



Agomab to Present STENOVA Open-Label Extension Data of Ontunisertib at UEG Week 2026 and Host Scientific Symposium on Fibro-Inflammation

October 8, 2026

-- *Open-Label Extension (OLE) Data of STENOVA Phase 2a study with ontunisertib in Fibrostenosing Crohn's disease (FSCD) selected for oral presentation at UEG Week 2026 --*

-- *Results support initiation of global NOV-ERA Phase 2b study in FSCD --*

-- *Agomab-sponsored symposium to discuss the importance of targeting fibro-inflammation in inflammatory bowel disease (IBD) --*

Antwerp, Belgium, October 8, 2026 – [Agomab Therapeutics NV](#) ('Agomab') a clinical-stage biopharmaceutical company focused on fibro-inflammation, today announced that OLE data of the Phase 2a STENOVA study will be presented in an oral session at United European Gastroenterology (UEG) Week 2026, taking place October 17-20 in Barcelona, Spain. The OLE study (*Part B* of STENOVA) evaluated long-term treatment with ontunisertib 200 mg BID for up to 60 weeks in symptomatic FSCD patients. The study assessed the long-term safety and PK profile of ontunisertib and explored the event rate and disease progression in FSCD patients.

The Company also announced that it will host an industry-sponsored scientific symposium focused on the role of fibro-inflammation in IBD. The symposium will explore the evolving understanding of fibro-inflammation in IBD, including the interplay between inflammation and fibrosis in structural disease progression, and emerging therapeutic strategies designed to address both inflammatory and fibrotic components of disease.

Florian Rieder, MD, Vice-Chair, Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic, commented:

"I am pleased to present the OLE data at UEG Week, which provide important insights into extended treatment with ontunisertib. The findings highlight the potential of ontunisertib to provide a meaningful clinical benefit for people living with FSCD. I also look forward to joining leading experts in the symposium on fibro-inflammation and discussing how a deeper understanding of the crosstalk between inflammation and fibrosis may help advance therapeutic approaches for patients facing therapeutic resistance and progressive bowel damage."

Philippe Wiesel, Chief Medical Officer of Agomab, added: "The oral presentation of the STENOVA OLE data at UEG Week provides an important opportunity to share the growing body of evidence supporting ontunisertib in FSCD with the global gastroenterology community. The OLE results reinforce our confidence in the potential of ontunisertib as we advance the global Phase 2b NOV-ERA study in the coming months. We are also delighted to convene leading experts for a discussion on fibro-inflammation, a rapidly evolving area of science that is reshaping our understanding of disease progression in IBD."

Details of the Company's events are as follows:

Agomab Scientific Symposium¹

Title: *A New Treatment Paradigm: Addressing Fibro-Inflammation in IBD*

Date & Time: Monday October 19, 17:30-18:30 CET

Presenters: Florian Rieder, M.D.; Geert D'Haens, M.D.; and Bruce E. Sands, M.D., M.S.

Location: Room D3

UEG Week Oral Presentation

Title: *STENOVA Trial Update: Open-Label Extension of Ontunisertib in Fibrostenosing Crohn's Disease with Objective Imaging Efficacy Assessments*

Date & Time: Tuesday October 20, 12:10-12:20 CET

Presenter: Florian Rieder, M.D.

Session: Looking into the future; Novel therapeutics in IBD (Part 2)

Location: Room B3

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

About STENOVA

STENOVA, a first-in-indication study, was a two-part Phase 2a trial in Crohn's patients with symptomatic ileal strictures. *Part A* was a randomized, double-blind, placebo-controlled study in a total of 103 participants. Participants were randomized to receive either 100mg QD or 200mg BID of ontunisertib or placebo for 12 weeks on top of standard of care, including anti-inflammatory

biologics. The study was conducted in investigational sites in the USA, Canada and six European countries. The primary endpoint was the evaluation of the safety and tolerability of ontunisertib in FSCD patients. Secondary endpoints included pharmacokinetics (PK) and target engagement. Exploratory endpoints included the Simple Endoscopic Score of Crohn's disease (SES-CD) and novel FSCD specific endpoints such as the Stricturing Patient Reported Outcome (S-PRO) score and MRE. Eligible study participants who completed the double-blind 12-week treatment period could participate in the OLE part of the STENOVA study (*Part B*) and receive ontunisertib 200mg BID for up to an additional 48 weeks. 49 patients rolled over (94% of eligible patients of STENOVA *Part A*) and 37 patients completed the 48-week OLE *Part B* of STENOVA. The OLE study assessed the long-term safety and PK profile of ontunisertib and explored the event rate and disease progression in FSCD patients.

About NOV-ERA

The planned NOV-ERA study is a randomized, double-blind, placebo-controlled, dose-ranging, multicenter Phase 2b trial to assess the efficacy and safety of ontunisertib in participants diagnosed with symptomatic FSCD. The trial is expected to enroll up to 320 adult patients globally. To be eligible for the trial, participants must have at least one naive or anastomotic endoscopically non-passable ileal stricture, confirmed by a centrally read Simple Endoscopic Score for Crohn's Disease (SES-CD). Upon study initiation, participants will be randomized in a 1:1:1:1 ratio to receive either ontunisertib at one of three dose levels (400 mg, 200 mg, and 100 mg), or a matching placebo, administered twice daily (BID). The trial will consist of a 6-week screening period, a 52-week treatment period, and a 2-week follow-up period. The primary endpoint is the proportion of patients achieving endoscopic passability of the ileal index stricture at Week 24. The Company plans to initiate the NOV-ERA study in the coming months.

About Ontunisertib

Ontunisertib (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. Ontunisertib 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. Ontunisertib has received U.S. FDA Fast Track Designation.

About Agomab

Agomab is a clinical-stage biopharmaceutical company focused on developing novel disease-modifying therapies for fibro-inflammatory diseases with high unmet medical need. Agomab's product candidates are designed to target established, potent pathways and utilize organ-restricted approaches, with the aim of increasing efficacy while minimizing safety liabilities. Fostering a culture of excellence, Agomab's mission is to pioneer therapeutics that aim to resolve fibro-inflammation and restore organ function to enable people with these disorders to live fuller and healthier lives.

Cautionary Note regarding Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are often identified by terms such as "continue," "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. "Forward-looking statements" include, without limitation, statements regarding the potential of ontunisertib for Fibrostenosing Crohn's disease, including its potential to deliver an improved safety profile over systemically available inhibitors in its class, the expected initiation and conduct of the NOV-ERA Phase 2b study, and our interactions with regulatory authorities. Forward-looking statements are based on Agomab's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties related to the results of our clinical trials, including the risk that Phase 2a results may not be predictive of Phase 2b or later-stage outcomes; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements for product candidates; the risk that the NOV-ERA Phase 2b study may not be initiated on the anticipated timeline, or at all; the impact of governmental laws and regulations on our business; competition and potential for technological or therapeutic change in the field; the substantial additional investment required before any product candidate may be commercialized; and disruptions caused by our reliance on third party suppliers and service providers. These and other risks and uncertainties are described more fully in our filings and reports with the SEC, including in our most recent annual report on Form 20-F filed with the SEC and our subsequent filings and reports filed with the SEC. Forward-looking statements contained in this announcement are made as of this date, and Agomab undertakes no duty to update such information except as required under applicable law. Readers should not rely upon the information in this announcement as current or accurate after its publication date.

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