Sant'Antimo, Naples, Italy and Castelvecchio Pascoliin Tuscany, Italy.

Significant work was completed in 2019 at the Sant'Antimo complex. The construction of two new buildings has been completed, one housing administrative offices and the other Quality Control and Research and Development labs.

In preparation for the production of our 10% Immunoglobulin, now ready for clinical trials, we have completed extensive modifications on the plant where purification will take place in Castelvecchio Pascoli. Fractionation and the production of intermediate paste for Klg10 will be carried out at our Melville plant.

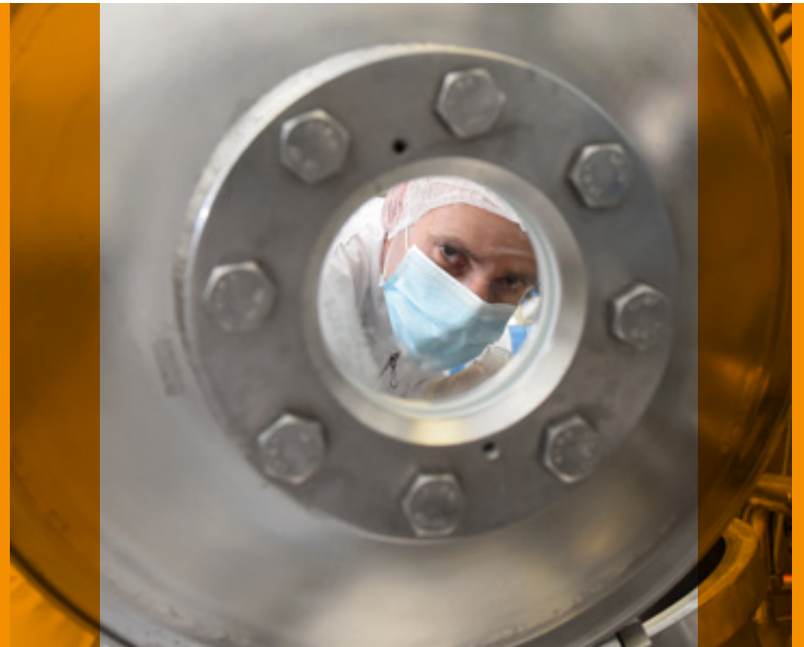
Ground was broken in 2019 for a new warehouse facility in New Jersey, USA for the storage of plasma from all KEDPLASMA collection facilities as well as products from the Melville plant. Built and operated by Preferred Freezer Services, now, with their parent company Lineage, the largest cold storage building and management company in the world, the warehouse will be dedicated exclusively for Kedrion use and will result in considerable savings.

NEW DIRECTIONS. NEW BRIDGES. BETTER WAYS.

Kedrion Biopharma's dedication to patients and the quality of their lives drives us to a continuous pursuit of excellence and innovation. The determined focus to get our Plasminogen and Klg10 to market is an example of this commitment.

"I have found here in Kedrion very, very dedicated people. I mean, they are really focused, committed, and feel personally engaged in the success of a project, and I cannot even mention an exception. The future is based on people... and when you have an army of this kind, you cannot lose the battle.

Alessandro Gringeri, Kedrion Chief Medical and R&D Officer



ENVIRONMENT. HEALTH. SAFETY. FOUNDATIONS OF THE BRIDGE

Environment. Health. Safety. Three legs that support the wellbeing of our people and their communities. Taking care of people – our patients, our employees and our neighbors - obliges us to attend to these vital factors.

While we continue to abide by many voluntary certifications applying to all of our various production, research and administrative sites around the world (including, for example OSHAS 18001, ISO 14001 and EMAS), we have initiated a number of specific and localized projects and events throughout the year to further enhance health, safety and the environment. Our Environmental Product Declaration (EPD®) has been extended to two more – now three - of our products from the Bolognana production plant (Italy).

"I will say about our progress in all our projects during this year," notes Marta Bonaldi, Head of Kedrion Environment, Health & Safety, Italy. "They may not be resounding projects; the results may not be big numbers (although some of them, yes), but they involve a lot of workers at different levels of the company. And most important, they are easy to follow, easy to understand, and they can last for a long time. So, they can change or modify or improve the habits of our workers and can influence also the community."

A very good example of this is the initiative introduced a few years ago, encouraging workers to engage in carpooling to save gas and climate-changing emissions. It met with moderate success, but when it was re-introduced for a three-month trial in 2019, "We wanted to reach 50,000 kilometers (of driving) saved by the end of the year. This was a challenge for us because we reached 36,000 kilometers in three years. (But) after only two months, we reached the goal and in the end we doubled the goal. And what is important is that the number of kilometers continued to increase even after the contest, so for me, it's a very big success because we tried to encourage a behavior and now it's a habit. When we can combine company goals with individual expectations, that is a success."
It is important because many people were involved. Many people could became aware of how important is a little drop in a river. But this drop is important. Many drops can make the river.

