Barinthus Bio Initiates Phase 1 Clinical Trial of VTP-1000 for the Treatment of Celiac Disease

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- *Investigational immunotherapy candidate, VTP-1000, seeks to address significant unmet need in people with celiac disease.*
- *An estimated one in 100 people globally suffer from celiac disease, for which no approved treatments currently exist.*
- *The first-in-human Phase 1 trial aims to evaluate the safety and tolerability in adults with celiac disease.*

OXFORD, United Kingdom, Sept. 24, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), a clinical-stage biopharmaceutical company developing novel immunotherapeutic candidates that guide T cells to control disease, announced the initiation of its first-in-human Phase 1 trial of VTP-1000 in adults with celiac disease. The randomized, placebo-controlled clinical trial, which includes a controlled gluten challenge, will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of VTP-1000.

The Phase 1 AVALON trial (NCT06310291) aims to enroll 42 participants with celiac disease and will be conducted in two parts: a randomized double-blind placebo controlled single ascending dose (SAD) part, followed by a randomized double-blind placebo-controlled multiple ascending dose part, incorporating a controlled gluten challenge to assess the impact of VTP-1000 administration on patients' exposure to gluten.

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 to promote immune tolerance to gluten.

"When a person with celiac disease eats even small amounts of gluten, their body mounts an autoimmune response that causes inflammation resulting in rapid gastrointestinal symptoms and damage to the lining of the small intestine. This can be a burden in everyday life, as accidental ingestion is very common, and gluten avoidance can be difficult due to prevalence of the protein in the western diet," said Dr. Leon Hooftman, Chief Medical Officer of Barinthus Bio.

"Celiac disease remains an area that currently does not have any approved treatments. VTP-1000 aims to restore immune system tolerance to gluten and we are very excited to see VTP-1000 and the SNAP-TI platform in the clinic for the first time," added Dr. Nadège Pelletier, Chief Scientific Officer of Barinthus Bio, "Restoring the correct balance of regulatory over pathogenic effector T cells aims to prevent or reduce inflammation in the small intestine following exposure to gluten.

About Celiac Disease

Celiac disease is caused by an autoimmune response to dietary gluten. It is relatively common, impacting an estimated one in 100 persons 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 Bio is a clinical-stage biopharmaceutical company developing novel immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases and autoimmunity. Helping people living with serious diseases and their families is the guiding principle at the heart of Barinthus Bio. With a focused pipeline built around our proprietary platform technologies, Barinthus Bio is advancing immunotherapeutic product candidates in infectious diseases and autoimmunity, including: VTP-300, that utilizing our ChAdOx/MVA platform designed as a potential component of a functional cure for chronic HBV infection and VTP-1000, utilizing our SNAP-Tolerance Immunotherapy (SNAP-TI) platform and is designed to treat people with celiac disease. Barinthus Bio is also conducting a Phase 1 clinical trial for VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer. Barinthus Bio's differentiated technology platforms 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 chronic infectious diseases and autoimmunity. 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, the expected benefits of our product candidates, including VTP-1000, and our ability to develop and advance our current and future product candidates and programs. 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, our ability to fund our operations and access capital, 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, including our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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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