Barinthus Bio Completes Enrollment for Phase 2b HBV003 Clinical Trial in Chronic Hepatitis B and Phase 1 PCA001 Clinical Trial in Prostate Cancer

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- *Investigational immunotherapy, VTP-300, is being evaluated as part of a potential functional cure regimen for chronic Hepatitis B.*
- *Interim data update for HBV003 anticipated in Q4 2024.*
- *Data update for PCA001 anticipated in H1 2025.*

OXFORD, United Kingdom, Oct. 01, 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 completion of enrollment for two clinical trials: HBV003, a Phase 2b clinical trial of VTP-300 in adults with chronic hepatitis B (CHB); and PCA001, a Phase 1 clinical trial of VTP-850 in men with rising prostate-specific antigen (PSA) after definitive local therapy for prostate cancer (i.e., biochemical recurrence).

“We continue to execute our strategy and are pleased to complete the enrollment in two different trials in CHB and prostate cancer, two diseases where recruitment can be a real challenge,” said Bill Enright, Chief Executive Officer of Barinthus Bio. “These two fantastic milestones keep us on track for anticipated data readouts from HBV003 in Q4 of 2024 and from PCA001 in the first half of 2025.”

The Phase 2b HBV003 trial (NCT05343481) has enrolled 121 participants and is designed to obtain critical dosing information for a potential functional cure regimen for CHB, with participants receiving VTP-300 and low-dose (LD) nivolumab. This trial design builds on positive monotherapy results from the clinical study HBV002, which included an evaluation of VTP-300 given alone and in combination with LD nivolumab. Earlier this year, interim data from the HBV003 trial was presented at the European Association for the Study of the Liver (EASL) Congress and demonstrated that treatment with VTP-300 and LD nivolumab is generally well-tolerated and led to a sustained decline in Hepatitis B surface antigen (HBsAg) levels. Participants reaching Day 169 were assessed for NUC therapy discontinuation eligibility in line with the study criteria, with 76% of participants meeting the criteria (n=16/21). 19% of the eligible participants (n=4/21) reached undetectable levels of HBsAg, with 2 of these patients maintaining undetectable levels for over 16 weeks.

The PCA001 Phase 1 trial (NCT05617040) has enrolled 22 participants and is designed to determine the recommended Phase 2 dosing regimen of VTP-850 as well as evaluate safety and efficacy, as measured by PSA and T cell response. VTP-850 is a next-generation prostate cancer immunotherapeutic candidate which utilizes Barinthus Bio’s ChAdOx/MVA platform of two proprietary nonreplicating viral vectors in a sequential dosing approach.

About Chronic Hepatitis B

Globally it is estimated that there are approximately 254 million people living with CHB infection. This includes up to 2.4 million in the U.S. and 10.6 million in Europe, with the highest prevalence in East Asia and Africa. Approximately 1.1 million people died from hepatitis B virus infection and related complications in 2022, such as liver cirrhosis and hepatocellular carcinoma. Due to low diagnosis rates, only 13% of people living with CHB are aware of their infection and less than 3% had received antiviral treatment at the end of 2022.

About Prostate Cancer

In 2020, prostate cancer was the fourth most common cancer worldwide, with 1.4 million new cases diagnosed. In the US, out of every 100 American men, an estimated 13 will get prostate cancer during their lifetime. In the UK, prostate cancer is the most common cancer in men, with more than 52,000 people diagnosed with the disease on average each year. 20-30% of patients experience rising levels of PSA after local therapy (e.g. prostatectomy), indicating that disease was not cured by local therapy. Of men who do experience biochemical recurrence, there is a 1 in 9 chance of developing metastases.

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, 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, 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, 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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