A major step for the environment was made at the Bolognana site with the completion of an upgrade from the plant's cogeneration system, which produces two forms of energy from a single source to a tri-generation system. The natural gas used at the plant produces electricity, heating and cooling, resulting in a significant increase in efficiency as well as significant decrease in pollution emissions. The Sant'Antimo plant (Italy) will undergo an even more profound transformation in the next two years, from a conventional grid-powered electrical plant to tri-generation.

Our safety record across plants continues to fall within targets for the sector with a constant goal of zero accidents and zero time lost. Special effort is concentrated on standardizing safety and health procedures across our plants globally and reconciling regulatory standards. Our general rule of operation is to abide always by the most stringent regulations regardless of the operational site.

FROM PRODUCT TO PATIENT

At Kedrion Biopharma we believe that our continued growth is dependent on adhering to our principles, especially our commitment to the support and mutual education of the communities of scientific research, healthcare and patient associations. We pursued this course by initiating, supporting and/or participating in major events and initiatives.

As described elsewhere, we gave unconditional support to The Second International Symposium for the Eradication of Rh Disease in Florence, Italy. The event marked the inauguration of a global initiative called WIRhE (Worldwide Initiative for Rh disease Eradication).

We also organized the event "Hemophilia Care: Building Confidence" ("Emofilia. La certezza della cura", also described elsewhere), a unique opportunity for clinical experts, healthcare institutions and industry representatives to come together with plasma donor associations, patient associations, and patients themselves.

Motivated by the belief that the active involvement of patients leads to greater adherence to therapy, especially in the treatment of chronic diseases such as Hemophilia, we have offered our support in Italy with an unconditional grant to the project "Words in Hemophilia: towards Patient Engagement", which will be conducted in 2020 by the EngageMinds HUB at the Research Center of the Catholic University of the Sacred Heart of Milan.

In parallel, we have supported a new project called ProPer (Personalized Prophylaxis), a series of training and refresher sessions for the medical community to encourage in-depth reflection on the customization of prophylaxis in Hemophilia A.

Also in Italy, Kedrion supported a symposium in Genoa, Italy, entitled "Von Willebrand Factor and Factor VIII: A Long Love Story" for the 10th edition of the BIC International Conference on coagulation pathologies, which was held jointly this year with the International Conference on Hemophilia Inhibitors.

Among our most recent European initiatives, Kedrion has joined the European Hemophilia Consortium (EHC) in the PARTNERS project, an initiative for improving access to treatment for coagulation disorders.

As part of our commitment to patients in Latin America, we have promoted a series of educational meetings on Hemophilia and its treatment in Colombia, with the medical-scientific support of internationally recognized expert, Dr. Carmen Escuriola.

In the field of Immunology, we continued our collaboration with the International Organization of Patients with Primary Immunodeficiencies (IPOPI), participating in the IPIC Congress in Madrid (Spain) and the Focused Meeting of the European Society for Immunodeficiencies (ESID) held in Brussels (Belgium). Addressing disparities in access to treatment,

we supported the sixth edition of the LASID Meeting organized by the Latin American Society of Immunficiencies in Cancún (Mexico).

In the area of diagnosis and treatment of peripheral nervous system disorders, we took part in several conferences organized by European countries, including the Congress of the German Society of Neurology held in Stuttgart (Germany); the annual Swiss Conference dedicated to this therapeutic area in Lausanne (Switzerland); and the Hungarian Congress of Neuroimmunology, held in the town of Visegrad.

In the US, we were among the primary supporters of the GBS-CIDP International Foundation in the United States, dedicated to the research, diagnosis and treatment of Guillain-Barré syndrome and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

We have continued our commitment in the field of liver transplantation with Epateam, the healthcare networking project dedicated to liver transplantation, by supporting its various initiatives, including the event "Stories of Transplantation" in Rome.

Kedrion Biopharma is committed to serving as a trusted resource for knowledge about Rabies,

participating in numerous activities and projects in the United States aimed at training and sharing with doctors and health professionals the latest understanding of pathology, prevention, and post-exposure prophylaxis. One such event was an educational meeting for the Guild of Philadelphia Hospital Pharmacists, where we presented to more than 30 key decision makers in the Philadelphia, PA region.

REACHING OUT

With the active encouragement and support of Kedrion, our employees engage in many community activities to help others in need. Examples of such contributions in the US include:

Sponsored participation in the IDF Walk in NYC for Primary Immunodeficiency; partnering with JERSEY CARES and the Center for Food ACTION, to provide food and clothing for local families in need.

