Agomab Reports Positive Phase 1 Results with AGMB-129, a GI-restricted ALK5 Inhibitor for Fibrostenosing Crohn's Disease

-- All dosing regimens were well-tolerated across the Phase 1 clinical study --
-- High local exposure to AGMB-129 in the ileum --
-- No clinically relevant systemic exposure to AGMB-129, confirming GI-tract targeted exposure --

Ghent, Belgium, February 2, 2023 – Agomab Therapeutics NV ('Agomab') today announced positive clinical results from its Phase 1 study evaluating AGMB-129, an oral gastro-intestinal (GI)-restricted small molecule kinase inhibitor of ALK5 (TGFβRI or ALK5), intended for the treatment of Fibrostenosing Crohn's Disease (FSCD). The trial, designed to evaluate the safety, tolerability, and pharmacokinetics (PK) of AGMB-129 in healthy subjects, demonstrated high local exposure to AGMB-129 in the ileum and no clinically relevant systemic exposure.

The Phase 1 study included single ascending dose (SAD), multiple ascending dose (MAD) and food-effect (FE) stages, as well as an additional stage for the assessment of local drug exposure in ileal mucosa, where the fibrostenotic strictures in FSCD patients are most often located. A total of 81 healthy subjects were randomized to receive either single or multiple daily oral doses of AGMB-129, or matching placebo.

AGMB-129 was well-tolerated at all doses tested. The incidence and intensity of adverse events were similar across all dose cohorts including the placebo cohort. No drug-related safety signal or dose-limiting toxicities were identified. The favorable safety profile from the Phase 1 study supports the evaluation of AGMB-129 in a planned global Phase 2a study in patients with FSCD. Plasma PK analyses showed no clinically relevant systemic exposure, whereas biopsies of the ileum showed high local concentrations of AGMB-129, confirming that the GI-restriction mechanism can operate efficiently in humans.

"The positive results of this Phase 1 study are an important first step in our clinical development of AGMB-129 and confirm its tolerability and GI-restricted mechanism," **said Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**. "We look forward to advancing AGMB-129 into a global Phase 2a study in patients with Fibrostenosing Crohn's Disease, a disease for which there are currently no medicinal products available."

About AGMB-129

AGMB-129 is an oral, small molecule GI-restricted inhibitor of ALK-5 (or TGFβR1) for the treatment of Fibrostenosing Crohn's Disease (FSCD). TGFβ is a known master regulator of fibrosis and preliminary clinical data supports targeting the pathway in fibrotic indications. AGMB-129 is specifically designed to inhibit ALK5 in the GI-tract. Rapid first-pass metabolism in the liver prevents clinically relevant systemic exposure, delivering an improved safety profile over other inhibitors in its class. Fibrostenotic complications occur in up to 50% of Crohn's disease patients and are the leading cause of bowel resection surgery. Yet, there are no approved specific therapies for FSCD.

About Agomab

Agomab is translating a deep expertise in growth factor biology to pioneer and develop novel treatments that aim to resolve fibrosis, repair tissue structure and restore organ function. Combining new scientific insights with robust drug development and a long-term corporate vision, we are building a broad clinical pipeline of differentiated programs with disease modifying potential in fibrotic diseases.

Contacts

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

Media Requests for Agomab
Dr. Stephanie May or Eva Mulder
Trophic Communications
Phone: + 49 171 185 5682
E-Mail: agomab@trophic.eu