AGOMAB

Agomab Announces Design of NOV-ERA Phase 2b Study with Ontunisertib in Fibrostenosing Crohn's Disease

-- Regulatory alignment with U.S. Food and Drug Administration (FDA) on key elements of NOV-ERA Phase 2b study design, including novel primary endpoint of endoscopic passability --

-- Study initiation on track, with first participants expected to be dosed in the second half of 2026 --

Antwerp, Belgium, June 23, 2026 – Agomab Therapeutics NV (Nasdaq: AGMB) ("Agomab" or the "Company"), a clinical-stage biopharmaceutical company focused on fibro-inflammation, today announced the design of its upcoming Phase 2b NOV-ERA study with ontunisertib, its investigational oral gastro-intestinal (GI)-restricted small molecule inhibitor of ALK5 (or TGF-β RI) for the potential treatment of Fibrostenosing Crohn's Disease (FSCD).

Approximately 46% of Crohn's disease patients have FSCD, or fibrotic strictures in the intestinal tract, which can cause obstructive symptoms leading to dietary change, malnutrition and surgery. Despite the large unmet medical need, there are no approved pharmacological therapies for FSCD.

The Company has aligned with the FDA on the study design of NOV-ERA, including the study's primary efficacy endpoint of endoscopic passability at Week 24 as assessed by the SES-CD narrowing score, as well as several secondary efficacy endpoints relevant to patients with FSCD. The protocol has been submitted to the FDA and has cleared central Institutional Review Board (IRB) approval in the U.S. In addition, the study has received approval by Health Canada. The Company has also submitted Clinical Trial Applications in multiple countries globally, including in the European Union and Asia Pacific territories. The Company expects to initiate the NOV-ERA study following receipt of applicable regulatory and ethics approvals and plans to dose the first participants in the second half of 2026.

"The NOV-ERA study breaks new ground as the first Phase 2b study in FSCD, an area of high unmet medical need, and will inform dose selection and pivotal endpoints," commented Philippe Wiesel, MD, Chief Medical Officer of Agomab. "The submission of the study protocol to key regulatory agencies is a crucial milestone in the late-stage development of ontunisertib in FSCD. We are now focused on completing operational preparations and look forward to initiating patient enrollment in the coming months."

NOV-ERA Phase 2b Study Design

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. The trial will consist of a 6-week screening period, a 52-week treatment period, and a 2-week follow-up period.

AGOMAB

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.
- 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 at Week 24 and Week 52.
- Time to an FSCD-related event (including surgery and endoscopic balloon dilation).

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

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

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 Fibrostenosing Crohn's Disease

Crohn's disease is a chronic progressive disease of the gastrointestinal tract. It is estimated that approximately 46% of patients with Crohn's disease have fibrosis of the gastrointestinal tract, resulting in stricture formation and intestinal obstructions, most frequently in the terminal ileum. These strictures can cause obstructive symptoms 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 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 "forward-looking statements" within the meaning of applicable securities laws, including, without limitation, statements regarding Agomab's plans, expectations and

development strategy for ontunisertib; the design, initiation, enrollment, dosing, conduct, timing and potential outcomes of the NOV-ERA Phase 2b study and statements related to interactions with regulatory authorities related thereto; the expected timing for dosing the first participants in the NOV-ERA study; the potential for the NOV-ERA study endpoints to validate and inform the selection of potential registrational endpoints for ontunisertib in FSCD; the potential therapeutic benefits, safety profile and clinical utility of ontunisertib; the potential of ontunisertib to address unmet medical need in FSCD; and Agomab's expectations regarding regulatory and ethics reviews, approvals and alignment, including with respect to CTAs submitted in multiple countries globally.

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 materially from those expressed or implied by such forward-looking statements include, but are not limited to, risks and uncertainties related to the risks inherent in biopharmaceutical product development; the initiation, timing, enrollment, conduct, completion and results of clinical trials; the ability to obtain and maintain regulatory and ethics approvals to initiate and conduct the NOV-ERA study in applicable jurisdictions; potential changes in regulatory requirements or feedback from regulatory authorities; the possibility that clinical trial results may not support further development or regulatory approval of ontunisertib; the possibility that the endpoints assessed in the NOV-ERA study may not validate or inform the selection of potential registrational endpoints; the safety, tolerability, efficacy and therapeutic potential of ontunisertib; Agomab's ability to manufacture and supply sufficient quantities of ontunisertib for clinical development; and other risks and uncertainties described more fully in the section titled "Risk Factors" in Agomab's filings with the Securities and Exchange Commission. 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.

Contacts
Investors
Sofie Van Gijsel
VP of Investor Relations
E-Mail: sofie.vangijsel@agomab.com
Phone: +1 781 296 1143

Media
Gretchen Schweitzer
Trophic Communications
E-Mail: agomab@trophic.eu
Phone: +49 172 861 8540