Agomab Receives FDA Fast Track Designation for AGMB-129 in Fibrostenosing Crohn's Disease and Starts STENOVA Phase 2a Clinical Trial

-- FDA Fast Track designation received for AGMB-129 in Fibrostenosing Crohn's Disease --
-- Global 12-week Phase 2a trial will evaluate Agomab's oral GI-restricted small molecule ALK5 inhibitor in 36 patients with symptomatic Fibrostenosing Crohn's Disease --

Ghent, Belgium, October 05, 2023 – Agomab Therapeutics NV ('Agomab') today announced that it received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for AGMB-129 for the potential treatment of Fibrostenosing Crohn's Disease (FSCD). In addition, Agomab has initiated its STENOVA Phase 2a clinical trial evaluating AGMB-129, an oral gastro-intestinal (GI)-restricted small molecule inhibitor of ALK5 (TGF-βRI or ALK5), in patients with symptomatic FSCD.

Fibrotic strictures develop in nearly 50% of patients living with Crohn's disease and remain a major therapeutic challenge as strictures are the main cause for bowel surgery, an outcome which occurs in approximately 75% of Crohn's disease patients. The TGF-β pathway is a key driver of fibrosis in the GI tract, and inhibition through its receptor ALK5 is considered the most effective therapeutic approach to block it.

AGMB-129 is the first drug candidate to receive FDA Fast Track Designation for the treatment of Fibrostenosing Crohn's Disease. Fast Track Designation is intended to expedite the development and review of new therapies that treat serious or life-threatening conditions for which there is an unmet medical need. To qualify, available clinical and non-clinical data needs to demonstrate the potential to address the unmet medical need. Benefits of Fast Track Designation include the opportunity for frequent meetings with the FDA to discuss trial design, development plans and data needed to support drug approval; the ability to submit a New Drug Application (NDA) on a rolling basis; and eligibility for priority review.

The STENOVA Phase 2a clinical trial is a randomized, double-blind, placebo-controlled study in 36 patients with symptomatic FSCD. Patients will be randomized to receive one of two doses of AGMB-129 or a placebo for 12 weeks. The multi-center study is global with investigational sites in the USA, Canada and Europe. The primary endpoints are the safety and tolerability of AGMB-129 in FSCD patients. Secondary endpoints include the pharmacokinetics and target engagement at the site of the ileal strictures.

"The start of this Phase 2a clinical study is an important milestone in the development of AGMB-129. Intestinal strictures cause severe obstructive symptoms, are thought to induce the formation of fistulae, and are the main cause of bowel surgery. Receiving the first FDA Fast Track Designation in fibrostenosing Crohn's disease indicates that the FDA acknowledges the severity and unmet medical need in this indication," **said Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**. "We look forward to working with investigators as well as the regulators to develop AGMB-129 in this particularly severe disease for which there is no approved therapy."

"Intestinal strictures remain the major therapeutic challenge in patients with Crohn's disease. Because available anti-inflammatory agents have limited efficacy on strictures, direct anti-fibrotic therapies are needed" **commented Florian Rieder, MD, Vice-Chair Department of Gastroenterology, Hepatology**

and Nutrition, Cleveland Clinic, Cleveland, OH, and co-lead of the STAR consortium, a network of academic and industry partners which aims to advance the development of new agents for FSCD. "The initiation of a Phase 2a trial with a potent anti-fibrotic agent as well as the Fast Track Designation represent a very exciting milestone for patients with Fibrostenosing Crohn's Disease."

AGMB-129 is an investigational drug and not approved by any regulatory authority. Its efficacy and safety have not been established.

About AGMB-129

AGMB-129 is an oral, small molecule GI-restricted inhibitor of ALK5 (or TGF- β RI) currently in clinical development for the treatment of Fibrostenosing Crohn's Disease (FSCD). TGF-β is a major regulator of fibrosis and preliminary clinical data support targeting this pathway in fibrotic indications in several organs. AGMB-129 is specifically designed to inhibit ALK5 in the GI-tract. Rapid first-pass metabolism in the liver prevents clinically relevant systemic exposure, potentially delivering an improved safety profile over systemically available inhibitors in this class. In a Phase 1 trial in healthy subjects, single- and multiple-dose AGMB-129 was well-tolerated at all doses tested. In addition, the trial confirmed that the GI-restricted mechanism operates efficiently in humans by showing high local exposure to AGMB-129 in the ileum but no clinically relevant systemic exposure. Fibrostenosing complications occur in nearly 50% of Crohn's disease patients and are the leading cause of bowel resection surgery, however there are no approved specific therapies for FSCD. AGMB-129 has received U.S. FDA Fast Track Designation.

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
Trophic Communications
Phone: + 49 171 185 5682
E-Mail: agomab@trophic.eu