Emmanuelle Lepine, CEO, mAbxience



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mAbxience's CEO Emmanuelle Lepine highlights the company's international expansion into highly regulated markets, new investment into its Spanish manufacturing facility, and its partnership with AstraZeneca on COVID-19 vaccine manufacturing in Argentina. As representatives from the US FDA carried out a Good Clinical Practice inspection in an adjacent office, Lepine outlined mAbxience's business-to-business model, its pipeline selection criteria, and the development of two novel molecules.

You have been mAbxience's CEO for over five years, leading a fast-growing biosimilars organization, but got your start in the pharma industry with a Canadian generics manufacturer. Can you comment on your background and what attracted you to mAbxience?

I joined mAbxience in October 2016 at a time when shareholders were looking to shift the company's focus from Latin America to global markets. After five years, this mission has been accomplished; mAbxience is now selling in Europe and is in the process of registering in the United States, along with many other countries.

Before going into biosimilars, my expertise laid in generics, having spent 12 years with Pharmascience in Canada where I worked across bioanalytics, regulatory affairs, and corporate business development.

My involvement with biosimilars started with a move to Alvogen, where I oversaw the company's move into biosimilars. Seeing a great opportunity, Robert Wessman, Alvogen's CEO, decided to create Alvotech and tasked me with building the business plan. In only three years, we went from concept to having a pipeline of six molecules and opening a brand-new greenfield biotech manufacturing plant. When I left, Alvotech had over 200 employees and had signed global partnerships; it was for me a real fairy-tale business adventure!

My journey allowed me to be part of the creation of the biosimilars industry because back in 2010 there were almost no regulations; only the EMA had developed guidelines and the FDA first published its own in 2012. We did not know if health authorities would accept extrapolation of indications, how to design clinical trials, or how many batches were needed to establish similarity. There was a big cloud of uncertainty, including the question of regulatory authorities accepting single-use bioreactors at a moment when the industry worked with stainless-steel bioreactors; no firm had been able to register a product made using a single-use bioreactor in the US at that point. mAbxience was one of the pioneering companies that took the risk and went in that direction. I was convinced that single-use bioreactors were part of the technology of the future because of the ability to control contamination and lower capital expenditure (CapEx) that they entail.

What attracted me to mAbxience, besides Madrid's nice weather, was the fact that the company already had a product on the market. I thought that their strategy was quite clever; going small and generating revenue to finance these expensive developments instead of starting from scratch and aiming for the largest and most highly regulated markets.

mAbxience started in Argentina 12 years ago when the Sigman family acquired a small biotech called pharmADN, a development laboratory with four smart owners that remain part of the company. They launched their first rituximab biosimilar following an update to Argentina's regulatory guidance in 2014, looking to register in markets that recognized Argentina as a competent authority by leveraging the critical process parameters (CPP) for biopharmaceutical development.

For me, mAbxience was a well-hidden secret with a fantastic platform and great potential that needed to be exploited. Furthermore, working with a private family-owned company was a big plus due to its quick decision-making process.

You mentioned that the company hired you to lead a towards globalization and that you have already reached some milestones. Can you update us on latest markets were you launched your products and the next steps?

Bevacizumab is our first approved biosimilar in highly regulated markets; it has obtained approval from the European Medicines Agency (EMA) and countries like Switzerland, United Kingdom, Canada, Australia, and Mexico. The next step for the product is approval in the United States, Japan, Korea, and Taiwan..

In fact, at this precise moment we are undergoing a Good Clinical Practice (GCP) inspection from the US FDA, which is part of their Pre-Approval Inspection (PAI) process. We are expecting the inspection of our manufacturing facility in the city of León over the next weeks and approval will hopefully follow in 2022.

How does mAbxience's business model and approach compare to those of its competitors in the biosimilars marketplace and how do you decide which molecules to include in your pipeline?

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mAbxience has more than 30 partners to cover the entire world for Bevacizumab – except China – which are key in the selection of our product pipeline; we work with them to understand the needs of local markets and be more competitive. The main strength of mAbxience (and its parent company Insud Pharma) is manufacturing competitiveness, which is why, unlike Big Pharma players, we develop biosimilars with a generic mindset instead of developing them thinking that they will be branded and marketed at high margins. If you have a generics background, you understand that this is not how it is going to end up; biosimilars are getting more competitive, especially in Europe's mature commercial landscape. Our game is to control our development and manufacturing costs for extremely high-quality products to create efficiency-led margins. The company aims to include pipeline items that have significant market share in local markets, but also has niche pipeline assets that can enjoy less competition and price erosion. We are focusing mainly on oncology biosimilars which compete in a tender by hospital dynamic.

The company's portfolio includes two novel molecules in addition to the biosimilar assets, what is the plan for them?

Our MB13 and AV02 assets are new pharmacological entities and represent truly innovative programs. We are developing them in collaboration with universities and partner companies which wanted to utilise our platform to ensure a more structured development process. In line with our B2B model, the intention is to partner up with another company at a certain stage in this development process.

