

ANNUAL REPORT **2019**

# NOVEL CORONAVIRUS APPENDIX

**KEDRION**  
B I O P H A R M A



## MESSAGE FROM PAOLO MARCUCCI

*Dear Readers*

This Annual Report for 2019 is being issued during the Covid-19 pandemic.

It is a time of great trial and distress here in Italy and around the world. I share the fear and sadness that has descended everywhere.

As the leader of a company that prides itself on its mission to take care of people and bring communities together, I feel a special burden of responsibility to protect our employees as well as the patients who have come to

depend upon our products.

And what's more: to strive to apply our special expertise and unique experience to help bring about the earliest possible end to this global threat.

Below we outline how we are responding to the crisis and what we are doing to accomplish our goals.

I am confident that, working together, we shall overcome.

Please be well and stay safe.

Paolo Marcucci,  
Kedrion Chairman and CEO



## MEASURES FOR SAFEGUARDING PERSONNEL

In order to guarantee and safeguard the health and safety of its employees and their families, Kedrion has taken immediate action following or exceeding the guidelines of international, national and local authorities, deemed necessary to prevent and limit the spread of the disease. These measures were applied first in Italy, one of the first European

countries to be affected by the Novel Coronavirus, and subsequently extended to the USA and to Hungary, where our other production plants and plasma collection centers are located and to all Kedrion subsidiaries around the world. These actions include offering to as many employees as possible the opportunity to work from home, adopting strict physical

distancing policies, adding additional specific cleaning and sanitizing programs, and providing employees with personal protective equipment. Additionally, we have offered remote training sessions and provided continual updates on how the emergency is being handled and recommendations on individual health and hygiene behavior.

## PROTECTING OUR DONORS

Donor safety is our top priority at KEDPLASMA. In the USA and Hungary, procedures and processes have been implemented to ensure our

donors are following and protected by all national and local guidelines while in our centers. Our centers have enhanced sanitization

procedures and implemented additional employee/donor training to provide the safest donation process possible.

## MAINTAINING PRODUCTION TO SUPPORT PATIENTS

The international medical-scientific community and the major associations in this sector, most notably the Plasma Protein Therapeutics Association (PPTA), agree that there is no evidence to suggest that the Covid-19 pandemic can in any way undermine the safety and quality of plasma-derived products. The stringent controls on plasma donation and on the raw material at source, and

the consolidated procedures of viral inactivation and removal which are carried out during the production process of our plasma-derived products, guarantee significant safety margins against this virus. Kedrion is recognized as an *essential business* in each of the Countries in which it carries out its production activities. Plasma and its intermediates are recognized both in the USA

and in Europe as *strategic materials* whose continued supply to health facilities must be guaranteed. Our global production network continues to be operational and to date there have been no specific critical issues or delays in work schedules, in relation both to plasma collection and to production of all our medicines, including Factor VIII, Factor IX, Albumin and Immunoglobulin.

# SUPPORTING OUR COMMUNITIES

Current difficulties have not prevented us from reconfirming our solidarity with patient associations, medical institutions, scientific societies and the world of donors. We are recommitted to maintaining the dialogue, exchange and trust built up over many years of collaboration. We have concentrated our focus

on patients and on guaranteeing them the supply of the medicines they need. To reduce the risk of exposure to Covid-19, we have supported initiatives such as home delivery of medicines, especially geared towards safeguarding those who are most vulnerable. In Italy, where we continue to

guarantee to the National Health System contract manufacturing services of plasma collected by the partner Regions, we work alongside donor associations in order to raise public awareness on the need to donate plasma, thereby maintaining the supply of life-saving medicines.

# COMMITMENT TO RESEARCH AND ACTION

As we write Kedrion is engaged on the front line in the fight against Covid-19. Our R&D Department has focused its efforts on the use of "convalescent plasma" - that is, plasma donated by patients

who have recovered from the disease and is therefore likely rich in anti-virus antibodies. This plasma might be an effective treatment when transfused into patients suffering from the virus. It can also be the source of more

concentrated Immunoglobulin that might likewise prove to be an effective treatment. We have just entered into an agreement that could put us in a leading position in the quest for

an effective Covid-19 treatment. Kamada Ltd. is an Israeli bio-tech company with which Kedrion already collaborates on the Anti-Rabies product KEDRAB®. Using convalescent plasma provided by Kedrion and a Kamada proprietary IgG platform technology, the team will produce a human plasma-derived Anti-SARs-COV-2 (Covid-19) polyclonal Immunoglobulin (IgG) product as a potential treatment for Coronavirus patients within a relatively short time - a hopeful and exciting prospect. The primary focus of the collaboration initially will be to provide the product as treatment to patients in Italy, Israel and the US

through various clinical programs, and subsequently expanding development and commercialization efforts to additional markets.

We have already begun to collect convalescent plasma in our KEDPLASMA collection centers in the US and Hungary.

The use of convalescent plasma is already producing promising results. We acted immediately by offering our expertise and technology to transfusion centers, which in many Regions throughout Italy have adopted this therapy on a trial basis. In these cases the plasma undergoes a viral inactivation process with the use

of equipment and kits which we have supplied to the National Health System.

The Italian Society of Transfusion Medicine recommends that Covid-19 convalescent plasma be virally inactivated and processed in a qualified plant. Kedrion can satisfy these requirements at our Sant'Antimo (Italy) plant where the Covid-19 convalescent plasma can undergo solvent/detergent (S/D) viral inactivation treatment.

We will continue to protect our employees, serve our patients, share with our communities and contribute to the local and global efforts to confront and defeat the Covid-19 pandemic.

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