Agomab Starts Phase 1 Clinical Study for AGMB-447 in Healthy Subjects and Patients with Idiopathic Pulmonary Fibrosis

-- AGMB-447 is an inhaled lung-restricted small molecule inhibitor of ALK5 --

Ghent, Belgium, December 14, 2023 – Agomab Therapeutics NV ('Agomab') today announced that it has dosed the first subject in a first-in-human Phase 1 clinical study of AGMB-447, an inhaled lung-restricted small molecule inhibitor of ALK5 (TGFβRI or ALK5). The study is evaluating AGMB-447 in healthy subjects and in patients with idiopathic pulmonary fibrosis (IPF).

The Phase 1 trial includes a Single Ascending Dose (SAD) and a Multiple Ascending Dose (MAD) evaluation of AGMB-447 in healthy subjects, followed by repeated dosing with AGMB-447 in IPF patients over a two-week treatment period. The trial is being conducted in 76 total subjects and patients in the U.K. Primary endpoints will be safety and tolerability. Secondary endpoints will include systemic and local Pharmacokinetics (PK).

"Starting clinical development for AGMB-447, our second ALK5 asset to enter the clinic, is exciting and a key milestone for Agomab, as it represents a step forward in providing a potential new treatment option for patients with IPF and other fibrotic lung diseases," **said Andrea Sáez, Chief Development Officer at Agomab Therapeutics**. "Thanks to its lung-restricted distribution, AGMB-447 has the potential to potently, yet safely, block TGFβ, a key fibrogenic pathway, selectively in the target tissue."

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

About AGMB-447

AGMB-447 is a small molecule lung-restricted inhibitor of ALK5 (or TGFβRI) for the treatment of Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic respiratory indications. IPF is a devastating disease affecting over 300,000 patients worldwide. 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 and hampers the patient's ability to breathe and reduces the absorption of inhaled oxygen in the blood. Even though some medicinal treatments are available, without a lung transplant, the average survival following diagnosis is only three to five years. TGFβ is a known master regulator of fibrosis in IPF and preliminary clinical data supports targeting the pathway. AGMB-447 is specifically designed to potently and safely inhibit ALK5 in the lung based on rapid metabolism through hydrolysis in plasma to prevent clinically relevant systemic exposure.

About Agomab

Agomab is focused on achieving disease modification by modulating fibrosis and regeneration 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 Hepatocyte Growth Factor - and by applying unique capabilities in organ-restricted small molecules and high affinity antibodies. With a differentiated clinical pipeline across several fibrotic disorders, end-to-end research and development capabilities, a proven BD track-record and a strong investor base, Agomab is building a leading European biopharma company.

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