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Laboratoires Pierre Fabre Announce FDA Fast Track Designation for elticertinib in non-small cell lung cancer

Castres, France, November 17, 2026 – Laboratoires Pierre Fabre announce that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to elticertinib[1] (also known as PFL-721 previously STX-721), for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") harboring EGFR exon 20 insertion mutations, whose disease has progressed on both platinum-based chemotherapy and amivantamab.

The FDA's fast track designation is designed to expedite the development and review of therapies to treat serious conditions with significant unmet medical needs. The designation has been granted based on nonclinical data as well as preliminary efficacy data from the ongoing Phase 1/2 clinical trial (NCT06043817). It provides Laboratoires Pierre Fabre with increased opportunities for interaction with the FDA, as well as eligibility for rolling and priority review, if relevant criteria are met.

Elticertinib is a highly differentiated, orally bioavailable, irreversible highly selective investigational tyrosine kinase inhibitor ("TKI") targeting epidermal growth factor receptor ("EGFR") and ERBB2 (HER2) Exon 20 insertion ("ex20ins") mutations.

NSCLC is the most common sub-type of lung cancer and various EGFR mutations are the most frequent drivers of NSCLC, occurring in up to 38% of tumors, depending on geography.[2,3,4] Of this population, up to 10% have ex20ins mutations.

"This fast-track designation is a first for Laboratoires Pierre Fabre, and a significant milestone that reflects the strength and maturity of our R&D capabilities in oncology. It confirms our ability to bring innovative, highly differentiated therapies from research to patients, and strengthens our ambition to become a recognized global player in precision oncology," said Eric Ducournau, Chief Executive Officer of Laboratoires Pierre Fabre.

"This designation underscores the urgent need for new treatment options for patients with EGFR ex20ins-mutated NSCLC, who still face limited efficacy and significant tolerability challenges with currently available therapies. It will allow us to engage more closely with the FDA to accelerate elticertinib development and bring this targeted therapy to patients faster" said Marie-Andrée Gamache, Laboratoires Pierre Fabre Pharma Chief Executive Officer.

About the Firs-In-Human PFL-721 Phase 1/2 Trial

The PFL-721 first-in-human Phase 1/2 Trial PFL721CI101 (NCT06043817) is a multi-center, open-label study designed to evaluate the safety, tolerability, pharmacokinetic ("PK") exposure, and preliminary antitumor activity of elticertinib (PFL-721) as single-agent or in

combination with carboplatin/pemetrexed, in participants with non-small cell lung cancer ("NSCLC") carrying EGFR or HER2 exon 20 insertion ("ex20ins") mutations. To learn more about the first-in-human trial of elticertinib, please visit this page.

About Laboratoires Pierre Fabre

Laboratoires Pierre Fabre is one of Europe's leading pharmaceutical laboratories and the world's second-largest dermo-cosmetics company. Its Pharma activity covers 5 main therapeutic fields: oncology, dermatology, rare diseases, primary care and family health care. The Dermo-cosmetics & Personal Care portfolio includes international brands such as Eau Thermale Avène, Dexeryl, Ducray, Klorane, A-Derma, René Furterer, Même Cosmetics, Darrow and Elgydium.

For over 40 years, Laboratoires Pierre Fabre 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 2025, Laboratoires Pierre Fabre's revenues in oncology came to 565 million euros, 71% of which were generated by international sales, out of a total sales figure of 3.2 billion euros.

Based in southwest France since its creation, Laboratoires Pierre Fabre manufactures nearly 90% of its products in France and employs 10,000 people worldwide. In 2025, its R&D budget amounted to 250 million euros, of which 67% is allocated to targeted therapies in oncology with 10 research and development programs underway.

Laboratoires Pierre Fabre's majority shareholder (86%) is an eponymous humanitarian Foundation. Employees constitute the company's other shareholder. This capital structure guarantees the company's independence, long-term vision and contribution to the common good. The dividends paid to the Pierre Fabre Foundation contribute to 43 healthcare-access programs deployed in 26 of the least developed countries in the world.

Laboratoires Pierre Fabre's CSR policy has been assessed by AFNOR Certification 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, @Laboratoires Pierre Fabre, @Pierre Fabre Oncology

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[1] Recommended INN, pending USAN
[2] The Prevalence of EGFR Mutation in Patients with Non-Small Cell Lung Cancer, Oncotarget, October 2016
[3] EGFR Mutation Incidence in Non-Small Cell Lung Cancer, J Cancer Res., August 2015
[4] Molecular Epidemiology of EGFR Mutations in Asian Patients, PLoS ONE, November 2015