PRESS RELEASE

First marketing authorizations in Europe for IQYMUNE®, LFB’s 10% liquid intravenous immunoglobulin

Les Ulis, 21th September 2015 – LFB SA announces the first two marketing authorizations for its 10% liquid intravenous immunoglobulin (IVIg) in Europe, namely in the United Kingdom and in Denmark. Thirteen more national marketing authorizations in Europe are expected in the coming months. Simultaneously to this ongoing European decentralized procedure, registrations are to take place in 33 countries in the rest of the world, for launches staggered between 2016 and 2020.

Since 26th August 2015, LFB’s “new generation” 10% liquid IVIg has been registered in the United Kingdom, and in Denmark since 4th September, in the Core SmPC indications. This immunoglobulin has a high-level of purity, relying namely on an innovative manufacturing process developed by LFB for its liquid immunoglobulins.

For rare immune system disorders. LFB’s 10% liquid IVIg IQYMUNE® will allow clinicians to treat rare immunity disorders, mostly hereditary, such as Primary Immunodeficiencies, Immune Thrombocytopenia, Guillain-Barré syndrome and Kawasaki disease, and acquired conditions such as Secondary Immunodeficiencies. These diseases concern tens of thousands of people in Europe, calling for chronic care most of the time.

Immunoglobulins being more and more prescribed in rare and severe dysimmune neuropahties, LFB is conducting two Phase III clinical trials in Europe in order to register IQYMUNE® in the indications of MMN and CIDP1, two severe dysimmune neuropathic diseases.

Registration on the way in 15 European countries. LFB chose a decentralized procedure for European registration, with the German Paul Ehrlich Institute (PEI) as the reference authority for the procedure. Following the United Kingdom and Denmark, registration for IQYMUNE® is expected in the following European countries: Austria, Germany, Belgium, Spain, Finland, Greece, Hungary, Italy, Luxemburg, the Netherlands, the Czech Republic, Slovakia and Sweden.

LFB reinforces its positions in Immunology. “The registrations for IQYMUNE® in Europe and in 33 countries are to contribute to LFB group’s rapidly growing international activity, with LFB currently making a third of its turnover with international business” points out Christian Béchon, CEO of the LFB group. “Given the increasing global demand in immunoglobulins, the launch of our 10% liquid IVIg, to start in 2016, is of strategic importance” adds Mr. Béchon. The registration of IQYMUNE® in many European countries is also a major milestone for LFB’s research and development policy, particularly active in the field of Immunology. “With two current phase III studies on IQYMUNE®, and the first anti-D monoclonal antibody under clinical trial (phase II b) in the world, for the prevention of haemolytic disease of the newborn, we have major developments to achieve in the coming years” stresses Guillaume Bologna, General Manager Development for the LFB group.

IQYMUNE® is to represent as much as 9 tons capacity in 2025, thanks to additional manufacturing capacities with upcoming new fractionation plant in France (city of Arras) that is to start around 2020.

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1 MMN: Multifocal Motor Neuropathy; CIDP: Chronic Inflammatory Demyelinating Polyradiculoneuropathy.
About the LFB group. The LFB group (www.lfb.fr) is a biopharmaceutical company that develops, manufactures, and markets medicinal products for the treatment of serious, and often rare, diseases in the fields of Immunology, Haemostasis, Perinatal and Intensive Care. The LFB group is the leading manufacturer of plasma-derived medicinal products in France and 6th worldwide, and is also among the leading European companies for the development of new-generation medicinal products or treatments based on biotechnologies. The LFB group is pursuing a growth strategy that seeks to extend its international activities and develop innovative therapies. Today, the LFB group markets its products in more than 40 countries around the world with a global turnover of € 501. 9 million in 2014. www.lfb.fr

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