Press Release

Sanofi's efdoralprin alfa earns orphan designation in the EU for alpha-1 antitrypsin deficiency related emphysema

- Additional orphan designation reinforces Sanofi's commitment to developing treatments for rare diseases
- Efdoralprin alfa, an investigational restorative recombinant therapy, recently met all primary and key secondary endpoints in phase 2 head-to-head study versus a plasma-derived standard of care

Paris, December 17, 2025. The European Medicines Agency (EMA) has granted orphan designation to efdoralprin alfa (SAR447537, formerly known as INBRX-101), an investigational recombinant human alpha-1 antitrypsin (AAT)-Fc fusion protein, for the potential treatment of alpha-1 antitrypsin deficiency (AATD) related emphysema, a rare respiratory condition with great unmet medical need.

The EMA grants orphan designation to potential new medicines addressing rare, life-threatening or debilitating medical diseases or conditions that affect no more than 5 in 10,000 individuals in the EU.

Efdoralprin alfa demonstrated superiority to a standard of care plasma-derived therapy in adults with AATD when dosed every three weeks (Q3W) or every four weeks (Q4W), meeting all primary and key secondary endpoints in the global phase 2 ElevAATe study (clinical study identifier: NCT05856331).

The US Food and Drug Administration (FDA) previously granted both fast track and orphan drug designation to efdoralprin alfa for the treatment of AATD related emphysema. Efdoralprin alfa is currently in clinical development, and its safety and efficacy have not been evaluated by any regulatory authority. Sanofi plans to present the data at a forthcoming medical meeting and engage with global regulatory authorities on the appropriate next steps.

About efdoralprin alfa

Efdoralprin alfa (SAR447537, formerly known as INBRX-101) is a recombinant human AAT-Fc fusion protein being investigated in adults with AATD emphysema, with Q3W or Q4W dosing. The investigational restorative recombinant treatment is being studied to restore functional AAT levels to the normal range and inhibit neutrophil elastase, an enzyme that can cause lung tissue damage in patients with AATD. Efdoralprin alfa was granted fast track designation and orphan drug designation by the FDA for the treatment of AATD emphysema in addition to this latest orphan designation from the EMA.

About AATD

AATD is a rare, inherited disorder characterized by low levels or absence of AAT, a protein produced by the liver that protects the lungs from inflammation and damage. The disease causes progressive deterioration of the tissue of the lungs and liver. Without adequate AAT levels, affected individuals often experience lung damage and develop COPD, including emphysema, and in severe forms of the disease, patients can sometimes require lung transplantation. Plasma-derived therapies were introduced in 1987 to treat the condition but since then, no new therapies have been introduced. About 235,000 people worldwide live with AATD, with nearly 100,000 people in the US, but about 90% of individuals with AATD are likely undiagnosed.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and

deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Sanofi forward-looking statements

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