In 2019, Kedrion continued to collaborate with the Italian National Blood Center (CNS) and various Italian regions (Tuscany, Emilia-Romagna, Marche) in projects to support less developed countries, including Albania, El Salvador and Afghanistan. We have facilitated humanitarian donations of coagulation factors, providing logistical and financial support.

Projects involving the donation of plasma-derived medicines that exceed national requirements ensure the ethical and rational use of plasma collected in Italy.

“

On behalf of Hemophilia patients, their families, parents and the Afghanistan Hemophilia Patients Association, I want to thank the Italian Government, blood donors, and Kedrion, which placed a focus on Hemophilia patients in Afghanistan. The majority of patients are children. Young patients arrive from all over Afghanistan accompanied by their parents, facing the danger of a long journey in order to visit the Hemophilia Center of Kabul to receive factor administration. Twelve years ago, we didn’t have access to the diagnosis of Hemophilia and Factors in Afghanistan. Today we are so pleased, as we have access to the diagnosis of Hemophilia and Factors. I would like to thank once again the Italian people who worked hard in Afghanistan. We hope that the collaboration continues on into the future.

Dr. Arif Oryakhail
Public Health Technical Advisor at the Italian Agency for Development Cooperation in Kabul, Afghanistan

ECONOMIC AND FINANCIAL INDICATORS

SIGNIFICANT EVENTS OF THE FINANCIAL YEAR

Kedrion ended 2019 with a record turnover of Euro 808.2 million, an increase of 17.5% compared with the previous year. The US, which grew by 24.7% compared to 2018, is the Group's top market (43.5% of turnover) followed by Europe with 31.5% of turnover (where Italy has 19.8%) and the Rest of the World with 25%. In line with the ongoing internationalization process aimed at consolidating Kedrion's presence on the main global markets, exports in 2019 represented 80.2% of turnover.
Revenues from the sale of plasma derivatives amounted to Euro 577.5 million, up by 12.4% compared to 2018, thanks to the positive performance of our Immunoglobulin products, both in terms of volume and price.
The US plasma-derivatives market increased by approximately 28% compared to the previous year, and all the other strategic markets are growing, led by Italy, Turkey, Mexico and Germany.
The plasma segment experienced an increase in the volumes available to the Group which allowed for a substantial increase in sales to third parties, once internal production requirements had been met, generating a turnover of Euro 209.6 million compared to Euro 155.1 million in 2018. EBITDA was Euro 101.3 million equal to 12.5% of turnover, more than doubling the value of the previous year. In fact, in addition to the growth in turnover there was a strong reduction in non-recurring costs (-36.6% compared to 2018) due mainly to the increase in volumes processed at the Melville plant.
Adjusted EBITDA in 2019 was Euro 166.1 million up by 11.7% compared to the previous year.
The margin percentage was 20.6% and suffers as light watering down in profitability due to the increased weight of the plasma segment compared to 2018. Furthermore, on 15 November 2019 the entry of a new partner in Kedrion S.p.A., has been finalized. Following the signing of an "Investment Contract" between Kedrion S.p.A., Sestant Internazionale S.p.A., Sestant S.p.A., FSI Investimenti S.p.A. and FSI SGR S.p.A., 50.27% of Kedrion S.p.A.'s share capital is now held by Sestant Internazionale S.p.A., 25.06% by FSI Investimenti S.p.A., 19.59% by FSI SGR S.p.A., 4.02% by Sestant S.p.A., 0.56% by Refin S.r.l. and 0.50% by PIPS S.r.l. The entry of the new partner together with a Euro 50 million participation by FSI SGR S.p.A. and Euro 16.7 million by CDP Equity to strengthen company capital, represent for Kedrion S.p.A. a strong contribution to tackle growth and new challenges from both domestic and international markets.

COMPLETION OF THE MELVILLE PLANT REFITTING

Compared to the previous year the main development, which has had an effect on current performance, is represented by the recovery in production of the fractionation line at the US plant in Melville; this follows completion of the refitting project after the inspection during the month of August 2018 and final approval in February 2019 by the FDA. From an industrial standpoint, the project was completed in 2018, when the fractionation line resumed production during the second half of the year (approximately 80,000 liters fractionated). During 2019, 480,000 liters were fractionated at the plant, consistent with planned growth prospects progressing to full production capacity utilization.
From 2016 to 2019 the Group has had to invest Euro 90.2 million in this project, including investments for building the fractionation and purification line for Immunoglobulin Anti-D (RhoGAM®), so that production of this specialty could be internalized. In November 2018 the FDA also carried out an inspection of this new line dedicated to the production of RhoGAM®, and in March 2019 it finally approved filling and packaging activities.

