We care about cancer

PRESS RELEASE

Oncodesign announces the launch of its first clinical study on a radiotracer in patients with non-small cell lung cancer

- First clinical study evaluating a mutated EGFR-receptor marker in patients using PET (Positron Emission Tomography) imaging
- First administration of a molecule generated by Oncodesign's Nanocyclix technology labelled with radioactive ^{18}F-fluorine in humans
- Phase 0/1 expected to recruit 20 patients during a period of 18 months, with interim stages to evaluate the potential of this biomarker

Dijon, France, July 12, 2016 – ONCODESIGN (ALONC – FR0011766229), a biotechnology company serving the pharmaceutical industry in the discovery of new therapeutic molecules to fight cancer and other serious illnesses with no known effective treatment, announces officially today the launch of a clinical study focusing on the evaluation of its first radiotracer in humans, as part of the IMAkinib project conducted jointly with Cyclopharma and the study sponsor, the Cancer Centre Georges-François Leclerc (CGFL) in Dijon.

The objective of this radiotracer (ODS2004436) is to measure increased EGFR[1] kinase activity during the development of a tumour, to select the treatment best suited to individual patients and to detect the emergence of any resistance early on. The radiotracer will be visualised by PET (Positron Emission Tomography), a standard nuclear imaging technique used for clinical diagnosis.

Mutations activating EGFR kinase are responsible for non-small cell lung adenocarcinoma, which accounts for 10 to 15% of lung cancers and affects 6,000 patients each year in France alone.

The clinical study, authorised by the French National Agency for Medicines and Health Products ANSM, is now ready to begin at the CGFL Cancer Centre, which has been granted the CLIP designation[2] to conduct early-stage clinical trials. The first patient with lung cancer will be recruited within the next few weeks in the medical oncology department of the CGFL Cancer Centre in Dijon (Dr. Isambert, Head of the early-stage unit).

The objective of this phase 0/1 is to demonstrate the sensitivity and specificity of the radiotracer in human lung tumours. The clinical study will include 3 successive stages, designed to verify the specific labelling of tumours expressing the mutated EGFR receptor, verify the absence of significant marking on non-mutated tumours, and finally confirm the findings in a larger number of patients.

"With the advent of targeted therapies and precision medicine, the development of new molecular imaging biomarkers has become essential to provide the best treatment for patients," comments Prof. Fumoleau, Director of the CGFL Centre. *"As a founding member of the Pharmimage platform with Oncodesign, it was only natural that we should conduct this phase 0/1 clinical study on the first radiotracer generated by the IMAkinib programme."*

"This radiotracer was generated using our Nanocyclix technology, a chemical platform of next generation kinase inhibitors. The specificity of our molecules is a key advantage for the development of therapeutic molecules as well as for associated biomarkers, in a context of precision medicine and personalised treatments," adds Jan Hoflack, PhD, CSO of Oncodesign. *"Our approach, which combines research on new therapies and identification of high-precision imaging tracers as of the first stage of our discovery programmes, is unique."*

[1] Epidermal Growth Factor Receptor
[2] Designation of early phase clinical trial centres in adult/paediatric oncology

"Reaching the clinical stage in the development of an internal program for the first time is crucial for Oncodesign and its teams. It marks the culmination of 20 years of work and commitment to Oncodesign's mission, i.e. provide patients with new cancer treatments," concludes Philippe Genne, PhD, founder and CEO of Oncodesign. *"The IMAkinib project launched in 2009 includes several radiotracer programmes, the most advanced being the development of the radiotracer targeting the activated EGFR receptor. Our role in this programme is that of a pioneer in pharmaco-imaging focusing on new molecular markers. As this approach may lead to more effective treatments of tumours expressing EGFR-activating mutations using specific kinase inhibitors, it is important to identify such mutations."*

About IMAkinib

IMAkinib is an Oncodesign research programme, conducted jointly with Cyclopharma and Ariana Pharmaceuticals. This programme received a grant from Bpifrance of €10.3m as part of the Industrial Strategic Innovation Programme, with an overall funding of €25m. The objective of IMAkinib is to develop biomarkers used in nuclear medicine to provide diagnostic solutions in oncology and help select the treatment best suited to individual patients, then monitor its efficacy and any potential resistance. The radiotracers developed are small molecules generated by Oncodesign's Nanocyclix® technology, labelled with radioactive ^{18}F-fluorine [18F]. The IMAkinib programme includes several independent projects, the most advanced entering its phase 0/1 clinical study in lung cancer. Oncodesign has also worked jointly with Guerbet, and the teams of Prof. Denis Guilloteau of University François Rabelais in Tours and Dr Louisa Barré of CEA-Cycéron in Caen, on the development of radiochemical synthesis and on the preclinical studies on the radiotracer targeting the EGFR receptor.

About Oncodesign: www.oncodesign.com

Founded over 20 years ago by Dr Philippe Genne, the Company's CEO and Chairman, Oncodesign is a biotechnology company that maximises the pharmaceutical industry's chances of success in discovering new therapeutic molecules to fight cancer and other serious illnesses with no known effective treatment. With its unique experience acquired by working with more than 500 clients, including the world's largest pharmaceutical companies, along with its comprehensive technological platform combining state-of-the-art medicinal chemistry, advanced animal modelling 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 $40 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, Ipsen and UCB. Oncodesign is based in Dijon, France, in the heart of the town's university and hospital hub. It has 103 employees and subsidiaries in Canada and the USA.

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