

Agomab Reports Positive Topline Data from STENOVA Open-Label Extension Study of Ontunisertib in Fibrostenosing Crohn's Disease

- Favorable safety and tolerability profile maintained through up to 60 weeks of treatment with ontunisertib in Fibrostenosing Crohn's disease (FSCD) patients --
- Low annualized FSCD-related event rate of 3%, with one endoscopic balloon dilation (EBD) and no surgeries reported over the full treatment period --
- Radiological assessment shows trend for fibrotic stricture stabilization over treatment course --
- Sustained disease control observed across symptoms and disease activity scores in Open-Label Extension Study (OLE) --
- Results support initiation of global NOV-ERA Phase 2b study in FSCD in the coming months --
- Company to host webcast today at 8:30 a.m. Eastern Time --

Antwerp, Belgium, October 1, 2026 – [Agomab Therapeutics NV](#) ('Agomab') a clinical-stage biopharmaceutical company focused on fibro-inflammation, today announced positive results of the 48-week OLE portion of the Phase 2a STENOVA trial evaluating ontunisertib in patients with FSCD, a severe manifestation of Crohn's disease characterized by progressive bowel fibrosis and intestinal strictures.

The OLE study (*Part B*) evaluated long-term treatment with ontunisertib 200 mg BID on top of standard of care. Of the participants eligible to roll over into the OLE study from the 12-week placebo-controlled *Part A* of STENOVA, 94% elected to enter the study (n=49).

The results demonstrated a generally favorable long-term safety and tolerability profile of ontunisertib 200 mg BID for up to 60 weeks of treatment, as well as maintenance of the gut-restricted pharmacokinetic (PK) profile observed in *Part A* of the trial. Sustained disease control, with low symptoms and disease activity scores and radiological stricture stabilization, was also observed. Importantly, a low FSCD-related annualized event rate of 3% was reported in patients treated with ontunisertib 200 mg BID up to 60 weeks.

"Fibrostenosing Crohn's disease remains one of the most significant unmet needs in fibro-inflammatory bowel disease, with no approved therapies targeting the fibrotic component of the disease," commented **Florian Rieder, MD, Vice-Chair, Department of Gastroenterology, Hepatology and Nutrition, Cleveland Clinic**. "Beyond the favorable safety and tolerability profile, what stands out in the OLE results is the sustained disease control as well as the low rate of interventions, with only one EBD and no surgeries reported. Importantly, patients appeared to continue to do well on long-term treatment with ontunisertib, maintaining low symptom levels and favorable outcomes on quality-of-life assessments. In a patient population often facing progressive bowel damage and recurrent procedures, these combined findings point to the potential of ontunisertib to provide a meaningful clinical benefit."

Philippe Wiesel, Chief Medical Officer of Agomab, added: “We are very pleased with the OLE results announced today. The favorable long-term safety profile, maintenance of gut-restricted exposure and signals of sustained disease control observed over up to 60 weeks of treatment provide strong support for the initiation of our global NOV-ERA Phase 2b study later this year. Importantly, these data further support our belief that targeting fibro-inflammation through a differentiated anti-fibrotic mechanism may address a key driver of disease progression that remains largely untreated today. We look forward to evaluating ontunisertib across multiple dose levels in NOV-ERA as we continue to advance what we believe is a potentially novel therapeutic approach for people living with fibro-inflammatory conditions.”

Topline STENOVA OLE results

Safety and tolerability profile

Ontunisertib 200 mg BID demonstrated a generally favorable safety and tolerability profile through up to 60 weeks of treatment. Five serious adverse events were reported in four patients in *Part B* of the STENOVA study (48-week OLE); all of which were considered unrelated or unlikely related to study treatment.

There were no signals of cardiac injury, pro-inflammatory effects, vasculitis, liver toxicity or thrombotic events during the extended treatment period.

Pharmacokinetic (PK) profile

Systemic exposure of ontunisertib remained low throughout the OLE period and consistent with observations from the randomized-controlled 12-week portion of STENOVA. Plasma concentrations remained well below IC₅₀ levels, supporting the efficient gut-restricted pharmacokinetic profile of ontunisertib and its differentiated approach to ALK5 inhibition.

Event rate

Only one FSCD-related event, an EBD procedure, was reported during the study, corresponding to an annualized event rate of 3%. No patients progressed to surgery during up to 60 weeks of ontunisertib 200 mg BID treatment. For reference, while not based on head-to-head studies, recent publications on a comparable FSCD patient population receiving advanced therapies reported annualized event rates ranging from 23-35%.^{1,2,3,4}

Imaging results

Magnetic resonance enterography (MRE) assessments performed at Weeks 24 and 48 of the OLE study suggested radiological stabilization of fibrotic strictures over the course of treatment with ontunisertib 200 mg BID. While patients receiving placebo showed a trend of radiological progression during the 12-week *Part A* of the STENOVA study, the OLE results suggest that when switching to ontunisertib,

¹ El Ouali et al. 2026, doi:10.1186/s12876-026-04815-4;

² El Ouali et al. 2022, doi:10.1002/ueg2.12314; and

³ El Ouali et al. 2026, doi:10.1093/ecco-jcc/jjag038.

⁴ Cross-trial comparisons are inherently limited due to differences in study design, patient populations, treatment regimens, endpoints and other factors, and no conclusions regarding the relative efficacy or safety of ontunisertib should be drawn from such comparisons in the absence of head-to-head clinical trials.

those patients stabilized and progressively caught up with those already exposed to ontunisertib in *Part A*.

Given the optional nature of the Week 48 endoscopy assessment in the OLE study, the available data were too limited to allow for a reliable interpretation.

Patient-reported outcomes

Patients maintained a low symptom burden and disease activity throughout the OLE period, with sustained improvements observed across stricture-specific symptom assessments, Crohn's disease activity score (CDAI) and quality-of-life measures. At Week 48 of the OLE, 97% of evaluable patients were in clinical remission as assessed by the CDAI score.

Next steps with ontunisertib: NOV-ERA Phase 2b study

Agomab recently completed regulatory filings for NOV-ERA, a global Phase 2b trial designed to evaluate ontunisertib in approximately 320 patients with symptomatic FSCD and plans to initiate the study in the coming months. In NOV-ERA, participants will be randomized to receive either ontunisertib at one of three dose levels (400 mg BID, 200 mg BID, and 100 mg BID), or a matching placebo. Together with the favorable safety and tolerability profile previously demonstrated in Phase 1 at doses up to 400 mg BID, the positive safety and tolerability findings of the OLE study provide strong support for the inclusion of a 400 mg BID treatment arm in the NOV-ERA Phase 2b study.

Agomab intends to present detailed STENOVA OLE results at a future scientific conference.

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

Webcast Event

The Company will hold a **live webcast on Thursday, October 1, 2026 at 8:30 a.m. Eastern Time** to discuss the STENOVA OLE results. Members of the Agomab management team will be joined by key opinion leader **Dr. Florian Rieder**. To register for the live webcast and replay, please visit the [Agomab](#) homepage.

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.

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, the expected initiation 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; 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 impact of governmental laws and regulations on our business; 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

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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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