Olivier Samama – General Manager, France & Head of Sales, France-Morocco-Algeria, Biotest

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Biotest's Olivier Samama outlines the changes that the takeover of the company has had on the French affiliate, the country's plasma market and pricing policy.

What has changed since the acquisition of Biotest by the Chinese investor Creat Group Corporation in 2017?

The main impact of the acquisition has been the sale of our American subsidiary, as the Committee on Foreign Investment in the United States did not approve the takeover. As a result, we sold our plasma collection centres in the U.S. and we have opened new centres across Europe within the last two years; securing the plasma remains a core strategic priority for the group.

There has also been a major overhaul of the commercial organization led by Dr Enrico D'Aiuto (Vice President, Head of Global Sales & Marketing), Commercial activities are now segmented into 4 regions and France belong to the one including Middle East, Africa and the Indian subcontinent. In this instance, France is the only country where we have a subsidiary and one of my new responsibility is to develop African countries with the potential for Biotest products.

Finally, the takeover has created new opportunities for strategic partnerships. Two years prior to the Biotest acquisition, the Creat Group invested in a UK-based company called Bio Products

Laboratory (BPL) that also works in the plasma industry. We are currently investigating other synergies between our two companies.

Looking at the French affiliate, what have been some of the exciting developments over the last 3 years?

The product offering remains essentially the same, but we have experienced rapid double-digit growth in the last 3 years in viral infectious disease after transplantation (such as hepatitis B, CMV and varicella). In fact, we now rank as the leader in hepatitis B prophylaxis after liver transplantation. This year, the overall growth of the French affiliate will be around 10% and we expect to maintain this dynamic next year. In order to keep expanding, we are developing new molecules to bring to market.

With regard to the CMV and varicella treatments, the regulatory context differs. Both treatments, are submitted to a Temporary Authorization for Use (ATU) from the National Agency for the Safety of Medicines and Health Products (ANSM). The medical need for CMV infection treatment has grown since 2016 and the first real-life data of Cytotect CP use in France has been published at the beginning of 2018. We also put in place a Protocol of Therapeutic Use (PUT). Right now, we are looking into how best to respond to demand and the time frames for bringing this therapy to market. We also need to collect additional data for the ANSM that can be reviewed by healthcare professionals and the scientific community.

In the case of varicella, there have been new treatment recommendations since 2016. Our medication is mainly used for seronegative pregnant mothers or newborns exposed to Varicella. We are working to understand patients and physicians' needs to evaluate the interest for registration in the future.

The last time we spoke 3 years ago, you mentioned the group's ambition to reach USD 1 billion in global sales by 2020. Are you on track to achieve this objective?

Reaching the USD 1 billion mark remains the target. However, the deadline has been pushed back due to some delays in building manufacturing facilities. Our new treatment for severe Community-Acquired Pneumonia (sCAP), currently undergoing international Phase III clinical trials, is part of that endeavour. We also possess other molecules in our development pipeline that will enter the market by 2021-2022. For our existing products, such as albumin, IgIV and coagulation factors, we

are ramping up our production capacity to face the worldwide increasing demand.

Do you consider France to be an attractive market compared to its peers?

France is the second European market for plasma products just after Germany. Moreover, demand for those products is still increasing especially for innovative treatments in rare diseases. In case of high medical need, the French Authority has led the way by introducing Temporary Authorization of Use (ATU) prior to registration to allow quick access to innovative treatments.

However, considering more “classical” plasma products such as polyvalent immunoglobulins, the attractiveness of the French market will depend on the local regulation on plasma origins, the selling price and the production capacities. As an example, IGIV products are submitted in France to public tenders in a highly competitive environment where competitors start waging a price battle. At the same time, worldwide demand for plasma products is increasing (also driven by emerging economies such as Asia), despite limited production capacities of manufacturers. This creates a paradoxical situation where French prices are flat or decreasing, while worldwide prices are going up. As consequences, some manufacturers decided to cancel the launch or to reduce products allocation in France according to IGIV prices.

Regarding pricing policy, I think the situation is changing in France. Authorities are starting to realize that setting prices too low can become an issue. Even though the market is large, restrictive market access and tough price negotiations can reduce the availability of medicines in France. The authorities need to strike the right balance.

How does Biotest engage with the authorities with a view towards tackling this problem?

Our main vehicle to engage with the authorities is the Plasma Protein Therapeutics Association (PPTA), an international organization that also counts CSL Behring, Grifols and Shire among its members. In fact, a roundtable organized by IRIS, a patient association focused on immuno-deficient patients, was organized end 2018 with deputies and senators. On the agenda is a discussion around the new law on bioethics that is due to be introduced next year. This will afford us the opportunity to make lawmakers aware of the problem and tackle some of the negative stereotypes surrounding the foreign pharmaceutical industry.

What are your key priorities for the coming years?

As I alluded to previously, one of my main missions is to develop our business in francophone countries, especially France and some African countries. We already implemented Biotest products in Algeria where we work with a local agent. We have just started operations in Morocco with a local distributor where we recently finalized registrations. Now, we want to introduce our innovative infection treatments already as there clearly is an unfulfilled medical need. For example, there are a lot of pregnant mothers with hepatitis B. We need to highlight the medical need and the benefits of our treatments. Aside from Algeria and Morocco, we're simultaneously pursuing opportunities in other French-speaking African countries.

In France, we need to consolidate and strengthen our position for already existing products, while bringing new innovative drugs to market. We have two products underway that should hit the market in the next two to three years. Another opportunity for our French operations will be to identify synergies with BPL, although it's too early to say what would be the areas where we could best work together and collaborate.

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