



PRESS RELEASE

Preclinical validation of Oncodesign's first radiotracer prior to human application

- Completion of the regulatory toxicology studies on the radiotracer targeting EGFR kinase and its mutant forms in a lung cancer indication
- GMP¹ production of the radiotracer tested successfully in Dijon
- Cyclopharma joins the IMAkinib project
- Application for clinical trial authorization to be submitted early 2016

Dijon (France), December 17, 2015 – ONCODESIGN (FR0011766229 - ALONC), a biotechnology company serving the pharmaceutical industry in the discovery of new therapeutic molecules to fight cancer and other serious diseases with no known effective treatment, announces the preclinical validation of its first radiotracer prior to human application, developed as part of the IMAkinib project.

Initiated in 2009, the IMAkinib project, led by Oncodesign, is a strategic industrial innovation program sponsored by Bpifrance. Dedicated to the development of novel imaging radiotracers for oncology, IMAkinib aims to find diagnostic solutions that will help select treatments best suited to individual patients, and monitor the treatment's efficacy thereafter. Within the IMAkinib project, radiotracers are expected to be developed up to the end of phase IIa.

These radiotracers are small molecules generated by Oncodesign's Nanocyclix technology and labeled with a radioactive fluoride (18F). They are used with a PET-Scan (Positron Emission Tomography) to produce images of tumors and metastases, to identify molecular targets on tumors, or to monitor the response to treatment.

The IMAkinib project includes several programs, the most advanced being the development of an EGFR kinase-targeting radiotracer. Mutations activating this kinase are responsible for non-small-cell lung adenocarcinoma, which accounts for 15% of lung cancers and affects almost 6,000 patients² each year in France.

The objective of this radiotracer is to measure increased EGFR kinase activity during the tumor's development, to select the treatment best suited to individual patients, and to detect any resistance early on. GMP production and qualification of the first clinical quality batches have just been conducted successfully with the R&D platform of the Pharmimage[®] GIE (Economic Interest group), using the cyclotron operated by Cyclopharma in its Dijon site. The toxicology studies were also performed over the past few months, and the application for clinical trial authorization to ANSM (French National Agency for Medicines and Health Products Safety) is expected early 2016.

Cyclopharma, a major actor focused on innovation-driven molecular imaging, will partner the IMAkinib project, particularly for the clinical development of radiotracers, bringing its know-how in the production and marketing of radiolabeled molecules used for diagnosis and treatment monitoring purposes. Like Oncodesign, Cyclopharma is also a member of the Pharmimage[®] GIE.

¹ GMP : Good Manufacturing Practices

² Source épidémio : INCA 2012

“The completion of production tests and regulatory toxicology studies on our first radiotracer confirms the capacity of Oncodesign to generate PET tracers based on its Nanocyclix and Pharmimage platforms, and designed to predict the suitability of targeted treatments for individual patients,” comments Philippe Genne, founder and CEO of Oncodesign. *“Cyclopharma joins the project at a key stage, with the upcoming clinical trial on the first radiotracer generated by IMAkinib. Cyclopharma will be a valuable partner, given its expertise in radiochemistry, clinical development, GMP production, and marketing.”*

“The personalization of patient care has become a public health issue, particularly in oncology, in terms of efficacy as well as cost control. Aware of this issue, Cyclopharma develops state-of-the-art solutions in molecular imaging, designed to improve diagnosis and treatment monitoring. The IMAkinib project provides us with a strategic asset to achieve this objective, and will allow to adapt the therapy to each patient” says Bernard Landès, CEO of Cyclopharma.

About Cyclopharma

Created in 2000, Cyclopharma specializes in the development and marketing of innovative solutions in molecular imaging, able to characterize diseases and suited to individual patients.

With over 100 employees and a turnover of €20 million, Cyclopharma focuses heavily on collaborative research and development. In 2015, it initiated its international development, supported by a dense and balanced territorial network, with a view to become a European leader in personalized medicine.

About Oncodesign: www.oncodesign.com

Founded 20 years ago by Dr. Philippe Genne, the Company’s CEO and Chairman, ONCODESIGN is a biotechnology company that maximizes the pharmaceutical industry’s chances of success in discovering new therapeutic molecules to fight cancer and other serious illnesses with no known efficient treatment. Backed by unique experience acquired through more than 600 clients, including the world’s largest pharmaceutical companies, and relying on a comprehensive technological platform combining state-of-the-art medicinal chemistry, advanced animal modeling and medical imaging, ONCODESIGN is able to predict and identify for every molecule, very upstream, its therapeutic use and its potential to become an efficient drug. Applied to kinase inhibitors, molecules that represent a market estimated at over 40 billion dollars in 2016 and accounting for almost 25% of the pharmaceutical industry’s R&D investments, ONCODESIGN’s technology has already enabled the targeting of 7 promising molecules with substantial therapeutic potential, in oncology and elsewhere, and the signing of partnerships, potentially worth €350 million in upfront payments should predefined milestones be reached, with pharmaceutical groups Sanofi, Ipsen and UCB. Based in Dijon, France, in the heart of the town’s university and hospital hub, ONCODESIGN has 103 staff.

Contacts

Oncodesign

Philippe Genne
President & CEO
Tel. : +33 3 80 78 82 60
investisseurs@oncodesign.com

NewCap

Investor & Press Relations
Julien Perez / Nicolas Merigeau
Tel. : +33 1 44 71 98 52
oncodesign@newcap.eu