With production resuming at the Melville plant, both in terms of fractionation and the RhoGAM® filling and packaging line, the income statement for the year significantly improved, mainly as a result of the reduced non-absorbed plant costs and the non-recurring project costs (-60% compared to the previous year), leading moreover to an increase in sales margins for products on the US market. Following the inspection by AIFA in November 2019 the Melville plant finally received the GMP certificate from the European Authorities in February 2020; this represents a further step forward in aligning and integrating it fully with the other plants of the Kedrion Group.

KIg10

During the financial year 2019 the project to build a plant for the purification of a 10% Immunoglobulin (KIg10) using the chromatographic method was also continued in Castelvecchio Pascoli (Lucca, Italy). Following IND (Investigational New Drug) approval by the FDA in January 2019, the first patient was enrolled in clinical trials in the USA in April 2019, whilst the last patient was enrolled in November 2019. The treatment of these patients is ongoing and to date no adverse reactions have been reported. The Company is looking to launch further clinical trials for other therapeutic indications. Production for use in clinical trials is currently being carried out at the Gödöllő plant in Hungary (purification phase) and technology transfer is in progress in the Castelvecchio Pascoli plant. Preliminary activities for obtaining the necessary authorizations and registration of the product have progressed as planned and according to schedule, there by determining an increase in investments and start-up costs. Project costs for the year not included in production and relative revenues amount to Euro 9.7 million, while overall investments amount to Euro 24.4 million.

THE NEW KEDRAB® PRODUCT

Sales of KEDRAB®, an Anti-Rabies Hyperimmune Immunoglobulin concentrate developed in partnership with Israeli pharmaceutical company Kamada Ltd. continued during 2019. Since 2018 Kedrion has exclusive distribution rights in the USA for this product and revenue from the first year of activity amounted to Euro 28.7 million, winning a 20% share of the market. The clinical trial for pediatric indication is in its final stage and FDA authorization of the indication is expected at the beginning of 2021.

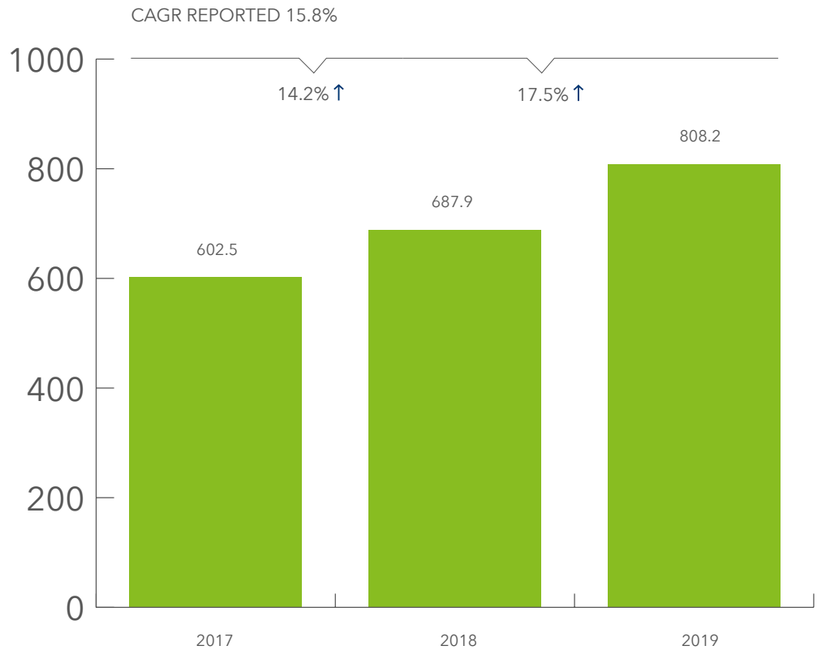
PLASMA COLLECTION CENTERS OWNED BY THE GROUP

Activities in this segment included both the sale of 4 plasma collection centers in Germany and the purchase / start-up of 6 centers in the USA during the course of the year, for a total of 29 Group-owned centers at the close of the year.

REVENUES

At 31 December 2019 turnover from production and commercialization of plasma-derived products was Euro 577.5 million (71.5% of total revenues) an increase of approximately 12.4% compared to 2018, thanks to the positive trend of Standard Immunoglobulin both in price and volumes and to the growth of the US market recording an increase of 28% compared to the previous year. At 31 December 2019 turnover from collection and commercialization of plasma was Euro 209.6 million, an increase of 35.2% compared to the previous year. This excellent result was made possible thanks to an increase in volumes of available plasma purchased from third parties and as a result of increased collection from Group-owned centers in the US and in Europe.

