

**Martin Dubuc General Manager, Biogen
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Martin Dubuc, general manager of Biogen France, discusses the company's strong leadership in neurosciences, its commitment to pioneering the high-risk field despite the withdrawal of many industry players, the strategy to keep MS at the core of its business while developing next-generation treatments in areas like Alzheimer's, and the important role that France and the affiliate play for Biogen globally.

What have been your main priorities taking on the general manager position for the first time?

Although this is my first general manager position, I have held several executive roles in other pharma companies before joining Biogen two years ago at the corporate headquarters in Boston. It has been a great experience to connect to the executive network and join the overarching global infrastructure of Biogen.

I have had the privilege of entering the position in a very dynamic market and my first key mission is to deliver on our financial plans and shape a high performing organization. This may seem like an obvious answer, but it is an important aspect to keep in mind while in a general manager role.

What priorities exist for Biogen France in particular?

As for Biogen France, there are three primary priorities to highlight. The first is to continue building our leadership and differentiation within neurosciences. We have a strong heritage in neurology, especially in multiple sclerosis (MS). In the field, we aim to advance on creating services beyond the pill, scientific excellence, and overall public presence of our biotechnology company.

Our second ambition is to actively build a structure and establish our team around the biosimilar area. We are in a shifting period for these products in France. It takes dedication and focus to advance the agenda and make sure we as a company are proactive in helping the biosimilar development in the market.

Lastly, we are excited to prepare for the future DMT for Alzheimer's therapy – we have six assets under development in this pathology. This is an initiative we have recently started in terms of setting up local infrastructure. As a general manager, I have to not only be focused on the short term but also build on the long-term opportunities available.

How does Biogen France mirror the ambitions of the global organization to be the reference company for neurosciences in the affiliate's domestic activities?

Biogen has publicly declared that our mission is to be pioneers in neuroscience. This is not an easy task and some companies have pulled out of the field. However, our own belief is that in order to be successful in neuroscience, we have to be focused and entirely dedicated as experts. Working in an area where there is so much unmet medical need, Biogen holds pride in pioneering this high-risk field and going where others are sometimes afraid to tread.

The way the trickling down of the global strategy touches a market like France is through clinical trials. There is a strong clinical infrastructure in France with superb centers in neurology which are leaders in nearly all areas of neurological disease. Biogen France trials have grown by nearly 30 percent over the past three years. We have 21 ongoing clinical trials as of today with more than 2,000 patients involved. The other part of preparing the new Biogen is going beyond leadership in just MS. We are looking at how can we be the authority in neuroscience, which has many specialties but is still connected together. The R&D activities and dedicated focus are all part of transferring the company's global vision into the affiliate on a local level.

How is Biogen limiting the risk exposure from specializing in neurology?

Despite the risk, we are very proud to operate within these areas. For example, Alzheimer's alone will cost USD 2 trillion to society in 2050 and without research in this field, the healthcare system cannot be sustainable in the future. The reality is, there needs to be a lot of investment into neuroscience to crack the treatment ceiling. Biogen is both the most advanced and invested company in Alzheimer's disease. We have six assets along with different modalities monoclonal antibodies, bace inhibitors, and antisense oligonucleotides, which are all different ways that may treat various phases of the disease.

We have built very strong expertise in our teams around imaging, genomics, biomarkers, cognitive tests, and other aspects. The more focused we are the quicker we can be in our own development and in finding the right partners to help drive progress forward. We had the first Alzheimer's asset to show dose and time-dependent impact on amyloid plaques levels and cognitive functions in Phase I trials.

We also have advanced 14 clinical programs since 2017 in diversified areas of neuroscience with large unmet medical needs.

How is Biogen's portfolio reflected in the French market and how do you prepare for competition in MS?

MS is our core business and will remain at the centre of Biogen. We have been leaders in the area for a long time - nearly one in two MS patients in France is treated by a Biogen therapy. We have five products in the area and we heavily invested in the day to day development of MS in the country. Biogen has a historic commitment to the diseases, and we will continue on this path moving forward. In terms of newer ventures, we expect SMA and biosimilars to be our main growth drivers for the next few years to come and Alzheimer's is a long-term strategy still yet to come.

Around competition, we welcome new therapies as MS is a very heterogeneous disease and patients live for many years with the condition. This can be rather complex because the disease can change, evolve, and adapt over time. Therefore, having many therapeutic alternatives and continuing to develop treatments to meet the remaining unmet medical need is crucial for the clinicians and patients. Every new treatment coming to market is an important “weapon” in the arsenal of health providers to take care of patients.

What factors make France such an attractive market for R&D investment?

As we think of scientists like Jean-Martin Charcot, considered to be the father of modern neurology, it is understood that France has a strong history of neuroscience. We have some of the largest expert centres in Europe in terms of MS and other areas. Clinically speaking, France has a strong value proposition for a company like Biogen who wants to be a frontrunner in neuroscience. This is why Biogen announced in October a global partnership with the French University PSL (Paris Sciences Lettres) under the form of a collaboration agreement intended to promote therapeutic research through a PhD exchange programme between PSL and Biogen. Additionally, in the 8th CSIS, the government announced the measures they are taking to simplify clinical trials which is a significant move by politicians to build an infrastructure that will care better for patients. These kinds of diseases require very strong connectivity between private institutions and hospitals which calls for a close healthcare network. These reforms are helping to structure the health continuum to a very unique level within Europe.

