Barinthus Bio Presents Interim Data from Phase 2b HBV003 Trial and Phase 2a AB-729-202 Trial in Collaboration with Arbutus Biopharma in Chronic HBV Patients at AASLD

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- *Initial data from the combination of imdusiran and VTP-300 show meaningful reductions of HBsAg levels that were maintained well below baseline.*
- *In HBV003, 31% of participants with screening HBsAg level of ≤200 IU/mL had >1 log HBsAg reductions.*
- *VTP-300 was generally well-tolerated in both trials.*

OXFORD, United Kingdom, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), formerly Vaccitech plc, today announced the presentation of data from two HBV clinical trials at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023. The presentations include an oral presentation of data from HBV003, an ongoing Phase 2b trial designed to further evaluate the safety and efficacy of VTP-300 when combined with a low-dose anti-PD-1 antibody, and standard-of-care (SoC) nucleos(t)ide analogue (NUC) therapy. Alongside this, a late-breaking poster presentation with interim data from patients with chronic hepatitis B (CHB) from the Phase 2a AB-729-202 trial combining Arbutus Biopharma Corporation's (NASDAQ: ABUS) RNAi therapeutic candidate, imdusiran (AB-729), with Barinthus Bio's T cell stimulating immunotherapeutic candidate, VTP-300, and SoC NUC therapy. Barinthus Bio is a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity, and cancer.

"We believe these early data are very encouraging. In HBV003, VTP-300 in combination with nivolumab continues to show meaningful and sustained HBsAg declines across all treatment groups, with the most prominent declines occurring in patients with lower baseline HBsAg levels at screening," said Bill Enright, Chief Executive Officer of Barinthus Bio. Regarding the combination trial imdusiran with VTP300, Bill added "Although these are preliminary data, we can already see that VTP-300 appears to show a meaningful impact in sustaining low HBsAg in patients after imdusiran treatment, with clear differences shown between placebo and VTP-300. It's very positive that we are seeing that all participants treated with imdusiran and VTP-300 have qualified to stop NUC therapy, which really highlights VTP-300's potential as an important component of a functional cure regimen."

Study HBV003: VTP-300 and Low-dose Nivolumab

HBV003 is designed to obtain critical information on treatment dosing regimen with patients receiving VTP-300 and low-dose nivolumab. All Groups receive ChAdOx at Day 1, Groups 1 & 2 receive MVA with nivolumab at Day 29 with Group 2 being dosed again at Day 85, Group 3 receives only MVA at Day 29, followed by nivolumab at Day 36 and a second MVA dose at Day 85 to evaluate PD-1 inhibition timing. Seventy-four out of a planned 120 virally suppressed CHB patients on stable NUC therapy have been enrolled in the trial and 57 have reached Day 113. VTP-300 in combination with nivolumab led to HBsAg declines in all treatment groups, particularly in participants with screening HBsAg levels ≤200 IU/mL.

- >0.5 and >1 log drops have been observed in all groups at Day 113 in 23% and 9% of participants, respectively.
- Participants with an HBsAg level of ≤200 IU/mL at screening were more likely to have >1 log HBsAg reductions (31%) compared to those with HBsAg levels >200 IU/mL at Day 1 (2%).
- Greater mean HBsAg log reductions were observed in Group 2 (ChAdOx-HBV Day 1; MVA-HBV and nivolumab Day 29 and Day 85) but insufficient data for definitive conclusion.
- Seven participants have met the criteria for NUC discontinuation; three have discontinued and two have restarted NUC therapy.
- Preliminary safety data suggest VTP-300 in combination with nivolumab has been generally well tolerated, with no treatment-related SAEs observed or reported. Thyroid dysfunction reported in seven participants attributed to nivolumab administration which has returned to normal in four patients.

The HBV003 trial protocol is currently being amended to include only participants with screening HBsAg ≤200 IU/mL. Participants with screening HBsAg ≤200 IU/mL have been observed to benefit the most in the preliminary data, with the trial protocol amendment being focused on improving the overall risk/benefit ratio. People with thyroid autoantibodies, family history of autoimmune thyroiditis, or abnormal thyroid levels will be excluded from trial eligibility to minimize the risk of thyroiditis.

