Agomab Receives FDA Orphan Drug Designation for AGMB-447 in Idiopathic Pulmonary Fibrosis

-- AGMB-447 is an inhaled lung-restricted ALK5-inhibitor currently in a Phase 1 clinical trial --

Antwerp, Belgium, June 6, 2024 – Agomab Therapeutics NV ('Agomab') today announced that it has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for AGMB-447, its inhaled, small molecule inhibitor of ALK5. Agomab is evaluating AGMB-447 as a potential treatment for Idiopathic Pulmonary Fibrosis (IPF) in a Phase 1 clinical trial (NCT06181370).

The FDA's Orphan Drug Designation program is designed to facilitate development of medicinal treatments for rare diseases that affect fewer than 200,000 people in the U.S. The designation provides companies with various development and commercial benefits, including market exclusivity and a range of financial incentives, such as tax relief for clinical research costs.

"Receiving Orphan Drug Designation from the FDA provides further support that AGMB-447's mechanism of action has the potential to achieve meaningful therapeutic benefits to IPF patients," **said Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**. "As we progress through our ongoing first-in-human Phase 1 trial, we look forward to evaluating the data from the single ascending dose and multiple ascending dose evaluation of AGMB-447 in healthy subjects and IPF patients."

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 100,000 patients in the U.S. IPF is characterized by unregulated production of fibrotic, scar-like tissue that builds up in the lungs. As a result, the fibrotic lung becomes stiff which hampers breathing 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 only in the lung due to its rapid metabolism through hydrolysis in plasma, which prevents 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 specialized 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.

Contacts

For Agomab Therapeutics
Tim Knotnerus, CEO
E-Mail: tim.knotnerus@agomab.com

Media Requests for Agomab
Dr. Stephanie May or Gretchen Schweitzer
Trophic Communications
Phone: + 49 (0) 172 861 8540
E-Mail: agomab@trophic.eu