

## **Agomab Announces First Patient Dosed in Global NOV-ERA Phase 2b Study of Ontunisertib in Fibrostenosing Crohn's Disease**

*-- NOV-ERA is designed to assess the efficacy and safety of ontunisertib in approximately 320 patients with symptomatic Fibrostenosing Crohn's disease (FSCD) --*

*-- Global, randomized, placebo-controlled, dose-ranging study to evaluate three dose levels of ontunisertib, with endoscopic passability at Week 24 as primary endpoint --*

*-- Study initiation represents an important milestone in the development of ontunisertib as a potential first targeted anti-fibrotic treatment for FSCD --*

**Antwerp, Belgium, October 13, 2026** – [Agomab Therapeutics NV](#) ('Agomab'), a clinical-stage biopharmaceutical company focused on fibro-inflammation, today announced that the first patient has been dosed in NOV-ERA, the Company's global Phase 2b study evaluating ontunisertib in patients with symptomatic FSCD.

NOV-ERA is a randomized, double-blind, placebo-controlled, multicenter Phase 2b study designed to assess the safety and efficacy of ontunisertib. The study is expected to enroll approximately 320 adult patients globally. 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 for a treatment duration of 52 weeks.

The initiation of NOV-ERA follows the positive Phase 2a STENOVA results that support continued clinical development of ontunisertib in FSCD. The recently announced positive long-term safety and tolerability findings of the open-label extension (OLE) part of the STENOVA Phase 2a study provide strong support for the inclusion of a 400 mg BID treatment arm in the NOV-ERA study.

**Philippe Wiesel, Chief Medical Officer of Agomab, commented:** "Dosing the first patient in NOV-ERA marks the beginning of an exciting next chapter for our Company and for the late-stage development of ontunisertib. FSCD is associated with progressive bowel damage and a substantial burden for patients; yet there are currently no approved therapies that specifically address the fibrotic component of the disease. NOV-ERA is designed to evaluate the efficacy and safety of ontunisertib and to provide important data across multiple imaging modalities, clinical endpoints, and patient-reported outcomes. We are grateful to the patients, investigators and clinical sites participating in this global study."

The initiation of the NOV-ERA study triggers a €7 million milestone payment to the former shareholders of Origo Biopharma under the terms of Agomab's 2021 acquisition of the company. The acquisition included up to €20 million in potential development and regulatory milestone payments. To date, €10 million has become payable, including a €3 million milestone paid in 2025, reflecting continued progress in the development of the program.

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

**About NOV-ERA**

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The 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 patients diagnosed with symptomatic ileal strictures. The trial is expected to enroll approximately 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 central reading. 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.

Key secondary efficacy endpoints include:

- Proportion of participants achieving endoscopic passability of the ileal index stricture at Week 52.
- Time to an FSCD-related event (including bowel surgery and endoscopic balloon dilation).
- Change from baseline in Magnetic Resonance Enterography (MRE) imaging features of the index stricture at Week 24 and Week 52.
- Change from baseline in total SES-CD at Week 24 and Week 52.
- Proportion of participants with an endoscopic response and remission at Week 24 and Week 52 compared to baseline.
- Change from baseline in Patient-Reported Outcome questionnaire for stricturing Crohn's disease (S-PRO 2.0) severity score, Crohn's disease activity index (CDAI) and quality of life instruments at Week 24 and Week 52.

The endpoints assessed in the NOV-ERA study are designed to inform the selection of potential registrational endpoints for ontunisertib in FSCD.

## About Ontunisertib

Ontunisertib (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. Ontunisertib 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. 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,"

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"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 conduct and progress 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 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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