Biosimilars are complex and require high levels of proficiency in both analytics and characterization, which is not the core of the development of innovative products. mAbxience is an analytical dynamo with all the technology in-house, so it is well equipped to engage in innovative development as well as biosimilars. Because of our complete biotechnology platform, we are offering CDMO services that are very attractive to smaller companies which do not have manufacturing and development under one roof.

Are you concerned that having resources allocated to the development of novel treatments could result in the company losing its biosimilars focus?

No because we yet at the early development stage for these assets. We have the capabilities to create a stable clone for early-stage development, create cell banks and characterize the molecule,

and then partner with third parties to do disease modelling and testing. We can accommodate the speed required at this stage and it is not as demanding from a resource perspective as we have a lot of capabilities in these areas across our different sites in Spain and Argentina.

mAbxience has made global headlines because of its partnership with AstraZeneca to manufacture their COVID-19 vaccine. Can you share how that collaboration came about and what made your company a good fit?

mAbxience was opening a new state-of-the-art greenfield biomanufacturing facility in Argentina when COVID-19 hit. We were starting to transfer our own products when AstraZeneca approached us to dedicate the facility to the manufacturing of their vaccine, which is what we did all last year and are continuing to do.

AstraZeneca identified mAbxience as a key CDMO partner because, having great experience in technology transfer, we understand the science and help them improve their own process. Tech-transfer in biotech is complex because you need to master the art of understanding the process, controlling variability to get the same quality profile.

Another important recent development for the company was the announcement of an expansion of its production facility in León, Spain. Can you comment on how the project fits into your growth strategy?

mAbxience established its León facility in 2014 with the idea of expanding it over time, giving us the opportunity to have a certain number of fermentation systems separated in two suites. The first suite was conditioned with the instalment of two bioreactors, which later became four and today we are starting with line number two with a larger bioreactor. We are scaling-up manufacturing as new markets are opened and demand increases, which is key for efficiency and control of the cost structure; it is the smartest way to build capacity. The expansion plan will be completed next year, and we are already thinking about expanding the Argentinian facility, which is less than two years old.

We are at a great moment from a business point of view, especially with the opening of the United States market, which the industry has desired for a long time and began to materialize last year with a biosimilar monoclonal antibody oncology molecule gaining a significant market share in a short time. Likewise, in Europe, we are seeing an acceleration of the conversion rate from

originator to biosimilar.

Sandoz CEO Richard Saynor recently said that the European biosimilars market is “in many ways behaving like classic generics.” Do you agree with his assessment?

The European markets are going towards that direction in terms of penetration rates but are not there yet as some countries do not yet have regulations in place for automatic substitution at a pharmacy level. From a pricing dynamic point of view however, yes, biosimilars are experiencing price erosion similar to that of generics in the majority of EU markets.

While adoption rates for biosimilars in Spain have been increasing rapidly in recent years, the country remains below the European average. How do you assess the industry’s momentum in mAbxience’s home market?

While biosimilars in Spain are experiencing rapid adoption and certain products have gained a high market share, the country lags behind other major European markets because of the decentralized nature of the system and the lack of unified national tenders.

I believe that the country, aware of the cost-saving opportunities, is trying to push biosimilar adoption as much as possible but a few barriers remain, some created by innovator companies through disinformation efforts. Countries where the government has shown leadership in breaking these false barriers are the ones with high adoption rates.

While the European biosimilars market has reached a certain maturity level, the United States remains a challenge due to its patent framework. How is mAbxience approaching market access in the US?

Each company is playing its own game, trying to beat each other to become the first to enter the US market. The main issue is the regulations and the so-called “patent dance” where biosimilars firms are required to inform the innovator company that they are filling a product that touches upon theirs and address a list of patents they have. Most of the time companies settle with the innovator companies. Companies can take both strategies, either making a deal with originators and agreeing to an entry date, or fight them through litigation, which has proven unsuccessful so far for most companies. Since mAbxience has partnered with an American company, they are

responsible for marketing authorization while we support them from the background.

EMA approval has already achieved and more highly regulated markets are on the horizon for mAbxience. With manufacturing expansion, new partnerships, and pipeline developments added to this mix, how should the industry think about the future of mAbxience?

It was important for mAbxience to enter regulated markets, and we now have the recipe to do it. The future of the company looks bright in the next five years; we will be pushing our pipeline, launching more products with our commercial partners, and expanding our manufacturing platform, offering more CDMO capabilities to the industry. We expect to have more products in the market, more partnerships and to add new technology that will allow us to venture into other areas of biotechnology, not only biosimilars.

As a successful builder and manager of biosimilar ventures, can you share your approach to organizational culture and what keeps you motivated?

As someone who loves to build, I am motivated by being part of a growth story. I love to create a culture that allows people to be passionate and enjoy what they do; I always tell the team that we work hard and play hard. The achievements of the company are quite remarkable, it is the only privately-owned company with less than 500 people that has launched a monoclonal antibody biosimilar in the entire world; this usually is not a small company game, and mAbxience did it. You can only get there by having a team aligned with a mission and by creating a fearless culture where people are not afraid of reporting their own errors. People should feel free to communicate mistakes instead of hiding them so that the organization can fix them at the right time and learn for the future. I aspire to create a positive working environment and achieve ambitious goals.

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