REVENUES (€ MLN)



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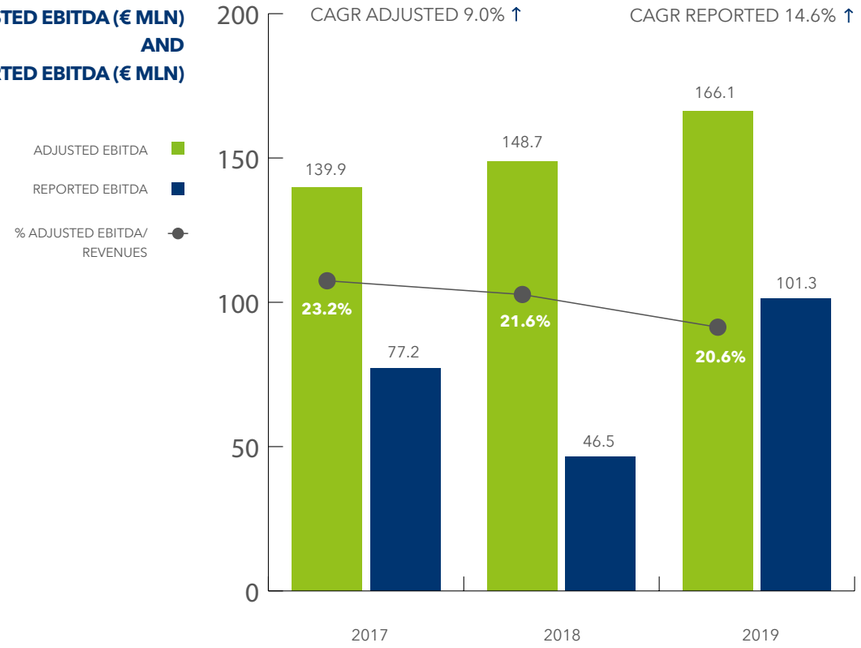
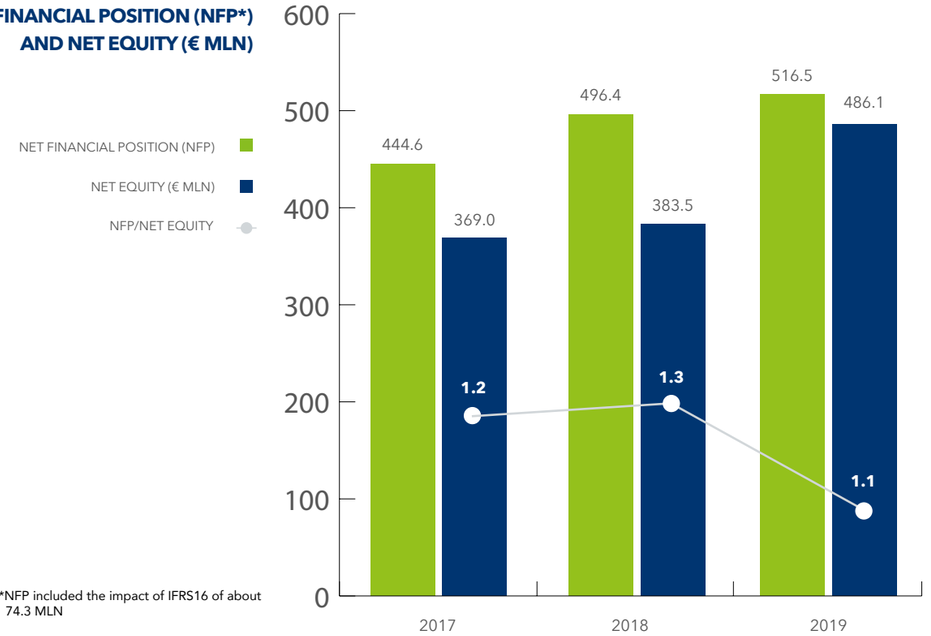
ADJUSTED EBITDA (€ MLN) AND REPORTED EBITDA (€ MLN)



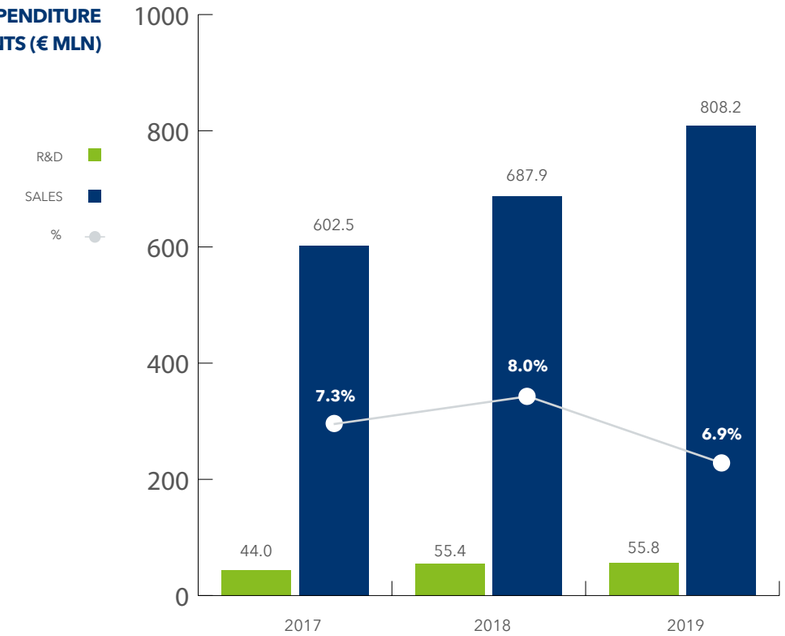
GROSS CAPEX INVESTMENTS (€ MLN)

