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Accord recognises biosimilars as a future growth driver for the company. It is common sense as medicine moves to biologics and biologics move toward gene and cell therapy.

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Accord's Marc Comas highlights the company's presence in Spain with leading oncology products, three biosimilars and investment in specialty pharma. He shares his views on the COVID pandemic, the future of the supply chain, the importance of Spain, Barcelona's attractiveness for the pharma industry, and explains why Accord will be able to compete on price due to its in-house manufacturing capabilities.

How would you characterise Accord's journey through the COVID-19 pandemic and the presence of the company on the market?

The team felt a real sense of accomplishment in being able to while in at-home isolation to continue bringing vital, life-saving medicines to hospital intensive care units (ICUs). In fact, Accord Spain received a certificate from the Spanish regulatory agency (AEMPS) acknowledging its work and efforts as one of the top suppliers of pharmaceuticals to the Spanish hospital sector.

Accord Spain markets approximately 122 different International Non-proprietary Names (INNs) with 37 in oncology. Furthermore, the company supplies critical care products which were crucial for COVID-19 patients in ICU. The volume of sales doubled in one month due to panic buying, which

was then followed by a large decrease and subsequently a return to normal levels.

All medicines were sold in large amounts including antiretrovirals, anti-inflammatory products, and antibiotics before certain products were determined useful and others, such as hydroxychloroquine (HCQ), less so. This product was approved with super-fast registration and a special designation approval. The API was airlifted from India to Europe and sent to Accord UK sites for tablet manufacturing. However, clinical trials did not demonstrate HCQ being effective to fight COVID.

With a large portfolio in oncology, some specialty brands and a few biosimilars, what can you say about the organisation's current focus areas?

The focus of the organisation is on the hospital space which includes generic products for oncology, a portfolio of 37 molecules, and specialty brands. Accord has three biosimilars on the market in Europe, two developed in-house (Accofil® and Pelgraz®) and the other is in-licensed (Zercepac®). Additionally, a fourth biosimilar also developed in-house (Sondelbay®) has recently received regulatory approval.

Accord does not want to compete in the generic substitution game in community pharmacies and therefore remains focused on the hospital space. While oncology is the main target, we also have a focus on autoimmune diseases where we have partnered with local championm Laboratorios Rubiã³.

Accord is about to enter the new therapeutic area of addiction with a new product. There is an interesting patient population addicted to opioids and this product will be launched across Europe with a new team targeting special centres. Our product represents an improvement on others currently available and we hope to be able to launch additional products in the addiction field in the coming years.

Why is Spain a key destination for oncology and how does the country play into Accord's development trials?

Like other EU member states, Spain is also a key destination for clinical trials, not only for oncology, thanks to a high quality network of hospitals. In Spain, Accord's parent company Intas is starting recruitment for a generic-plus type of product that will be developed with extra strength in a slow-release formulation. This differs from today's standard of immediate-release tablets taken several times a day. Intas will run a 3 arm non-inferiority trial in Spain, France, and Germany with more than 100 patients recruited in each country.

The company is aiming to migrate away from the standard generic that competes on price to adding additional value to the patients with its specialty brand offering. However, on the generic offering, all companies can add value regarding packaging, stability data, colour range, and safety features. Therefore, price continues to be a factor to sell the product worldwide and Accord is able to compete for tenders due to its cost of goods and in-house production.

This shift away from product pricing to specialty brands is the area that is demonstrating strong growth and greater profitability. The benefit of solidifying a brand in the market provides stable profitability and recurrent income that is highly valued in the business world. Accord has several exciting new launches of specialty brands coming this year.

What has changed in the hospital market after COVID?

Following an initial period of uncertainty and panic buying, we are back to a normalized situation, but with less face-to-face and more digital interactions with healthcare professionals. .

However, what has not changed is the challenge we face to get our innovations recognised at a fair price. If we challenge the current standard of care with a better product, we think it is unfair to be given the same price currently paid for reimbursement. We feel the Ministry of Health does not necessarily value all the patient benefits enough and basically takes into consideration the budget impact.

