Barinthus Bio Announces Update on Phase 1 AVALON Clinical Trial of VTP-1000 for the Treatment of Celiac Disease

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- *VTP-1000, an antigen-specific immunotherapy to treat celiac disease, showed a dose-dependent pharmacological effect in the SAD portion of the trial*
- *VTP-1000 was well-tolerated with no treatment-related SAEs*
- *The MAD portion of the trial, which includes a gluten challenge, is ongoing*

GERMANTOWN, Md., Dec. 10, 2025 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS) (“Barinthus Bio,” or the “Company”), an immunology and inflammation (“I&I”) company focused on developing immune tolerance therapies with curative potential, today announced an update on its first-in-human Phase 1 trial of VTP-1000 in adults with celiac disease. In the single ascending dose (“SAD”) portion of the trial, VTP-1000 was well tolerated with no treatment-related serious adverse events (“SAEs”) and a dose-dependent pharmacological effect observed. The multiple ascending dose (“MAD”) portion of the trial, which includes a gluten challenge, is ongoing with data expected in the second half of 2026.

The SAD portion of the Phase 1 AVALON trial (NCT06310291) enrolled 18 patients in three placebo-controlled cohorts of ascending doses. VTP-1000 was well tolerated at all dose levels with no treatment-related SAEs. Pharmacological data collected showed a dose-dependent effect.

“I’m encouraged by the results from VTP-1000, the first antigen-specific immune tolerance therapy for celiac disease to utilize an immunomodulator," said Dr. Leon Hooftman, Chief Medical Officer of Barinthus Bio. "The treatment was well-tolerated across all dose levels, with no therapy related serious adverse events. Importantly, the IL-2 response observed at all doses together with the safety data demonstrates immune recognition without serious inflammation. These dose-dependent pharmacological effects are promising, and upcoming results from multiple dosing and further immunological analysis will be critical in refining the optimal regimen and understanding the therapy's potential for true disease modification and patient benefit.”

VTP-1000 is an investigational, injectable antigen-specific tolerance immunotherapy that utilizes Barinthus Bio’s proprietary SNAP-TI platform to co-deliver multiple gluten-derived peptide antigens (from wheat, barley and rye proteins) and the immunomodulator rapamycin in nanoparticles designed to promote immune tolerance to gluten.

"These data from the SAD portion of the AVALON trial demonstrate the ability of a single dose of VTP-1000 to stimulate a robust targeted immune response that may minimize adverse effects associated with gluten antigen exposure in patients with celiac disease,” said Bill Enright, Chief Executive Officer of Barinthus Bio. "We look forward to providing details of the data, including pharmacological responses, at a scientific conference in 2026.”

About Celiac Disease

Celiac disease is caused by an autoimmune response to dietary gluten. It is relatively common, impacting an estimated one in 100 people of all ages (approximately 80 million people globally) and increasing in incidence. When people with celiac disease eat even small amounts of gluten-containing foods, their body mounts an autoimmune response consisting of T effector cells that cause inflammation. This can lead to rapid onset of symptoms (vomiting, diarrhea, etc.), as well as damage to the mucosal lining of the small intestine that can cause long-term consequences (*e.g.*, malnutrition and vitamin deficiencies). Celiac disease is an area of high unmet need with no currently approved treatments; instead, people with celiac disease are advised to strictly avoid consuming gluten, which can be difficult due to the presence of gluten in many foods and cross-contamination of food production surfaces.

About Barinthus Bio

Barinthus Biotherapeutics (NASDAQ: BRNS) is a clinical-stage biopharmaceutical company developing novel immunotherapeutic candidates for treating autoimmune and inflammatory diseases with curative potential. Barinthus Bio's pipeline for I&I indications is enabled by our proprietary and highly differentiated platform for promoting immune tolerance, SNAP-TI, that is designed to guide a patient's T cells to reduce inflammation and restore the natural state of immune non-responsiveness to healthy tissue. Our lead candidate, VTP-1000, is designed to restore immune non-responsiveness to gluten in patients with celiac disease and is currently in a Phase 1 clinical trial. Barinthus Bio’s differentiated technology platform and therapeutic approach, coupled with deep scientific expertise and focus on clinical development, uniquely positions the company to navigate towards delivering treatments that improve the lives of people with autoimmune and inflammatory diseases. For more information, visit www.barinthusbio.com.

Forward Looking Statements

This press release contains forward-looking statements regarding Barinthus Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, which can generally be identified as such by use of the words “may,” “will,” “plan,” “forward,” “encouraging,” “believe,” “potential,” “expect,” and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, express or implied statements regarding our future expectations, plans and prospects, including our product development activities and clinical trials, including timing for readouts of any preliminary, interim or final data for any of our programs, the timing for initiation of any clinical trials, our anticipated regulatory filings and approvals, our cash runway, our ability to develop and advance our current and future product candidates and programs, and the terms and timing of the restructuring and related activities. Any forward-looking statements in this press release are based on our management’s current expectations and beliefs and are subject to numerous risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to the success, cost and timing of our pipeline development activities and planned and ongoing clinical trials, including the risk that the timing for preliminary, interim or final data or initiation of our clinical trials may be delayed, the risk that interim or topline data may not reflect final data or results, our ability to execute on our strategy, regulatory developments, the risk that we may not achieve the anticipated benefits of our pipeline prioritization and corporate restructuring, our ability to fund our operations and access capital, our cash runway, including the risk that our estimate of our cash runway may be incorrect, global economic uncertainty, including disruptions in the banking industry, the conflicts in Ukraine, Israel and Gaza, and other risks identified in our filings with the Securities and Exchange Commission (the “SEC”), including our most recent annual report on Form 10-K and subsequent filings we may make with the SEC. We caution you not to place undue

reliance on any forward-looking statements, which speak only as of the date they are made. We expressly disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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