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argenx Announces Positive Topline Results from Phase 2 Study of FB102 in Celiac Disease

- *Study met primary endpoint of change from baseline in the ratio of Vh:Cd ($p=0.0176$)*
- *First Phase 2 evidence that blocking CD122 can prevent gluten-induced intestinal damage in people living with celiac disease*
- *argenx plans to advance FB102 into Phase 3 development*

October 8, 2026, 7:00 AM CET

Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology innovation company, today announced positive topline results from the Phase 2 study evaluating FB102, a first-in-class CD122 inhibitor, in adults with celiac disease. These results represent the first clinical readout of FB102 following argenx's acquisition of Forte Biosciences in August 2026.

Patients treated with FB102 demonstrated a statistically significant and clinically relevant treatment effect compared to placebo. The study met its primary endpoint of change from baseline in the ratio of villus height-to-crypt depth (Vh:Cd) at day 78 versus placebo in adults with celiac disease undergoing a gluten challenge ($p=0.0176$). Broad efficacy measures, including intraepithelial lymphocyte (IEL) density, villus height-to-crypt depth intraepithelial lymphocyte (VCIEL) composite score, and symptoms, were consistent with the primary endpoint, providing additional evidence of effect across histologic, inflammatory, and clinical measures.

The observed safety profile was consistent with prior studies and the known safety profile of FB102, with no new safety signals identified.

"These positive Phase 2 results strengthen our conviction in the potential of FB102 to address a significant unmet need for people living with celiac disease, where there are currently no approved therapies," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "The study builds on the Phase 1b trial, providing consistent clinical evidence that CD122 blockade can protect against gluten-induced intestinal damage and prevent emergence of patient symptoms, even under a more intense gluten challenge, validating CD122 as a promising therapeutic target in celiac disease. Combined with the consistent safety profile observed across studies, these findings support advancing FB102 into Phase 3 development and further exploring its broader potential across immune-mediated diseases."

Detailed results from the Phase 2 study will be shared at an upcoming medical meeting. FB102 continues to be evaluated as a potential treatment in other autoimmune diseases, including vitiligo and alopecia areata.

FB102-301 Study Design

FB102-301 ([NCT06982963](#)) is a randomized, double-blind, placebo-controlled, Phase 2 study evaluating FB102 in adults with celiac disease. The study enrolled 126 patients with confirmed celiac disease who were symptom free on a strict gluten-free diet for at least 12 months. Participants were randomized (2:2:1) to receive intravenous infusions of FB102 (two dose levels) or placebo while undergoing a controlled, eight-week oral gluten challenge. The primary endpoint was change from baseline in the ratio of villus height-to-crypt depth (Vh:Cd) at day 78 versus placebo, aimed at determining whether FB102 protects the intestine from gluten-induced damage over the challenge period.

About Celiac Disease

Celiac disease is a chronic autoimmune condition triggered by ingesting gluten, a group of proteins found in wheat, barley, and rye. In people with celiac disease, gluten triggers an immune response that damages the lining of the small intestine. Over time, this damage leads to impaired nutrient absorption and symptoms that include abdominal pain, bloating, diarrhea, and fatigue. There are no approved medicines to treat celiac disease and the current standard of care is a strict gluten-free diet. Unintended exposure to gluten through consumer products, like prepackaged foods, cosmetics, toothpaste, vitamins, and nutritional supplements, is common. Many people living with celiac disease also experience challenges eating out of the home at restaurants, work, or while traveling, which impacts their quality of life. It is estimated that approximately 1 percent of people worldwide have celiac disease, and studies show the incidence is rising by about 7.5% per year. The burden of symptoms, growing prevalence, and lack of any approved therapeutic options reinforce the critical need for medications that can address the underlying causes of intestinal damage and improve symptoms and outcomes in people living with celiac disease.

About FB102

FB102 is an investigational, first-in-class anti-CD122 antibody being studied as a potential treatment for several autoimmune diseases, including celiac disease, vitiligo, and alopecia areata. CD122 is a key component of IL-2 and IL-15 signaling pathways involved in the activation and maintenance of disease-driving immune cells. FB102 is designed to block CD122 to selectively modulate IL-2 and IL-15 pathways that cause inflammation while preserving regulatory T-cell function and immune balance. The U.S. Food and Drug Administration has granted FB102 Fast Track Designation for celiac disease.

About argenx

argenx is a global immunology innovation company committed to improving the lives of people suffering from severe autoimmune diseases. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx developed and is commercializing the first approved neonatal Fc receptor (FcRn) blocker and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on [LinkedIn](#), [Instagram](#), [Facebook](#), and [YouTube](#).

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

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Forward Looking Statements

The contents of this announcement include statements that are, or may be deemed to be, “forward-looking statements.” These forward-looking statements generally can be identified by the use of forward-looking words, such as “aim”, “anticipate”, “aspire”, “believe”, “can”, “continue”,

“could”, “estimate”, “expect”, “entail”, “forecast”, “future”, “goals”, “hope”, “intend”, “is designed to”, “likely”, “may”, “might”, “objective”, “plan”, “possible”, “potential”, “pursue”, “project”, “predict”, “seek”, “should”, “strategy”, “target”, “will” and other words and terms of similar meaning and expression, including in connection with any discussion of future operating or financial performance. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx’s actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including but not limited to, the results of argenx’s clinical trials; uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development risks and setbacks; interpretation of argenx’s clinical trial data by regulatory authorities and argenx’s ability to obtain regulatory approval; the risk that early stage clinical trials may not be predictive of results in later stage or large scale clinical trials; the occurrence of adverse safety events or participant dropouts; the acceptance of its products and product candidates by its patients as safe, effective, and cost-effective; the impact of governmental laws and regulations, including tariffs, export controls, sanctions and other regulations on its business; the impact of healthcare regulations, including rules on reimbursement for argenx’s products; competition in drug discovery, development and commercialization efforts; its reliance on third-party suppliers, service providers and manufacturers; and instability and conflicts in the regions in which the company has suppliers or markets for its products. A further list and description of these and other risks, uncertainties, and factors that could cause actual results to differ materially from those referred to in the forward-looking statements can be found in argenx’s U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx’s most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these risks and uncertainties, the reader is advised not to place undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this press release. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.