This requires market access work with governmental bodies, which has consistently felt like playing against the referee.

The private hospital market is important for Accord and accounts for approximately 20 percent of overall sales. These hospitals may not launch tenders as they are able to use their own sourcing strategies.

Spain comprises 17 autonomous regions, including both public and private hospitals with different tendering processes. Furthermore, different public hospitals will be more efficient than others regarding the paperwork and preparation for a tender compared to others. Consequently, this is a case-by-case process with hundreds of different hospital tenders that can last up to four years.

What is Accord's view on and approach to, biosimilars?

Accord recognises biosimilars as a future growth driver for the company. It is common sense as medicine moves to biologics and biologics move toward gene and cell therapy. Fortunately, Accord through its parent company, Intas Pharma, are developers and manufacturers of biologics. Moreover, the company has a GMP certified site that is able to develop both types of microbial and mammalian proteins with the fill and finish of vials or prefilled syringes.

Similar to hospital generics, if the go-to-market-channel for a biosimilar is a tender, then price will be a very important factor too. Accord will be able to remain in the market for the long-term as it will be able to compete regarding price due to its large in-house manufacturing capabilities.

How are patients factored into Accord's biosimilar market approach?

Patients are at the heart of everything we do at Accord. We try to develop and market better products and better devices to ease administration, like our Pelgraz® and Methofill® pre-filled injectors. Accord belongs to BioSim, the Spanish Biosimilars Association, which aims to educate all stakeholders about the value of biosimilars.

Like generics, increased biosimilars usage will free public budget that can be reinvested into developing expensive CAR-T therapies for example.

Do you have any particular vision for supply chain reliability and how Accord can contribute?

Supply chain is becoming a very complicated business. Commercial teams struggled to predict stable sales in these past uncertain times, while managing the global surge in costs and a shortage of transportation.

The entire industry needs to improve, however, hospitals, governments, and others involved in the sourcing of these products need to provide greater visibility on the volumes they will source. Producing a medicine takes months from the making of the API to the production of the tablet or vial. Subsequently, it is sent to Europe for warehousing, testing, releasing, and is then sent to a hospital to be administered to a patient. As a result, all parts of the supply chain need to assist each other to allow for greater lead times to supply the appropriate quantities to the patients at the end of the chain.

How is Accord managing its production in Europe and the challenges of the distance from crucial APIs in China and India?

Much of the resilience of today's EU based industry relies on supply chains that begin in Asia. Re-locating all that API and FDF out-sourced production to the EU is impossible, but it is true that post-COVID we expect a surge in local production preference if an option to choose is available.

In order to manage these supply chain risks, Accord has recently acquired a large site from Teva in Schimatari (Greece) to establish its new European hub for batch testing and release, primary and secondary packaging of tablets, capsules and vials for further distribution to all European affiliates.

Why do you think that more multinational companies are choosing to base some of their service hubs in Barcelona?

The talent pool around Barcelona is extremely competent and the area has a booming biotech sector. The city can attract further talent because of its weather, food, architecture, and culture that all make it a good place to live and work.

In five or 10 years, what will be the role of Spain in life sciences?

Spain does not wish to be seen as a cheap country and to compete on costs alone. The country has access to high quality universities, some of the best business schools in Europe, a great network of private and public hospitals as well as cutting-edge industry.

While the costs in Barcelona may not be as high as cities such as London or Paris, it is not as cheap as other potential destinations. Therefore, Spain would like to become the destination for an equilibrium of quality and quantity.

What would you like to accomplish at Accord?

Recently, Accord has achieved certification as a Great Place to Work® for 2022. The company received a high Trust Index rating with high participation from its employees.

In the short term, the aim is to complete the expansion and refurbishing of our offices in the WTC building complex in order to begin working in a hybrid manner. Additionally, in the mid to long-term,

Accord hopes to continue bringing affordable generic products to hospitals as well as specialty brands that can improve the standard of care for prescribers and patients.

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