Interview with Christian Bechon, Chairman & CEO, LFB

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In the wake of the most recent CSIS meeting, LFB and Sanofi-Aventis announced the intention to collaborate in bioproduction. What are the terms to this agreement and what are the objectives?

On April 2010, the sanofi-aventis group and the LFB group have signed a partnership agreement in France and are creating an economic interest group called LFB BIOTECHNOLOGIES-SANOFI CHIMIE. This long-term cooperation is intended to facilitate and develop mutual, preferential use of production resources based on cell culture, biological product purification and pharmaceutical preparation. It will also lead to a joint bioproduction offering for third parties. Finally, BIOTECHNOLOGIES-SANOFI CHIMIE will make it easier to transfer knowledge and pool training in biotechnological professions between the two companies. This agreement stems from the industrial cooperation project in bio-production in France, announced at the health Industries' strategic council meeting in October 2009. This cooperation between our two groups is in line with the will to develop French strengths in biotechnologies and combine our expertise for the success of our projects. Following the creation of the economic interest group, specific agreements will be signed. The first of these, currently in the negotiation process, is likely to cover the future industrial-scale production of a medicinal product being developed at LFB BIOTECHNOLOGIES.

Biotechnologies involve more than just isolating a molecule; they rely on a platform for bioproduction that does not exist in France. Can you speak to the need to improve these capacities in France and LFB's rationale behind developing the sector?

As you may know, reports have stated for years that France is lacking in bioproduction capacities and is behind the UK, Germany and even the Netherlands.

Sanofi-aventis and the LFB group have decided to work together to better organize their production forces and build complementary know-how in the field of bioproduction in France.

This collaboration project is an important step towards the reinforcement of France's wealth in this area and comes on the heels of Sanofi-aventis' announced launch of the Biolaunch project on the Vitry-sur-Seine (France) site in May 2009 and the extension of the capacity of LFB's bioproduction subsidiary (MAbgène) in Alès (France), slated to be operational by 2010. It is crucial that French pharmaceutical companies acquire their own bioproduction capacity. The development of adequate installations represents a strategic industrial milestone for France.

LFB is one of the top 5 French companies in the market and the leader in France for plasma derived medicinal products. Could you provide some insight on what LFB has contributed to the French healthcare sector since your arrival in 2006?

LFB is overall the 3rd supplier for medical drugs in French hospitals after Roche and Sanofi-Aventis. 2009 was an extremely active year for LFB in obtaining Marketing Authorizations.

We are collecting the benefits of our continued research and development efforts over the past several years. In 2009, LFB Group allocated a total of € 76 million, or 20.2 % of its turnover, to innovation and product development. The R&D budget increased by 14 % in 2009. Our portfolio of new medicinal products has been expanded with, in particular, the triply-secured fibrinogen already launched in France in 2009 and the new liquid immunoglobulin that will be available on the same market in 2010. We have also continued the European development of these new products. The authorization obtained for our Von Willebrand Factor in Germany, the reference member state in our European Mutual Recognition procedure, illustrates conclusively our ability to extend the geographical presence of our products. At the same time, we also significantly reinforced our production capacities with the opening of key industrial facilities that were started three years ago. Those are focused on our two industrial sites in France and are aimed at doubling our total fractionation capacity and create a production unit for our new liquid immunoglobulin. In 2009, we entered into the qualification phases of these new facilities.

What are LFB's specificities as a pharmaceutical company?

We are specialists in plasma-derived proteins and monoclonal antibodies. Our goal is to focus on rare pathologies and currently unmet medical needs. Our portfolio of medicinal products under development is perfectly consistent and concentrated on the therapeutic areas that we know well : immunology and onco-immunology, hemostasis and intensive care.

In 2009 our recombinant anti-CD20 monoclonal antibody was granted the Orphan Drug status in Europe for the treatment of B-Cell Chronic Lymphocytic Leukemia. LFB's 'Complement Factor H' medicinal product was granted the orphan drug status by the US Food and Drug Administration

(FDA) for the treatment of atypical Hemolytic Uremic Syndrome (aHUS). We have concluded a contract in 2010 with Thallion, a Canadian company, for the development and marketing of antibodies indicated for the treatment of Shiga-toxin producing E. Coli infections.
International activities are a key factor in the development of the Group (10% of our 2009 €376 millions sale). Their contribution to the 7 % increase of our turnover in 2009 should not be overlooked. Continuation of these successful international efforts is clearly among the Group's top priorities and we will continue to actively work in this direction in 2010. To promote further development of our activities, we will also pursue our strategy started in 2009 to conclude partnerships, especially in industrial areas. We signed an agreement with the Canadian company Therapure for the production in North America of two plasma-derived medicinal products for hemostasis applications.

And as a plasma player?