Finally, France is the fifth largest pharmaceutical market in the world and the fourth most important for Biogen. Biogen has 200 employees in France; 180 for the French affiliate and 20 attached to international roles but hosted in our Paris office. Moreover, there has been a 30 percent increase in our workforce over the last 12 months.

On the other side of the balance sheet, what are the challenges encountered in the French clinical trials ecosystem?

While the level of quality and infrastructure is excellent, there continues to be a seven-month delay on average to begin a study in France. This is unacceptable in comparison to competition for trials coming from other countries. We are very pleased to hear that the Macron administration is planning to take steps to shorten the process to a substantial degree. Nevertheless, despite the positive ambitions, the day to day reality of the environment remains difficult in France.

How ready is the market to embrace the emerging field of biosimilars?

In France, we are confident in the positive changes we have seen in regard to biosimilars, especially in incentivization. Indeed, France is very slow in the adoption of biosimilars and we have one of the lowest penetration rates in Europe. On the other hand, there is a political agenda to reach 80 percent penetration by 2022. Concrete advancements have been made over the last year, such as Article 51, an experiment to examine the effect of incentivization on biosimilar adoption when some of the savings generated by biosimilars go back into patient care in the services of the hospital where the biosimilars are used. Encouragingly, we have already begun to see positive changes in the 40 centres which are part of this experiment. Even so, the authorities will need to accelerate their processes if they hope to reach their goal in the next three years.

Biogen is proud to stand as the only company in Europe with three anti-TNF biosimilars, which constitute a very important class of therapies from a healthcare standpoint. Our vision as a company is to be both an innovative and responsible organization, and biosimilars play a key role in building the path to create a sustainable healthcare model from a financial standpoint. There is an unprecedented flow of innovation coming from areas like precision medicine and gene therapies, and biosimilars play a very important role in rendering the system sustainable so that this rhythm of innovation can be maintained.

What is your assessment of market access conditions in France?

When it comes to the speech delivered by the Prime Minister at the last CSIS, there seems to have been a lot of positive work conducted between the authorities, the LEEM, and industry stakeholders. Having the change in tone of this dialogue sparked positive optimism about the potential future of the French market. However, there has admittedly been a bit of a reality check when the draft PLFSS (Social Security Financing Bill) was unveiled.

The industry wants to see changes made to access, better valuation of innovation and shorter approval times become a reality. The average period between the European marketing authorization and the publication of the negotiated price in France lasts more than 500 days; France ranks 18th in Europe on this issue.

There is a need to breathe new oxygen into the pharmaceutical market for growth, but we cannot expect to see policy transformations happen overnight. As of today, we have not seen concrete improvements and we can only hope to have progress soon. As a general manager, the delays in bringing products to market and the lack of willingness to value innovation is very difficult to explain to our global headquarters, this, in turn, damages France attractiveness. The mindset of seeing new innovations exclusively as an additional cost should really change.

What capabilities does the affiliate possess in regard to embracing digitalization?

At Biogen, we think of neuroscience in a broad fashion and have therefore decided to build a global team dedicated to innovating healthcare solutions based here in Paris. This is not related to our products but rather helping patients and healthcare professionals by developing solutions outside of the pill. For example, we have released an app called Cleo in six of our markets (called Aby in the United States) to be a digital companion for patients living with MS.

France has one of the most vocal presidents about creating a startup nation, supporting entrepreneurs, leveraging artificial intelligence, and so on. In this agenda, some very concrete measures have taken place such as a EUR 10 billion (USD 11.4 billion) investment into the evolution of certain strategic fields. France also has a broad talent population of engineers, scientists, digital experts. Once the structure is established, the rest is driven by the human capital which together makes Paris a good setting for a digital ecosystem in France.

Biogen has recently received the Prix Galien France 2018 for its SMA therapy. How significant is this achievement?

Winning this award is a very proud moment for Biogen. Working on drugs like SPINRAZA®[®], meeting the families and receiving these recognitions triggers the feeling of why we are doing what we do every day. SPINRAZA®[®] has received seven national Prix Galien awards in 2018 and the international recognition in Dakar, Senegal. In the history of the foundation, it is the drug that has received the most awards in such a short amount of time.

Winning the Prix Galien does not, unfortunately, translate into any changes in the complex and lengthy market access process going on since over 600 days for SPINRAZA®[®]. We remain hopeful and work closely with the authorities to find a path for sustainable access for SPINRAZA®[®] in France for all the patients in need.

Any final concluding messages for our international readers?

Biogen is proud of its heritage in neuroscience and we will continue to apply ourselves in the areas which have the most unmet medical needs. Diseases like MS and SMA once had no treatment available but have been revolutionized today and this area is where our dedication is.

The French market can be seen in many different lights and while we do sometimes speak in contradiction to the optimism, we do believe the situation of the industry will evolve positively. We trust the government will take our cause seriously and implement the requisite transformations and reforms to place the country at the forefront of international life sciences innovation which should be considered a Strategic industry.

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