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Plasma-derived therapies are unique life-saving treatments based on a very special and finite raw material, therefore regulations should take this into account

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Maria Jose Sanchez Losada, general manager for CSL Behring Iberia, highlights the challenges that plasma-derived therapies faced during the COVID-19 pandemic, how the firm competes with well-established local players in the Spanish market, and its exciting upcoming therapies across immunology, respiratory, cardiovascular diseases, transplantation and haematology.

Can you begin with a brief introduction to your background in the pharma industry and rare diseases in particular?

My background is in economics and I began working in the pharmaceutical industry by pure chance, first with Bristol Myers Squibb and later with other companies in a variety of positions mostly commercial. All in all, my career in the pharmaceutical industry spans 25 years, most of it in Spain but also in global positions with my previous company, Roche. I have had the privilege to work very closely to operations, now at CSL Behring this is something that I really enjoy because of the ability to live the environment up close, bringing value through products and activities.

I have developed my career within specialized markets, mostly in the hospital setting, and have plenty of experience in infectious diseases and oncology. The world of rare diseases and the development of orphan drugs is highly rewarding. I had the opportunity to see how our job had a direct impact on people living with different diseases and their families, that is my driver. Overall, I

think I have been very fortunate.

CSL Behring is well known for its plasma-derived products and for operating one of the largest plasma collection networks in the world. Can you explain the company's presence, structure, and portfolio in the Iberia region?

CSL Behring Iberia covers two commercial affiliates, Spain and Portugal. The Iberian organization started three years ago but the company's presence in these two countries goes way beyond that, back almost 40 years.

Today, around 60 percent of our employees work in both countries and the two affiliates are well integrated.

The company's portfolio is very alike in both countries and is also similar to what CSL Behring commercializes globally.

Our current focus is on five key therapeutic areas, some with commercialized products and others in development. The first key area is immunology due to the immunoglobulins commercialized by CSL Behring.

The second is haematology where we have launched two new products in the last few years and have a large footprint; the two products launched are recombinant products in haemophilia A and haemophilia B, those are blood clotting disorders, rare in the case of Haemophilia B, which causes easy bruising and bleeding due to an inherited gene mutation. In addition, we continue developing innovation in Hematology with for instance and advanced development in Gene Therapy, which is very exciting for the whole organization.

Our other key areas are rare respiratory and angioedema, and CSL Behring is also preparing for the future as development moves forward in cardiovascular disease and transplantation.

To what extent was your organization affected by the COVID-19 pandemic and supply chain disruption?

The pandemic has been a challenge for CSL Behring and all other plasma-derived companies due to a decrease in donations. Since many of our products rely on plasma coming from abroad – the company has around 300 centres, the most of any plasma-based therapy manufacturer, with most

of them in the United States – we must wait for the material and later fractionate it into different proteins, which takes time. Luckily, the situation continues to improve as more people get vaccinated.

How challenging or encouraging is it to compete with Grifols, another big player in plasma, in its home market, Spain?

We compete in the market with many companies, but it is a healthy competition in the sense that it forces everyone to improve the way they work, it pushes everyone to be excellent and put together programs that support clinicians, pharmacists, and patient advocacy groups better. Competing with Grifols in its home market is a motivating factor for our organization.

You mentioned disruptions to the plasma market during the pandemic. What can you tell us about CSL Behring's performance in Spain and Portugal?

Overall, CSL Behring can be proud of the performance in Iberia, we have experienced double-digit growth for many years. This year the company will deliver on expectations, with a more stable performance despite the pandemic's impact on the plasma market.

In the mid- to long-term, the company will keep growing, driven by lifecycle management of the products that CSL Behring manufactures, but also because of the focus on very specific therapeutic areas in which it has great expertise. The future looks bright and the organization's decisions as it relates to investments in the portfolio are solid. Beyond that, our capital investment is also consistently high, as we seek to expand production as a reliable partner for health systems and, ultimately, our patients.

As a commercial organization, CSL Behring Iberia must deliver on its commitments, improving its performance every step of the way. This helps us to build and maintain trust, allowing us to deliver on our promise to patients. As I mentioned earlier, we do not have a large workforce, so every single employee counts and has a very meaningful role to play. It is therefore of key importance to take care of our people.

Your colleague from CSL Behring Turkey, Ercin Kugu, explained to us that plasma products enjoy a different regulatory framework from other therapies. Is that the case

in Iberia?

Plasma-derived products are not treated differently than other pharmaceuticals in Spain, an issue that has its limitations. Plasma-derived therapies are unique life-saving treatments based on a very special and finite raw material, therefore regulations should take this into account. We keep developing products, improving with innovation and technology our manufacturing processes to make the most out of it, but the fact that it is a limited resource and that we depend on donations is sometimes a challenge. These are elements that should be taken into consideration.

How important are patient advocacy groups for CSL Behring Iberia and what has been your approach to collaborating with them?

Our organization is constantly looking for ways to contribute as much as possible, including collaboration with patient advocacy groups such as the *Federación Española de Enfermedades Raras* (FEDER) or the *Federación Española de Hemofilia* (FEDHEMO). Bringing the patient perspective in everything you do drives our everyday work at CSL Behring.

More importantly, we also work with patient associations at a local level, not only national. We try to support patients as much as we can through local initiatives.

You mentioned that the workforce in CSL Behring Iberia is relatively small compared to the work you do. What is your approach to company culture?

CSL Behring culture and values are highly important, and something that we are very proud of. In Iberia, we work on team spirit, collaboration, patient focus and integrity, as they are four factors that put us in the best position to succeed. Managers inside the organization understand that we must keep developing people, supporting them in many ways, because they are the drivers of innovation. We bring innovation not only to our products but also in how to do our everyday work with all the different stakeholders.

Also, our company moved quickly at an early stage of the pandemic, to provide its staff with the flexibility to work remotely when needed. We have furthermore introduced an “agile working policy” which helps staff to maintain a good work/life balance.

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