Safety and treatment for patients with rare diseases are "the core" of our ethical commitment. LFB Group has always made the biological safety of its medicinal products a top priority. In particular, it has pioneered nanofiltration, a technique used to eliminate pathogenic agents. Both the French authorities and the key european and international bodies have recognized the efficacy of this technique, particularly for the elimination of viruses and prions. In the area of Unconventional Transmissible Agents (UTAs) such as "prions", LFB Group has patented a validation method for the efficacy of prion elimination based on an in vitro cell test. LFB Group is developing this method at its Biological Safety Laboratory in the "Neuroprion" Platform of CEA, the French Atomic Energy Commission. In 2001, LFB set up ISAC, the International Safety& Advisory Committee of International Experts led by Professor Paul Brown, a worldknown specialist in prion diseases, to reinforce its biological safety strategy.LFB Group develops and offers therapeutic solutions for patients with rare diseases. LFB Group develops and offers therapeutic solutions for patients with rare diseases. Moreover, LFB is also one of the only pharmaceutical companies in the world to offer a therapeutic solution for coagulation factor XI deficiencies, a pure Von Willebrand factor and an Alpha-1-antitrypsin in France.

Along these same lines, LFB's commitment in this area is illustrated by the initiation of clinical trials to validate the therapeutic benefits of certain proteins, mainly for autoimmune diseases. For example, in 2006, the Afssaps approved the indication of IV (intravenous) human normal immunoglobulin for the treatment of Multifocal Motor Neuropathies (MMN). This MA granted to LFB BIOMEDICAMENTS' immunoglobulin is the first MA granted in the world for the treatment of MMN. In 2009, LFB BIOMEDICAMENTS obtained the indication for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

What is your position on the French plasma derivatives Market ?

In France, PDMPs are used for the treatment of around 80 different diseases affecting around 500,000 patients per year. We are the leader on the French market with a wide range of 19 products and the 6th worldwide.

In France, several players are active in the plasma-derived markets. Pharmaceutical companies with Marketing Authorizations (MA) in France bid for tenders from hospitals and clinics. A unique feature from the French legislation is that, for ethical reasons, access to the market is reserved to plasma products from unpaid donations. Several companies thus regularly bid for tenders from French hospitals with products manufactured around the globe with plasma that in principle comes from unpaid donations. LFB BIOMEDICAMENTS is the only entity authorized by law to fractionate plasma collected by the French National Blood Organization (EFS) in France. In exchange, LFB BIOMEDICAMENTS must give priority to meeting the country's demand with products derived from that plasma.

You mentioned that there are two directions for LFB at the moment, one being diversification into biotechnologies while the other is internationalization. What are your ambitions in regard to the international sphere and what are the key markets for the future?

LFB is very pragmatic about our size and possible outcomes at this stage, thus our strategy is to focus on a niche product. To promote further development of our activities, we will also pursue our strategy started in 2009 to conclude partnerships, especially in industrial areas. One of our major R&D goals for the coming year is also to enter into key alliances to achieve great synergies. We will also create value from our partnership with GTC for the development of transgenic proteins and, most importantly, the activated factor VII that is planned to enter clinical trials starting 2010. The unique profiles of our two monoclonal antibodies currently in phase I/II (anti-CD20 and anti-D) should also convince potential partners to join us during the phase III development stage.

Brazil is a key country for our international activities. LFB S.A. was chosen by the Brazilian government to assist the local state-owned company, Hemobras, in building a fractionation plant in Brazil. In 2008, with the help of its subsidiary LFB BIOMEDICAMENTS, LFB S.A. completed the upstream plant design and in 2009 provided technical support to Hemobras, who will carry out the plant in further stages. Moreover, this plant will benefit from the various manufacturing processes developed and used by LFB Group. A specialized LFB Group team will spearhead this technology transfer phase and train the Hemobras personnel.

Last year you grew by 9%, what are the financial ambitions for 2009 and the year ahead?

It is worth nothing that in 2007 we grew by 20% Our rate of growth was 7% in 2009. Nevertheless, I think that we will renew our two digit growth by 2011 as we are in the process of launching new products having acquired market authorization earlier in the year.

As you say you can fail just as well as succeed; according to you, what are the criteria for success? What is your message to potential partners, who are you looking for and why should they consider LFB?

We are industrial experts in the highly-specialized area of biology. In my opinion, our innovative spirit and our ability to meet industrial challenges will create a winning environment in which we can undertake a pathway for growth while fulfilling our commitments as a healthcare player towards Patients and Society as a whole. We have the capability of providing very interesting products and markets to other companies. As we are not a global player with a worldwide distribution network, we will need a partner in this segment moving forward in addition to possibilities in co-development, specifically in the U.S. as all of our products are developed to international standards.

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