Calluna Pharma Completes Enrollment in Phase 2 AURORA Study of CAL101 for Idiopathic Pulmonary Fibrosis (IPF)

Study of CAL101, which targets a novel upstream pathway implicated in fibrotic disease, enrolls 161 patients more than six months ahead of plan; topline data expected Q1 2027

Drug candidate, a monoclonal antibody which targets S100A4, a novel upstream pathway implicated in fibrotic disease, aims to preserve lung function in IPF patients

Oslo, Norway and Boston, Massachusetts, 22 April 2026: Calluna Pharma AS (Calluna), a clinical-stage biotechnology company pioneering first-in-class antibodies to treat inflammatory and fibrotic diseases, today announced that it has completed enrollment in its global Phase 2 AURORA study of CAL101 for IPF.

The AURORA study finished enrolling patients more than six months ahead of schedule. It is a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of CAL101. The study enrolled 161 adult patients with IPF across more than 50 sites in the US, UK, EU, Turkey, and South Korea. The study's primary endpoint is lung function, as measured by change from baseline in forced vital capacity (FVC).

Patients entered the AURORA study following an initial 28-day screening period, after which they were randomized to receive monthly intravenous infusions of CAL101 or placebo for six months at a 3:2 randomization ratio. Calluna anticipates topline data from the AURORA study in Q1 2027.

"The completion of enrollment in AURORA is an important operational milestone for Calluna," said Jonas Hallén, M.D., Ph.D., Co-Founder and Chief Medical Officer of Calluna Pharma. "We are deeply grateful to the patients who chose to participate in this study, and to the investigators and site teams whose commitment and efficiency enabled rapid enrollment across a broad range of countries and sites. Their collective effort has positioned us well to generate high-quality data on the safety and potential efficacy of CAL101 in IPF."

"We are thrilled with the rapid and high-quality execution of the AURORA study," said Mark Gaffney, Chief Executive Officer and Board member of Calluna Pharma. "AURORA enables us to have a comprehensive understanding of CAL101 and its readiness for late-stage and pivotal studies in pulmonary fibrosis as well as its potential in other inflammatory or fibrotic diseases."

About CAL101

CAL101 is a systemically administered monoclonal antibody targeting the DAMP protein S100A4. S100A4 is activated when tissue is stressed or injured, triggering multiple downstream pathways. It is associated with pathological activation and proliferation of fibroblasts (the key effector cells driving progression of fibrosis), and pro-fibrotic immune response connected to fibrotic disease. Targeting S100A4 has the potential to re-establish tissue homeostasis by switching off the downstream pathways involved in the persistent and maladaptive scar tissue formation characteristic of IPF.

A randomized, double-blind, placebo-controlled Phase 1 study of CAL101 demonstrated a favorable safety profile, predictable PK properties, and PD effects consistent with extracellular S100A4 neutralization. Preclinical studies have shown CAL101 to prevent and treat fibrosis and modify the disease-specific activation of fibroblasts.

About IPF

Idiopathic pulmonary fibrosis (IPF) is a progressive lung disease where an inappropriately activated wound-healing response causes the lung tissue to become thickened and scarred, making it difficult to breathe. The exact triggers of IPF are unknown, but it is believed to be a combination of genetic and environmental factors. Over time, the scarring in the lungs worsens, leading to respiratory failure and ultimately death, with a 3-5-year median survival rate. Primarily found in older adults, the disease impacts approximately 233,000 people in the US and EU.

About Calluna Pharma www.callunapharma.com
Calluna Pharma is a global clinical-stage company pioneering a breakthrough approach to treating inflammatory and fibrotic diseases by leveraging the body's innate immune system. The Company's therapeutic approach targets upstream amplifiers of disease, offering potential applicability across a diverse array of medical conditions. Calluna has a robust pipeline of selective antibodies targeting immunological diseases with enhanced efficacy.

Calluna is incorporated in Oslo, Norway and operates globally.

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