Pierre Fabre Laboratories Announce First Patient Dosed in Phase I/II Clinical Trial of PFL-002/VERT-002, an Innovative Targeted Therapy Intended to Treat Non-Small Cell Lung Cancer with MET Alterations

PFL-002/VERT-002 is a monoclonal antibody with a novel and differentiated mechanism of action, acting as a degrader of c-MET, with the potential to be a best-in-class treatment for cancer driven by MET alterations

Castres, France, October 24, 2024 – Pierre Fabre Laboratories announced today that the first patient has been dosed with PFL-002/VERT-002, a monoclonal antibody acting as a degrader of c-MET, in a phase I/II first-in-human dose-escalation, dose-optimization and dose-expansion trial, for patients with Non-Small Cell Lung Cancer (NSCLC) harbouring MET alterations.

The PFL-002/VERT-002 phase I/II trial is an open label, multi-centre study that aims to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary clinical efficacy of PFL-002/VERT-002, as a monotherapy for patients with MET-dependent tumors, including those emerging with acquired resistance to other treatments.

Non-small cell lung cancer (NSCLC) is the most prevalent form of lung cancer, accounting for approximately 85% of newly diagnosed lung cancer cases, and MET, also known as hepatocyte growth factor receptor (HGFR), is an oncogene driver in subsets of patients suffering from NSCLC.[1-4] MET exon 14 skipping mutation and MET amplification are found as primary oncogenic drivers and MET amplification as a resistance mechanism to selected targeted therapies.

“PFL-002/VERT-002 targets a clinically validated oncogenic driver with a unique and differentiated mechanism of action, triggering the degradation of the c-MET oncogene. Thus, it provides the opportunity to test a novel therapeutic approach for patients with MET driven tumors. We are looking forward to collaborating with the investigators participating in the first-in-human trial to assess the safety and efficacy of this new agent.” said Francesco Hofmann, Head of Research and Development for Medical Care at Pierre Fabre Laboratories.

MET TKIs (Tyrosine Kinase Inhibitors) are approved therapeutic options for the treatment of NSCLC with MET exon 14 skipping mutation. However, there is no approved MET targeted therapy for patients presenting with MET amplification.

About PFL-002/VERT-002

PFL-002/VERT-002 is a monoclonal antibody developed by Vertical Bio, offering a unique and differentiating mechanism of action, acting as a degrader of c-MET, a known disease driver in patients with solid tumors, including non-small cell lung cancer (NSCLC) presenting mutations or amplification of MET. The antibody has been optimized preclinically by Vertical Bio, which has been acquired by Pierre Fabre Laboratories.
PFL-002/VERT-002 is a potential best-in-class therapeutic option for patients with MET alterations, including resistance settings.

About Pierre Fabre Laboratories R&D pipeline

Pierre Fabre Laboratories has expanded its efforts in precision oncology by adding several assets to its R&D pipeline. In partnership with Scorpion Therapeutics, PFL-241/STX-241 and PFL-721/STX-721, two mutant-selective EGFR inhibitors, will be developed for the treatment of EGFR-driven non-small cell lung cancer (NSCLC) patients. Through the acquisition of Vertical Bio, PFL-002/VERT-002 will undergo clinical testing in solid tumours driven by MET genetic alterations. More recently, the pan-RAF inhibitor exarafenib was acquired from Kinnate Biopharma with the aim to expand targeted therapy options for RAS/RAF-driven solid tumours. These new additions to its clinical development portfolio complement Pierre Fabre Laboratories' existing precision oncology portfolio targeting BRAF, MEK, HER2, with encorafenib, binimetinib and neratinib, respectively.

About Pierre Fabre Laboratories

Pierre Fabre Laboratories is one of Europe's leading pharmaceutical companies. For over 40 years, it has established itself as an international player in oncology, mastering the entire value chain from R&D to marketing. Its portfolio of oncology specialties covers colorectal, breast, lung and skin cancers, as well as certain hematologic malignancies and precancerous dermatological conditions such as actinic keratosis. In 2023, its oncology revenue amounted to nearly 500 million euros, over 90% of which was generated outside France.

In 2023, Pierre Fabre Laboratories posted 2.83 billion euros in revenue, 70% of which came from international sales in 120 countries. Its portfolio includes several international brands and medical franchises such as Pierre Fabre Innovative Oncology, Pierre Fabre Medical Dermatology, Pierre Fabre Pharmaceutical Care, Eau Thermale Avène, Ducray, A-Derma, Klorane, René Furterer and Même Cosmetics.

Historically based in the southwest of France and manufacturing 95% of its products in France, Pierre Fabre Laboratories employs over 10 000 people worldwide. Its annual R&D budget amounts to nearly 200 million euros, of which about 50% is dedicated to targeted therapies in oncology and 40% to skin health and care solutions.

Pierre Fabre Laboratories' majority shareholder (86%) is the eponymous Foundation, which is recognized by the French government as being a public–interest foundation. This capital structure guarantees the company's independence and long-term vision. Dividends paid to the Pierre Fabre Foundation enable it to design and finance healthcare-access programs in developing countries. Employees are the company's secondary shareholder, through an international employee shareholding plan.

Pierre Fabre Laboratories' sustainability policy has been assessed by the independent AFNOR Certification body and has been awarded the "Exemplary" level of its CSR label (ISO 26 000 standard for sustainable development).

For more information, visit www.pierre-fabre.com, @Pierre Fabre Oncology.

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