Barinthus Bio Announces Results From Ongoing Phase 2b Chronic Hepatitis B Trial, Including Achievement of Functional Cure and HBsAb Seroconversion

Nov 15, 2024

- *Eight participants achieved HBsAg loss at any time.*
- *Two participants met criteria for functional cure.*
- *Two participants who discontinued NUC therapy seroconverted to HBsAb positivity.*

OXFORD, United Kingdom, Nov. 15, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), today announced the most significant data so far from the ongoing Phase 2b HBV003 clinical trial. The data will be presented by Dr. Chun-Jen Liu as an oral presentation on November 18, 2024, at 17:30 PT at the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2024. Barinthus Bio is a clinical-stage biopharmaceutical company developing novel immunotherapeutic candidates that guide T cells to control disease.

The HBV003 study (NCT05343481) is fully recruited with a total of 121 participants, including 69 participants who had entered the trial with HBsAg levels below 200 IU/mL. The study is evaluating different dosing regimens of VTP-300 in combination with low-dose nivolumab, an anti-PD-1 monoclonal antibody. The new data showed that as of data cut off, eight participants were reported with complete HBsAg loss (defined as HBsAg levels below the lower limit of quantitation [<LLOQ, 0.05 IU/mL]) and two participants met the criteria for functional cure.

Uniquely, two of the eight participants with HBsAg loss, became positive for anti-hepatitis B antibodies (HBsAb) that they did not have before, including one of those who met functional cure criteria. The data from this ongoing study indicate that stronger responses may happen in participants treated with the combination of VTP-300 and a low dose of the anti-PD1 antibody nivolumab (Groups 1 and 2).

“Sustained HBsAg loss has proven to be the largest hurdle in getting chronic hepatitis B patients to functional cure,” said Dr. Chun-Jen Liu, investigator on HBV003 and Director of the Hepatitis Research Center and Clinical Trial Center, National Taiwan University Hospital, Taiwan. “The data we are seeing with VTP-300 is unique because they indicate a durable loss of HBsAg in participants, including two who met the criteria for functional cure. Although the study is still ongoing, these early data may bring us a step closer to potentially allowing some patients with chronic hepatitis B to come off antiviral treatment without their chronic hepatitis B progressing.”

40 participants, with HBsAg below 200 IU/mL at screening, who had reached Day 169 were assessed for nucleos(t)ide analogue (NUC) discontinuation. The data showed the following:

- 24 were eligible for NUC discontinuation.
- Eight achieved HBsAg loss at any time, two of whom achieved it after Day 169.
- Nine participants chose to discontinue NUCs.
    - 66% (n=6/9) remained off NUC therapy, five for more than six months.
        - Two of these six have met the criteria for functional cure.
        - Two of these six seroconverted to HBsAb positivity.
        - Follow up is continuing with the remaining participants to assess if they will meet functional cure criteria.
- Durable HBsAg declines were observed in all treatment groups, consistent with data previously presented at the European Association for the Study of the Liver (EASL) Congress, in June 2024.
- Preliminary safety data indicate that VTP-300 in combination with low-dose nivolumab was generally well tolerated with no treatment-related SAEs observed or reported as of data cut off.

"These Phase 2 data are incredibly encouraging and highlight the ability of VTP-300 to stimulate the immune response and induce sustained reductions in HBsAg to the point of meeting functional cure criteria,” said Dr. Nadege Pelletier, Chief Scientific Officer of Barinthus Bio. "Moreover, the finding that one of the participants meeting functional cure criteria had antibodies against hepatitis B is promising as HBsAb positivity is associated with long-term control of the infection by the immune system.”

Functional cure is defined by AASLD as sustained HBsAg loss and hepatitis B virus DNA <LLOQ for 6 months off-treatment. Data cut off was September 30, 2024, for lab data and October 8, 2024, for clinical data.

About the HBV003 Trial
The HBV003 trial is designed to obtain critical information on treatment dosing regimen with participants receiving VTP-300 and low-dose (LD) nivolumab. All Groups received ChAdOx at Day 1; Groups 1 & 2 received MVA with nivolumab at Day 29; Group 2 was dosed again with MVA and nivolumab at Day 85; Group 3 received only MVA at Day 29, nivolumab at Day 36, and a conditional second MVA dose at Day 85 to evaluate anti-PD-1 inhibition timing. The conditional MVA dose was administered if participants had HBsAg ≥10 IU/mL. In 2023, the study inclusion criteria was amended from people with CHB with HBsAg ≥10 and <4,000 IU/mL to ≥10 and ≤200 IU/mL, as strongest responses were observed in participants with HBsAg ≤200 IU/ml.

About VTP-300
VTP-300 is an immunotherapeutic candidate consisting of an initial dose using the ChAdOx vector and a secondary dose(s) using the MVA vector, both encoding multiple HBsAg, including full-length surface, modified polymerase, and core antigens. VTP-300 is the first antigen-specific immunotherapy that has been shown to induce sustained reductions in HBsAg. Barinthus Bio is studying VTP-300 in combination with other agents, including siRNA and low-dose anti-PD-1 antibodies in the ongoing IM-PROVE II trial, to control the infection, and counterbalance the immune suppression and T cell exhaustion in the liver caused by chronic HBV infection.

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, 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 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.

Barinthus Bio's 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," 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 product development activities and clinical trials, including timing for readouts of any interim data or next steps for any of our programs, including VTP-300 and the HBV003 trial, the tolerability or potential benefits of VTP-300 or imdusiran, including in combination with nivolumab, 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, 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 conflict in Ukraine, the conflict in 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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