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Late-Breaking Interim STENOVA Data for AGMB-129 in Fibrostenosing Crohn's to be Presented at Digestive Disease Week® 2025

Antwerp, Belgium, April 10, 2025 – Agomab Therapeutics NV ('Agomab') today announced that 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) for the potential treatment of Fibrostenosing Crohn's Disease (FSCD), will be presented as a late-breaking presentation 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 a total of 90 patients with symptomatic FSCD. Patients are randomized to receive one of two doses of AGMB-129 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 primary endpoints are the safety and tolerability of AGMB-129 in FSCD patients. Secondary endpoints include pharmacokinetics and target engagement as measured through transcriptomics in mucosal biopsies collected at the site of the ileal strictures.

Details of the presentation are as follows:

Abstract	**Session**	**Title**
Tue May 6, 2025, 10:00 AM - 11:30 AM PDT		
4301266	DDW Clinical Late Breaking Session 5275	A Phase 2a, Randomized, Placebo-controlled, Double-blind Study to Assess the Safety, Pharmacokinetics (PK) and Pharmacodynamics (PD) of AGMB-129 in Patients with Fibrostenotic Crohn's Disease: Interim Results from the STENOVA Trial **Presenter:** Florian Rieder, MD, Vice-Chair Department of Gastroenterology, Hepatology and Nutrition, at Cleveland Clinic, Ohio

"We are thrilled that DDW has accepted the interim STENOVA results as a late-breaking presentation, and we look forward to sharing details on AGMB-129 in Fibrostenosing Crohn's disease patients at this year's meeting," **said Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**.

"AGMB-129 is a novel, anti-fibrotic product candidate with the potential to address the high unmet medical need that remains in Fibrostenosing Crohn's disease," **commented Florian Rieder, MD, Vice-Chair Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic, OH**. "I am looking forward to presenting interim data from the STENOVA study at DDW."

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

[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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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 tract. It is estimated that approximately 50% of patients with Crohn's disease develop fibrosis of the gastrointestinal (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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