NET FINANCIAL POSITION (NFP*) AND NET EQUITY (€ MLN)



*NFP included the impact of IFRS16 of about 74.3 MLN

R&D TOTAL EXPENDITURE AND INVESTMENTS (€ MLN)



USA

In 2019 turnover in this area was Euro 351.8 million, an increase of 24.7% compared to the previous year, retaining its leading market position for Kedrion with a 43.5% share of total revenues. Standard Immunoglobulin was the main driver in the growth of revenue, followed by sales of Plasma, the new Anti-Rabies Immunoglobulin and Albumin.
Anti-D Immunoglobulin (RhoGAM®) and Factor VIII experienced a slight decrease in volumes sold.
In addition to sales of plasma-derived products, turnover was also generated by activities carried out for third parties at the Melville plant, with a sharp increase in plant operations.

ITALY

At 31 December 2019 the Italian market turnover decreased by 8.3% compared to the previous year, reaching Euro 159.8 million equal to 19.8% of total revenues, thanks to sales of finished products on the commercial market and to contract manufacturing operations carried out for the Italian National Health System. This decrease compared to the previous year is mainly due to the reduction in contract-manufactured volumes carried out for the National Health System.

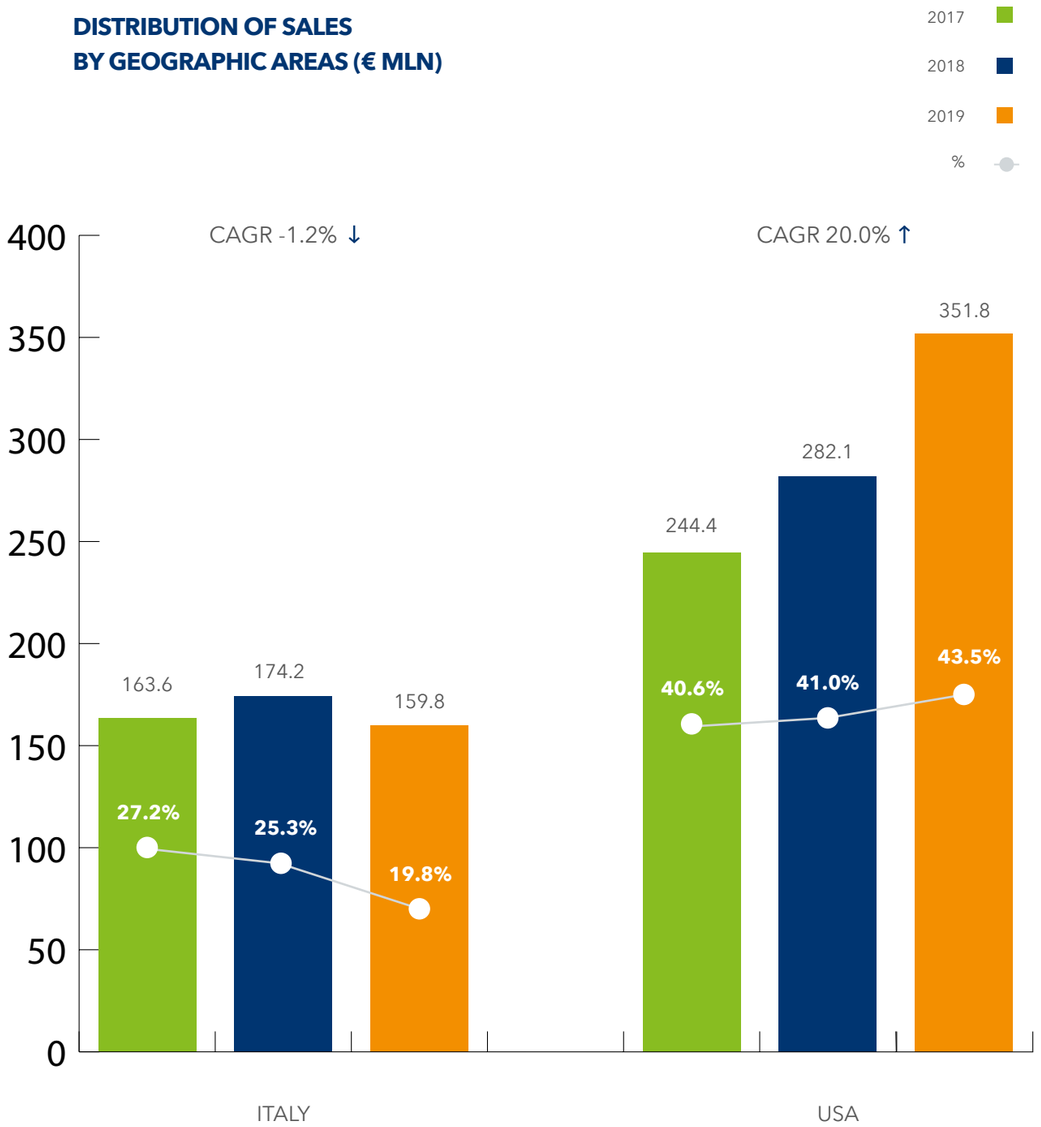
EUROPEAN UNION

At 31 December 2019 turnover in other countries of the European Union was Euro 94.7 million equal to 11.7% of total revenues, recording a significant increase (26%) compared to 2018. This growth is due to both the increase in Plasma sales to European customers (mainly in Germany), which amount to Euro 28.9 million, and to the higher volumes of Standard Immunoglobulin sold in Poland and Austria. Germany, Austria, Poland, Portugal and Hungary are our main European markets in 2019.

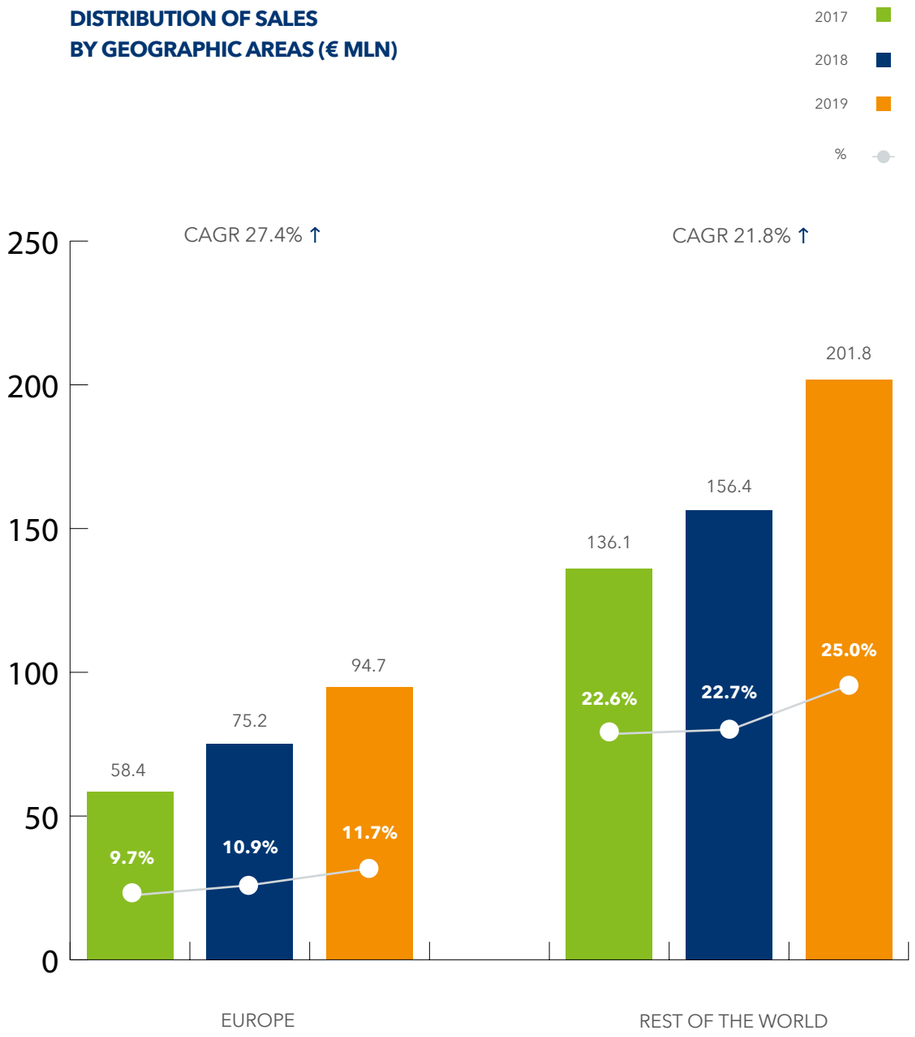
THE REST OF THE WORLD

At 31 December 2019 turnover in this area was Euro 201.8 million, an increase of 29% compared to 2018, representing 25% of total revenues. Compared to 2018 Turkey outperformed Mexico (despite the fact that both countries were affected again by the weakness of their local currencies) and became the area's top market in terms of turnover, reaching Euro 39.4 million, followed by Switzerland (mainly for Plasma sales) and of course Mexico; in addition, together with Russia, India and Saudi Arabia these countries accounted for approximately 71% of total revenues for this area.

