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Late-Breaking Interim STENOVA Data Presented at Digestive Disease Week® 2025 Demonstrate Potential of AGMB-129 in Fibrostenosing Crohn's Disease

Antwerp, Belgium, May 6, 2025 – Agomab Therapeutics NV ("Agomab") today announced late-breaking interim data from the ongoing STENOVA[1] Phase 2a clinical trial for AGMB-129, an oral gastro-intestinal (GI)-restricted small molecule inhibitor of ALK5 (TGF-β RI or ALK5) developed for the potential treatment of Fibrostenosing Crohn's Disease (FSCD). The interim results were presented by Florian Rieder, MD, at Digestive Disease Week® (DDW) 2025, taking place in San Diego on May 3-6, 2025.

STENOVA is a randomized, double-blind, placebo-controlled study in 103 patients with symptomatic FSCD. Patients are randomized to receive one of two doses of AGMB-129 (200mg twice-daily or 100mg once-daily) or placebo for 12 weeks on top of standard of care, including anti-inflammatory biologics. The multi-center study is global with investigational sites in the USA, Canada and Europe.

The interim analysis was conducted on the first 44 patients after 12 weeks of treatment and indicated that the primary endpoint of favorable safety and tolerability of AGMB-129 was met at both doses. The severity and incidence of adverse events were similar among treatment arms, including placebo, and there were no signs of cardiac toxicity, no pro-inflammatory effects, and no signals in safety labs, vital signs, physical exams or ECGs.

The study also met its two predefined secondary endpoints of pharmacokinetics (PK) and target engagement in the first 44 patients. The PK data indicated very low systemic exposure to AGMB-129 and high exposure to its inactive main metabolite MET-158. These results are consistent with prior data in healthy subjects and support the gut-restricted profile of AGMB-129 in FSCD patients.

Target engagement, measured through transcriptomics in mucosal biopsies collected at the site of the ileal strictures at screening and Week 12, showed significant downregulation of both fibrotic ($p=0.0036$) and inflammatory pathways ($p<0.0001$) for the high dose cohort versus placebo.

A consistent positive trend was also observed for the high dose versus placebo across several exploratory endpoints, including stricturing patient-reported outcome (S-PRO) and disease severity in centrally read Simple Endoscopic Score (SES-CD).

The STENOVA study is fully recruited, and on track to report results on 103 patients in the fourth quarter of this year.

"Fibrostenosing Crohn's disease is an area of high unmet medical need, and the interim STENOVA results presented at DDW® show the potential of AGMB-129 as a novel drug candidate for patients. The target engagement data point to the potential dual anti-inflammatory and anti-fibrotic effect of AGMB-129, on top of standard of care. Moreover, the consistent trend observed for several of the exploratory clinical endpoints after 12 weeks is very encouraging," **said Florian Rieder, MD, Vice-Chair Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic, OH**.

[1] Study Details | STENOVA - A Study to Evaluate Safety, Tolerability, PK and PD of AGMB-129 in Patients With Fibrostenotic Crohn's Disease | ClinicalTrials.gov

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"The positive interim data for the STENOVA Phase 2a clinical trial are an important step forward in the development of our gut-restricted ALK-5 inhibitor AGMB-129 in patients with Fibrostenosing Crohn's disease," **said Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**. "The STENOVA study is now fully recruited, and the swift enrollment underscores the high unmet medical need that exists in this indication. We want to thank all patients and investigators for their participation in this landmark study."

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 driver of fibrosis. AGMB-129 is specifically designed to inhibit ALK5/TGF-β 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-doses of AGMB-129 were generally well-tolerated at all doses tested. In addition, the trial showed high local exposure to AGMB-129 in the ileum but no clinically relevant systemic exposure, demonstrating that the GI restricted mechanism may operate efficiently in humans. AGMB-129 has received U.S. FDA Fast Track Designation.

About Fibrostenosing Crohn's Disease

Crohn's disease is a chronic progressive disease of the gastrointestinal (GI) tract. It is estimated that approximately 50% of patients with Crohn's disease develop fibrosis of the GI tract, resulting in stricture (stenosis) formation and intestinal obstructions, most frequently in the terminal ileum. These strictures can cause obstructive symptoms such as nausea, vomiting and severe pain after meals, leading to dietary change, malnutrition and surgery. Despite the large unmet medical need, there are no approved pharmacological therapies for FSCD.

About Agomab

Agomab is focused on achieving disease modification by modulating inflammation and fibrosis 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 by applying specialized capabilities in organ-restricted small molecules. With a differentiated clinical pipeline across several fibrotic disorders, end-to-end research and development capabilities, a proven track-record and a strong investor base, Agomab is building a transformational company with the aim to have a real impact on patients' lives.

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 3-6, 2025. The meeting showcases nearly 6,000 abstracts and 1,000 invited talks on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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Contacts

Investors
Sofie Van Gijsel
VP of Investor Relations
E-Mail: sofie.vangijsel@agomab.com
Phone: +1 781 296 1143

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