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Agomab Announces Positive Phase 1 Interim Results with AGMB-447 in Healthy Participants and Initiation of Idiopathic Pulmonary Fibrosis Cohort

-- Interim data from Phase 1 with single and multiple ascending doses show no safety signals and a generally favorable tolerability profile of AGMB-447 in healthy participants --

-- Pharmacokinetic profile in healthy participants shows low systemic exposure of AGMB-447, with high exposure to the lung --

-- Robust dose-dependent target engagement of ALK5 observed with AGMB-447 in healthy participants --

-- First patients dosed in the Idiopathic Pulmonary Fibrosis cohort of the study --

Antwerp, Belgium, January 8, 2026 – Agomab Therapeutics NV ('Agomab'), a clinical-stage biopharmaceutical company focused on fibrosis, today announced positive interim results of the Phase 1 study of AGMB-447 in healthy participants. AGMB-447 is an inhaled lung-restricted small molecule inhibitor of ALK5 (or TGFβR1) intended for the treatment of Idiopathic Pulmonary Fibrosis (IPF).[1]

TGFβ is a master regulator of fibrosis, and an extensive body of evidence supports its role in IPF. AGMB-447 is specifically designed to act locally, potently inhibiting ALK5 in the lung, while avoiding clinically relevant systemic exposure through local administration via inhalation and rapid hydrolyzation in plasma into one main metabolite inactive in cells. With AGMB-447, Agomab aims to significantly improve the standard of care for IPF patients by safely targeting the key fibrogenic pathway driving lung fibrosis.

The ongoing Phase 1 study with AGMB-447 is a three-part, double-blind, randomized, placebo-controlled single ascending dose (SAD; Part A) and multiple ascending dose (MAD; Part B) study in healthy participants and multiple dose study in IPF patients (Part C). AGMB-447 is administered via nebulization, as a single dose in the SAD, over seven days in Part B and over 14 days in Part C.

A total of 108 healthy participants have been included in the SAD and MAD parts of the study reported on today. At the different dose levels tested, no safety signals were observed, and AGMB-447 showed a generally favorable tolerability profile. Across cohorts, low systemic exposure of AGMB-447 was observed, with high exposure to the lung, supporting the lung-restricted pharmacokinetic (PK) profile of AGMB-447 in healthy participants. Target engagement, assessed through pSMAD3 reduction in bronchoalveolar lavage (BAL) cells, indicates robust and dose-dependent TGFβ inhibition in the lungs of healthy participants.

"We are very pleased with the Phase 1 results for AGMB-447 announced today. The data point to a generally favorable safety, tolerability and PK profile of AGMB-447 and show proof-of-mechanism of TGFβ/ALK5 inhibition in the lungs of healthy participants." **said Philippe Wiesel, Chief Medical Officer at Agomab**.

[1] Study Details | Phase I Study to Assess Safety, Tolerability, PK and PD of AGMB-447 in Healthy Participants and Participants With IPF | ClinicalTrials.gov

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The company also announced that the first patients have been dosed in the IPF cohort (Part C) of the study.

Based on the positive results observed to date, the company plans to initiate a Phase 2 study in IPF patients in 2026.

Agomab intends to present detailed Phase 1 results at a future scientific conference.

AGMB-447 is an investigational drug and not approved by any regulatory authority. Its efficacy and safety have not been established.

About IPF

Idiopathic Pulmonary Fibrosis (IPF) is a devastating disease affecting approximately 240,000 patients in the U.S., Japan, and the largest European markets (EU4+UK)[2]. IPF is characterized by unregulated production of fibrotic, scar-like tissue that builds up in the scaffolding of the lungs. As a result, the fibrotic lung becomes stiff, hampers the patient's ability to breathe and reduces the absorption of inhaled oxygen in the blood. Despite the commercial availability of two approved therapies, without a lung transplant, the median survival following diagnosis is only 3-5 years. Moreover, these therapies do not halt but only slow down disease progression and have significant side effects that reduce tolerability and lead to treatment discontinuation in many patients.

About AGMB-447

AGMB-447 is an inhaled lung-restricted small molecule inhibitor of ALK5 (or TGFβR1) intended for the treatment of Idiopathic Pulmonary Fibrosis (IPF). TGFβ is the master regulator of fibrosis, which is the key mechanism driving IPF disease progression. AGMB-447 is specifically designed to inhibit ALK5 in the lung while avoiding clinically relevant systemic exposure through local administration via inhalation and rapid hydrolyzation in plasma into one main metabolite inactive in cells. Through AGMB-447, Agomab aims to offer a potentially safe and effective novel anti-fibrotic therapeutic option to IPF patients.

About Agomab

Agomab is focused on achieving disease modification by modulating inflammation and fibrosis in chronic indications such as Fibrostenosing Crohn's Disease and Idiopathic Pulmonary Fibrosis. We do this by targeting biologically validated pathways, including Transforming Growth Factor β, and by applying specialized capabilities in organ-restricted small molecules. With a differentiated clinical pipeline across several fibrotic disorders, end-to-end research and development capabilities, a proven track-record and a strong investor base, Agomab is building a transformational company with the aim to have a real impact on patients' lives.

Contacts

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[2] Based on demographics (US census, Eurostat, ONS UK, Japan Census) and IPF prevalence (Maher et al. 2021; Kondoh et al. 2022)

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