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- Press Release -

Inaugurating the CELLforCURE Industrial Facility Manufacturing Cell Therapies, Attended by Arnaud Montebourg, Minister of Industrial Renewal

The industrial component of the French cell therapy sector was built with the backing of BPI France (the French public investment bank) under France's "Investing in the Future" program. The first products will be produced on the plant by the end of 2013. CELLforCURE is inaugurating the first-ever European facility for the large-scale manufacturing of advanced therapy medicinal products. At the inauguration, a first international partnership agreement with the Canadian organization Héma-Québec will also be signed.

The new manufacturing facility is located in Les Ulis (Essonne), France and is operated under the coordination of CELLforCURE, a specialized subsidiary established in 2010 by the French biopharmaceutical group LFB. The facility is a key component of the path for the future of the French cell therapy industry.

The new facility will allow autologous and allogeneic cell therapies R&D projects resulting from public research or by small and medium businesses, all the way through to industrial production. With this pharmaceutical platform, cell therapies will be more accessible to patients and will position French cell therapy industry on the international scene. Les Ulis plant will have an annual production capacity of 5000 therapeutic batches and will have the capacity to manufacture 8 different products simultaneously. The LFB group has invested 18 million euros in the facility.

Starting the production with five Cell Therapies

Five innovative cell therapy medicinal products, that are currently being developed as part of the C4C* project funded by the "Investing in the Future" program and BPI France, will be first manufactured in the CellforCure facility. C4C is based on the expertise of CELLforCURE and its partners: biotechnology companies (Celogos and Clean Cells), the EFS (French National Blood Bank) through its regional branches in the Aquitaine–Limousin and Pyrénées-Méditerranée regions, Bordeaux University Medical Center, the Lille Regional University Medical Center/University of Lille 2, the Nantes University Medical Center, the Toulouse University Medical Center, and the Tissue and Cell Bank [Banque de Tissus et de Cellules—BTC] and Civil Hospices of Lyon [Hospices Civils de Lyon—HCL]. These products use various types of cells: cord-blood stem cells, lymphocytes, hematopoietic stem cells, immunologically competent cells, and progenitor or adult somatic cells.

In addition to the five cell therapy products of the C4C* Project, the new industrial facility will be manufacturing products for other customers in the private and public sectors beginning in 2014.

^{*}C4C is an ambitious project that has attracted 80 million euros in investment from the consortium members from which 30 million euros were provided by BPI France, France's state innovation agency. C4C was selected by BPI France as part of the "Investing in the Future" call for tenders for France's first industry-academic gateway in the field of cell therapy research, development and industrial production.

Signing a First International Partnership Agreement

On the occasion of the inauguration, CELLforCURE will sign its first international partnership agreement, with the Canadian non-profit organization Héma-Québec; Jean de Serres, president and CEO of this organization, will be there for the signing. This agreement will provide CELLforCURE with a North American production partner approved by the U.S. and Canadian authorities. It will speed up access to the North American continent for both CELLforCURE's products and those of its European customers. By the same token, CELLforCURE will be able to offer a European entry point to Héma-Québec customers wishing to expand their products' markets into Europe.

Cell therapy: definitions and issues

Although Europe's first marketing authorization for a cell therapeutic was granted in October 2009,¹ the cell therapy market is set to be worth an estimated 5 billion US dollars by 2015 and could double again to reach 10 billion US dollars in 2020².

Cell therapy involves the administration of human cells to prevent, treat or alleviate a disease. In some situations, the administered cells repair and/or rebuild damaged tissue. In others, modified cells are used to provide tissue with compounds that it previously lacked.

Cell therapy is at the heart of tomorrow's personalized medicine and is expected to provide new ways of preventing or treating a wide range of diseases – many of which currently lack effective therapeutic solutions (e.g. certain cancers, neurodegenerative diseases, neuromuscular diseases and degenerative diseases like myocardial infarction, heart failure and rheumatoid arthritis). In fact, this type of therapy is a "cell transplant" in which cells taken from the patient him/herself ("autologous" grafts) or a donor are selected, modified or treated *in vitro* before being administered (usually by injection) to the patient. Hence, this approach often requires the use of completely new production models that are far removed from "traditional" pharmaceutical or biotechnological manufacturing processes.

The dedicated cell therapy company CELLforCURE is a subsidiary of the leading French biopharmaceutical company LFB Biotechnologies. LFB is a French biopharmaceutical group that develops, manufactures and markets plasma-derived medicines indicated in the treatment of severe and often rare pathologies in several major therapeutic areas: immunology, hemostasis and intensive care. The LFB group is number one in France and fifth in the world in the plasma-derived medicinal products. The group is also one of the top European companies in the development and production of proteins and new generation treatments derived from biotechnologies. In 2012, almost 80 million euros were invested in research and development, for a turnover of 466 million euros.

Christian Béchon is the President of the group, which has 1900 staff. http://www.lfb.fr/
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¹ The first cell therapy product to be authorized in Europe was ChondroCelect®, developed by the Belgian company Tigenix to repair lesions in knee cartilage.

² World Stem Cell Summitt 2011