



## Promising clinical results for innovative mutated anti-EGFR radiotracer in patients with non-small cell lung cancer

- First stage of Phase 1 clinical study completed with promising results
- Launch of second stage to evaluate the specificity of the radiotracer
- Full study results expected in H1 2018

**Clermont-Ferrand and Dijon (France), December 18, 2017 06:00pm CET** - ONCODESIGN (ALONC – FR0011766229), a biopharmaceutical company specializing in precision medicine, and CYCLOPHARMA, a company developing leading molecular imaging solutions, in cooperation with Centre Georges François Leclerc (CGFL), the regional cancer research and treatment center for Burgundy, have announced promising results for the Phase 1 study of the first radiotracer<sup>1</sup> to come out of the IMAkinib program.

The radiotracer, labelled with radioactive <sup>18</sup>F-fluorine, is a molecule generated using Oncodesign's Nanocyclix technology whose use as a companion biomarker in targeted EGFR inhibitor therapy<sup>2</sup> is being assessed in patients with lung tumors.

The current clinical study has as its primary objective the assessment of the clinical advantages of the radiotracer using PET<sup>3</sup>, by determining its sensitivity and specificity in patients with pulmonary tumors treated with targeted anti-EGFR therapy. It is the product of cooperation between Centre Georges François Leclerc, Cyclopharma and Oncodesign as part of the Dijon-based Pharmimaging cluster.

The first stage of the clinical trial, in 8 patients with EGFR mutations, has produced very encouraging results in terms of product safety, dosage and fixing on pulmonary tumors expressing mutated EGFR. These results allow the launch of the second stage of the clinical study, with the inclusion of 6 new patients with non-mutated EGFR receptors. The aim of this second stage is to demonstrate the radiotracer's specificity.

Full results from the Phase 1 study are expected in the first half of 2018. Positive results would directly allow the design of a Phase 3 clinical study, with the final objective of application for Marketing Authorization.

*"Measuring EGFR receptor activity in lung cancer enables early detection of tumor resistance to anti-EGFR therapies, and thus better care for patients,"* said Philippe Genne, founder, Chairman and CEO of Oncodesign. *"In comparison with other types of companion biomarkers, using liquid or solid biopsy techniques, the advantage of a PET-based approach is that it gives clinicians an idea of the heterogeneity of the disease in the whole of the patient's body. Together with our partners we have been pioneers in this approach."*

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<sup>1</sup> [18F]-ODS2004436

<sup>2</sup> Epidermal Growth Factor Receptor

<sup>3</sup>Positron Emission Tomography, a standard technique in clinical diagnostics.

Activating mutations for EGFR kinase are a cause of non-small cell pulmonary adenocarcinomas, which represent between 10% and 15% of lung cancers in the Caucasian population and between 30% and 50% of those in patients of Asian origin. This type of cancer affects nearly 6,000 patients in France each year, with a projection of 1.3 million patients worldwide by 2022 (up 22% in 10 years). The main treatments for this pathology include tyrosine kinase inhibitors that target EGFR, meaning that the use of a biomarker that can help clinicians in their selection of treatments is a major step forward in precision medicine.

**About ONCODESIGN:** [www.oncodesign.com](http://www.oncodesign.com)

Founded over 20 years ago by Dr Philippe Genne, the Company's CEO and Chairman, Oncodesign is a biopharma company dedicated to the precision medicine. With its unique experience acquired by working with more than 600 clients, including the world's largest pharmaceutical companies, along with its comprehensive technological platform combining state-of-the-art medicinal chemistry, pharmacology, regulated bioanalysis and medical imaging, Oncodesign is able to predict and identify, at a very early stage, each molecule's therapeutic usefulness and potential to become an effective drug. Applied to kinase inhibitors, which represent a market estimated at over \$46 billion in 2016 and accounting for almost 25% of the pharmaceutical industry's R&D expenditure, Oncodesign's technology has already enabled the targeting of several promising molecules with substantial therapeutic potential, in oncology and elsewhere, along with partnerships with pharmaceutical groups such as Bristol-Myers Squibb and UCB. Oncodesign is based in Dijon, France, in the heart of the town's university and hospital hub, and within the Paris-Saclay cluster, Oncodesign has 220 employees and subsidiaries in Canada and the USA.

**About Cyclopharma:** [cyclopharma.fr](http://cyclopharma.fr)

Since its creation in 2000, Cyclopharma has developed molecular imaging solutions to allow the observation of cell function *in vivo* as part of the targeted treatment of cancer, in order to improve individualized treatment plans for patients in terms of diagnostics, monitoring and therapeutic effectiveness, whilst also reducing costs.

With more than 120 employees and revenue of €23 million, Cyclopharma invests more than 10% of revenue in research into novel molecular imaging tracers. Since 2015 it has built on dense and balanced geographical coverage to drive international growth, with the aim of becoming a major European force in personalized medicine.

**About Centre Georges-François Leclerc (CGFL) :** [www.cgfl.fr](http://www.cgfl.fr)

The cancer center Georges-François Leclerc, founded in 1967, is the only healthcare facility exclusively dedicated to oncology for the whole region of Burgundy / Franche-Comté. In 50 years, it has become a reference center located between Paris and Lyon for the fight against cancer and for the benefit of 22,000 patients treated each year with the development of multiple innovative activities: molecular medicine, genomics, immunotherapy, pre-clinical and clinical imaging, early development of new drugs, high-precision radiotherapy, ambulatory surgery, quality of life.

Its internationally renowned team of physicians-researchers offers a personalized medicine and a research that directly benefits patients through its state-of-the-art platforms listed in the catalog of the University of Burgundy among which one for early clinical research, the only one in the whole Great East of France to be labeled by the National Cancer Institute. Centre Georges-François Leclerc has conducted research on an advanced personalization of treatments by having a comprehensive view, from basic research to clinical research. The CGFL is the only institution in our region that prohibits its physicians from having a liberal activity and overrun fees, thus offering all patients an access to innovative care without anything to pay. With 10% of its annual budget (€ 85M) devoted to research, 771 employees including 133 medical doctors and 48 researchers, this private nonprofit health institution, with public service missions of care, training and cancer research, is responsible for more than 22,000 patients each year, including 4,800 inpatients. Centre Georges-François Leclerc is a member of the Unicancer Group.

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