DISTRIBUTION OF SALES BY GEOGRAPHIC AREAS (€ MLN)



DISTRIBUTION OF SALES BY GEOGRAPHIC AREAS (€ MLN)



CONSOLIDATED FINANCIAL STATEMENT

CONSOLIDATED INCOME STATEMENT (in thousands of Euro)	**12/31/19**
Revenues from sales and services	808,209
Cost of sales	612,008
Gross operating margin	**196,201**
Other income	49,469
General and administrative expenses	85,140
Sales and marketing expenses	55,041
Research and development expenses	36,705
Other operating costs	8,402
Operating result	**60,382**
Financial charges	35,849
Financial income	17,596
Result before tax	**42,129**
Income taxes	3,963
Net result for the period	**38,166**
of which:	
Group result	**36,740**
Minorities result	**1,426**

OTHER COMPREHENSIVE INCOME (In thousands of Euro)	**12/31/19**
Profit for the period	**38,166**
Other comprehensive income	
Other comprehensive income to be reclassified to profit or loss in subsequent periods:	
Net movement on cash flow hedges	77
Income tax effect	(19)
Exchange differences on translation of foreign operations	2,939
Net other comprehensive income to be reclassified to profit or loss in subsequent periods	**2,997**
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:	
Re-measurement gains (losses) on defined benefit plans	(191)
Income tax effect	44
Net other comprehensive income not to be reclassified to profit or loss in subsequent periods	**(147)**
Other comprehensive income for the year, net of tax	**2,850**
Total comprehensive income for the year, net of tax	**41,016**
Attributable to:	
Equity holders of the parent	39,601
Non-controlling interests	1,415

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	**12/31/19**
NON CURRENT ASSETS	
Property, plant and equipment	282,270
Investment property	2,267
Goodwill	243,882
Right of use	72,363
Fixed term intangible assets	112,799
Investments in other companies	2,240
Other non current financial assets	9,929
Deferred tax assets	12,676
Other non current assets	1,002
TOTAL NON CURRENT ASSETS	**739,428**
CURRENT ASSETS	
Inventories	324,956
Trade receivables	123,169
Contractual activities	26,920
Current tax credits	8,865
Other current assets	31,204
Other financial current assets	1,912
Cash and cash equivalents	121,468
TOTAL CURRENT ASSETS	**638,494**
Assets available for sale	
TOTAL ASSETS	**1,377,922**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (In thousands of Euro)	**12/31/19**
SHAREHOLDERS' EQUITY	
GROUP SHAREHOLDERS' EQUITY	
Share capital	60,454
Reserves	383,438
Group net income	36,740
TOTAL GROUP SHAREHOLDERS' EQUITY	**480,632**
MINORITIES SHAREHOLDERS' EQUITY	
Minorities capital and reserves	4,017
Minorities net income	1,426
TOTAL MINORITIES SHAREHOLDERS' EQUITY	**5,443**
TOTAL SHAREHOLDERS' EQUITY	**486,075**
NON CURRENT LIABILITIES	
Medium/long-term debt	569,048
Financial liabilities	396
Provisions for risks and charges	762
Payables for employee benefits	6,294
Other non current liabilities	5,086
TOTAL NON CURRENT LIABILITIES	**581,586**
CURRENT LIABILITIES	
Financial liabilities	68,103
Current portion of medium/long-term debt	12,217
Provisions for risks and charges	1,680
Trade payables	175,155
Contractual liabilities	12,782
Current tax payables	6,325
Other current liabilities	33,999
TOTAL CURRENT LIABILITIES	**310,261**
TOTAL LIABILITIES	**891,847**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	**1,377,922**

CONSOLIDATED CASH FLOW STATEMENT (In thousands of Euro)	**12/31/19**
Net cash flow generated by operating activities (A)	107,554
Net cash flow absorbed by investment activities (B)	(83,325)
Net cash flow absorbed by financing activities (C)	(19,396)
Total net cash generated/(absorbed) flow D=(A+B+C)	**4,833**
Cash and cash equivalents opening balance (E)	116,323
Net effect of conversion of foreign currencies on cash and cash equivalents (F)	295
Cash and cash equivalents closing balance G=(D+E+F)	**121,451**

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