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PRESS RELEASE

Accinov, the Innovation Centre of Lyonbiopole, obtains the authorization to open a pharmaceutical site from the French Health authority (ANSM)

Lyon, September 22nd 2014 - Lyonbiopole announces that the French Health authority (ANSM) delivered to Accinov, its Innovation Centre, the authorization to open a pharmaceutical site. This authorization will allow Accinov to support the companies hosted in the Centre for the production of biological drugs for clinical trials in particular with the pharmaceutical responsibility of Accinov.

On September 11th, the French Health authority (ANSM) delivered to Accinov the authorization to open a pharmaceutical site in its facilities located in Lyon-Gerland Biodistrict. This authorization followed an application submitted by Accinov to the ANSM and a favorable inspection completed on the site by the French Agency.

The authorization allows Accinov to provide companies involved in drug development programs with ready-to-use industrial facilities and pharmaceutical support services including quality assurance and batch release. Indeed, the ambition of Accinov is to ease and support the manufacturing of innovative biological drugs. Therefore, with this authorization, **Accinov is now able to fulfill the needs of biopharmaceutical companies who want to start manufacturing GMP batches with a lot of flexibility and a full control of their know-how.**

This authorization enables Accinov to achieve a new stage in the development of its unique biomanufacturing business model in Europe.

About Accinov

Accinov, the Innovation Centre of Lyonbiopole, opened in November 2013. The Centre provides biotechnology and biopharmaceutical companies with ready-to-use laboratories and biomanufacturing units dedicated to pharmaceutical production of biological drugs. These facilities are associated to quality assurance support services and pharmaceutical support services including pharmaceutical responsibility. Thus, Accinov enables GMP biomanufacturing, bio-analytical activities and other high value-added activities such as the manufacturing of medical devices.

The aim of the Centre is to allow companies developing their project as fast as possible. Indeed, Accinov empowers companies to control their process, their know-how and their intellectual property. This is possible by a range of infrastructure solutions and flexible services that enables compliance to quality requirements of the pharmaceutical industry (Good Manufacturing Practices, ISO...).

About Lyonbiopole

As a biocluster, Lyonbiopole is the one-stop shop for healthcare innovation in Rhône-Alpes, France. It aims to support the emergence and development of innovative technologies, products and services in 4 main strategic areas: human medicine, veterinary medicine, in vitro diagnostics, medical devices and medical technologies. Focused on infectious diseases since its creation in 2005, Lyonbiopole is now supporting ambitious projects and companies in other fields like cancer, nutrition, metabolic diseases and neurosciences. In 2013, Lyonbiopole represented a community of 139 members: 4 world-class leaders as Lyonbiopole's founders (Sanofi Pasteur, bioMérieux, Meril, BD) – 19 Research Centers including 3 Hospital University Centers and almost 116 SMBs.

More information: www.lyonbiopole.com



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Annex: Accinov in more details

Unique in Europe, Accinov Innovation Centre has been specially designed to host biotechnology companies that develop breakthrough technologies and innovative products or services. The objective is to enable hosted companies to develop their projects within the shortest timeframe, with industrial facilities and compliance to quality requirements of the industry.

Indeed, the companies can entirely focus their effort on the development of their products and services while the staff of Accinov ensures that infrastructures are fully operational. Accinov also provides comprehensive supports through a range of integrated services (quality assurance, pharmaceutical responsibility including batch release).

In concrete terms, Accinov provides two distinct offers to assist companies in their project:

- An offer including a range of laboratories of 20 or 50sqm each perfectly suited to analytical activities, cell culture, process development and production of medical devices. This offer is associated with a set of support services comprising quality assurance, technical and operational support.
- A specific offer with 200sqm private modules dedicated to the manufacturing of biologics for clinical trials. These modules, which are located in GMP-certified premises, benefit from industrial facilities such as HVAC system and purified water production. They are operated by companies and managed by Accinov according to the Good Manufacturing Practices (**GMP**).

Accinov – Key figures

- **A building of 6,500sqm with laboratory, biomanufacturing modules and private offices**
- **24 BSL-2 laboratories**
- **3 biomanufacturing modules of more than 200sqm each**
- **1 GMP certification for the production of biologics received from French authorities.**
- **An investment of M€19.5**

Created by Lyonbiopôle, Accinov Innovation Centre was selected under the call for projects "Plateformes Mutualisées d'Innovation" launched jointly by the DGCIS from the Ministry of Economy, Industry and Employment and the Caisse des Dépôts et Consignations. Accinov is also supported by local authorities, the Greater Lyon and Rhône-Alpes Regional Council, as part of the 2007-2013 CPER frameworks (Contract between State and Regions). The construction, which began in April 2012, lasted 16 months and the building was inaugurated on November 7 2013. In September 2014, Accinov received the authorization to open a pharmaceutical site from the French Health authority (ANSM). The Centre is now hosting 5 companies in its premises alongside with scientific teams from the Technology Research Institute Bioaster.

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