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# Agomab Announces Positive Phase 1 Results for AGMB-447 in Patients with Idiopathic Pulmonary Fibrosis and Design of Phase 2 INSPIRIA Study

*-- Topline Phase 1 data shows generally favorable safety and tolerability profile of AGMB-447 --*

*-- Pharmacokinetic profile confirms efficient lung restriction with low systemic exposure and high exposure of AGMB-447 in the lung, in line with prior results observed in healthy participants --*

*-- Robust target engagement of ALK5 observed with AGMB-447 in IPF patients --*

*-- Clinical Trial Application (CTA) for INSPIRIA Phase 2 study in IPF patients submitted; Company intends to initiate study before year-end --*

**Antwerp, Belgium, September 14, 2026** – Agomab Therapeutics NV ('Agomab'), a clinical-stage biopharmaceutical company focused on fibro-inflammation, today announced positive results of the Phase 1 study of AGMB-447 in IPF patients. AGMB-447 is an investigational inhaled lung-restricted small molecule inhibitor of ALK5 (or TGFβR1) intended for the treatment of Idiopathic Pulmonary Fibrosis (IPF).[1]

The Phase 1 study of AGMB-447 is a three-part, double-blind, randomized, placebo-controlled single ascending dose (SAD; Part A; dose range: 1 mg QD (once daily) to 20 mg QD) and multiple ascending dose (MAD; Part B; dose range: 1 mg QD to 6 mg BID (twice daily)) study in healthy participants and multiple dose study in IPF patients (Part C; dose range: 4.5 mg BID to 6 mg BID). AGMB-447 was 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 10 IPF patients were included in Part C. In line with the data in healthy participants reported previously, AGMB-447 was observed to have a generally favorable safety and tolerability profile in IPF patients at 4.5 mg BID. While a higher incidence of adverse events was reported at 6 mg BID, no new specific safety signals were identified, and no systemic safety signals were detected at any dose. The most frequently reported adverse events were cough and bronchospasm. Cough episodes were short and mostly limited to the inhalation period. Furthermore, no increase in the severity of disease-related cough was reported at any dose over the 14-day dosing period.

Low systemic but high pulmonary exposure of AGMB-447 was also measured in IPF patients, supporting its lung-restricted pharmacokinetic (PK) profile. In IPF patients, daily doses of 4.5 mg BID achieved average bronchoalveolar lavage (BAL) fluid levels above $IC_{90}$ for at least 6 hours post-inhalation, and above $IC_{50}$ for 24 hours, in line with the PK profile observed in healthy participants.

In IPF patients, pSMAD3 reduction in BAL cells of >50% was achieved at the 4.5 mg BID dose, indicating robust target engagement in line with the results observed previously in healthy participants and supporting further clinical development of AGMB-447 for the treatment of IPF.

[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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"We are very pleased with the Phase 1 results of AGMB-447 in patients with IPF announced today. In line with the positive interim data in healthy participants announced earlier this year, the data indicated a generally favorable safety, tolerability and PK profile of AGMB-447 and provided proof-of-mechanism of TGFβ/ALK5 inhibition in the lungs of IPF patients," **said Philippe Wiesel, Chief Medical Officer at Agomab**. "We believe that by blocking the TGFβ/ALK5 pathway locally in the lung, AGMB-447 has the potential to offer a potent anti-fibrotic therapy to IPF patients. The extensive data collected in our broad Phase 1 program supports the initiation of our Phase 2 INSPIRIA study later this year."

The company also announced the design of INSPIRIA, its planned Phase 2 study with AGMB-447 in IPF. INSPIRIA is a 24-week Phase 2, randomized, double-blind, placebo-controlled study in approximately 120 patients with confirmed IPF. Patients will be randomized 2:1 to receive AGMB-447 4 mg twice daily or placebo, administered by inhalation on top of standard of care. The study is designed to evaluate the safety, pharmacokinetics and efficacy of AGMB-447 in IPF patients. The primary endpoint will be the change from baseline in forced vital capacity at Week 24. The CTA for INSPIRIA has been submitted, and the study is anticipated to begin in the second half of 2026 across a large European site network.

"We have long known that the TGFβ pathway is a central driver of fibrosis in IPF. Targeting this key pathway through ALK5 inhibition with AGMB-447 is a promising approach. With a convenient twice-daily dosing schedule, AGMB-447 could represent an attractive option for monotherapy or combination therapy with systemic standard of care therapies. The INSPIRIA study is designed to further explore the therapeutic potential of this novel inhaled approach in people living with IPF," said **Toby Maher, M.D., PhD, Professor of Clinical Medicine at Keck School of Medicine of USC.**

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 255,000 patients in the U.S., Japan, and the largest European markets (EU4+UK). 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 three 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 side effects that reduce tolerability and lead to treatment discontinuations.

**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.

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**About Agomab**

Agomab is a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases with high unmet medical need. Agomab's product candidates are designed to target established, potent pathways and utilize organ-restricted approaches, with the aim of increasing efficacy while minimizing safety liabilities. Fostering a culture of excellence, Agomab's mission is to pioneer therapeutics that aim to resolve fibro-inflammation and restore organ function to enable people with these disorders to live fuller and healthier lives.

**Cautionary Note regarding Forward-Looking Statements**

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are often identified by terms such as "continue," "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. "Forward-looking statements" include, without limitation, statements regarding the potential of AGMB-447 for the treatment of IPF, the design of the planned Phase 2 clinical trial with AGMB-447 for IPF, our expectation to initiate our Phase 2 clinical trial of AGMB-447 in IPF in the second half of 2026, and our interactions with regulatory authorities. Forward-looking statements are based on Agomab's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to the results of our clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements for product candidates; the impact of governmental laws and regulations on our business; and disruptions caused by our reliance on third party suppliers and service providers. These and other risks and uncertainties are described more fully in our filings and reports with the SEC, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Agomab undertakes no duty to update such information except as required under applicable law. Readers should not rely upon the information in this announcement as current or accurate after its publication date.

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