



## Agomab Announces Positive Topline Phase 2a Interim Results for AGMB-129 in Fibrostenosing Crohn's Disease

-- AGMB-129 hit all primary and secondary endpoints in interim read-out from 44 patients after 12 weeks treatment --

-- Detailed interim STENOVA results to be presented at future scientific conference --

-- STENOVA clinical trial on track to report full results in the fourth quarter of 2025 --

-- Open-label extension study initiated --

**Antwerp, Belgium, March 10, 2025** – [Agomab Therapeutics NV](#) ('Agomab') today announced positive interim results from 44 patients completing treatment in the ongoing STENOVA<sup>1</sup> Phase 2a clinical trial for AGMB-129, an oral gastro-intestinal (GI)-restricted small molecule inhibitor of ALK5 (TGF- $\beta$  RI or ALK5) for the potential treatment of Fibrostenosing Crohn's Disease (FSCD).

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 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 the pharmacokinetics and target engagement at the site of the ileal strictures as measured through transcriptomics. All primary and secondary endpoints were met.

The company has also initiated the open-label treatment extension of the STENOVA study with AGMB-129. Study participants who have completed the double-blind 12-week treatment period are eligible to participate and can receive treatment for up to an additional 48 weeks.

"The positive interim data for the STENOVA Phase 2a clinical trial represent a significant milestone for this program, and we look forward to presenting the detailed results at a scientific conference in the near-term," said **Philippe Wiesel, Chief Medical Officer at Agomab Therapeutics**. "We want to thank all patients and investigators for participating in this trailblazing study, which aims to address the high unmet medical need that exists in the field of 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- $\beta$  RI) currently in clinical development for the treatment of Fibrostenosing Crohn's Disease (FSCD). TGF- $\beta$  is a major driver of fibrosis. AGMB-129 is specifically designed to inhibit ALK5/TGF- $\beta$  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

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<sup>1</sup> [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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subjects, single- and multiple-dose AGMB-129 was 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. 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 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  $\beta$ , 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.

## **Contacts**

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