Study AB-729-202: VTP-300 in Combination with Imdusiran (AB-729)

Clinical trial AB-729-202 enrolled forty non-cirrhotic, virally suppressed CHB patients that were on stable NUC therapy. The patients initially received imdusiran (60mg every 8 weeks) for 24 weeks and were then randomized to receive either VTP-300 or placebo at week 26 and 30 (and conditionally at week 38 if they experienced a >0.5 $\log_{10}$ decline in HBsAg between Weeks 26 and 34), in addition to ongoing NUC therapy. The preliminary data include a subset of patients that received the two dose VTP-300 regimen (28/40 patients) and available follow-up data to Week 48 (12/40 patients) and showed the following:

- Robust reductions of HBsAg were seen during the imdusiran treatment period (-1.86 log10 mean reduction from baseline after 24 weeks of treatment). This decline in HBsAg is comparable to the declines seen with imdusiran in other clinical trials conducted to date.
- 97% of the imdusiran treated patients (33/34) had HBsAg <100 IU/mL at the time of the first VTP-300/placebo dose.
- VTP-300 treatment appeared to contribute to the maintenance of low HBsAg levels in the early post-treatment period, as the mean HBsAg levels in the placebo group begin to increase starting approximately 12 weeks after the last dose of imdusiran.
- All VTP-300 treated patients have maintained HBsAg <100 IU/mL through week 48, 60% have maintained HBsAg <10

IU/mL, and all have qualified to stop NUC therapy.
- Preliminary immunology data suggests HBV-specific T cell IFN-γ production was enhanced in patients receiving imdusiran plus VTP-300 compared to placebo.

The preliminary safety data from this trial demonstrate that imdusiran and VTP-300 were both generally well-tolerated. There were no serious adverse events, Grade 3 or 4 adverse events or treatment discontinuations.

Dr. Karen Sims, Chief Medical Officer of Arbutus Biopharma, commented, “Imdusiran consistently delivers compelling efficacy and safety data in multiple Phase 2a populations and combinations. In this trial, all but one patient reached surface antigen levels below 100 IU/mL and one reached <LLOQ (lower limit of quantification) with 24 weeks of imdusiran plus NUC therapy alone, which is a meaningful achievement as we believe lowering surface antigen is key to promoting host HBV-specific immune reawakening. As we continue to dose and follow these patients, I look forward to seeing the potential that imdusiran, VTP-300, and NUC therapy can have on achieving a functional cure for patients with CHB.”

The presentation for HBV003 and poster for AB-729-202 can be found on the Barinthus Bio website at https://investors.barinthusbio.com/events-presentations.

About Barinthus Bio’s 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 hepatitis B antigens, 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, to control the infection and counterbalance the immune suppression and T cell exhaustion in the liver caused by chronic HBV infection.

About imdusiran (AB-729), Arbutus’ Lead RNAi Therapeutic

Imdusiran is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient’s immune system to respond to the virus. Imdusiran targets hepatocytes using Arbutus’ novel covalently conjugated N-Acetylgalactosamine (GalNAc) delivery technology enabling subcutaneous delivery. Clinical data generated thus far has shown single and multiple doses of imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. Imdusiran is currently in multiple Phase 2a clinical trials.

About Hepatitis B Virus (HBV)

Globally it is estimated that there are more than 300 million people, including up to 2.4 million in the U.S. and 14 million in Europe, living with chronic HBV infection, with the highest prevalence in East Asia and Africa. Approximately 820,000 people die each year from HBV and related complications, such as liver cirrhosis and hepatocellular carcinoma. Due to low HBV diagnosis rates of about 10.5% aware of their infection coupled with strict treatment eligibility guidelines, only 6.6 million (2.2%) people with chronic HBV are receiving treatment and less than 10% will achieve a functional cure with existing therapies.

About Barinthus Bio

Barinthus Bio is a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity, and cancer. Helping people living with serious diseases and their families is the guiding principle at the heart of Barinthus Bio. With a broad pipeline, built around four proprietary platform technologies: ChAdOx, MVA, SNAP-TI, and SNAP-CI; Barinthus Bio is advancing a pipeline of five product candidates across a diverse range of therapeutic areas, including: VTP-300, an immunotherapeutic candidate designed as a potential component of a functional cure for chronic HBV infection; VTP-200, a non-surgical product candidate for persistent high-risk human papillomavirus (HPV); VTP-1000, an autoimmune candidate designed to utilize the SNAP-TI platform to treat patients with celiac disease; VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer; and VTP-1100, a preclinical cancer candidate designed to utilize the SNAP-CI platform to treat patients with HPV-related cancer. Barinthus Bio’s proven scientific expertise, diverse portfolio and focus on pipeline development uniquely positions the company to navigate towards delivering treatments for people with infectious diseases, autoimmunity and cancers that have a significant impact on their everyday lives. For more information, visit www.barinthusbio.com.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to identify and develop novel therapeutics with distinct mechanisms of action, which can be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). Arbutus believes the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Arbutus’ pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729), and an oral PD-L1 inhibitor, AB-101. Imdusiran has generated meaningful clinical data demonstrating an impact on both surface antigen reduction and reawakening of the HBV-specific immune response. Imdusiran is currently in two Phase 2a combination clinical trials. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. Additionally, Arbutus has identified compounds in its internal PD-L1 portfolio that could also be used in oncology indications. For more information, visit www.arbutusbio.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: Barinthus Bio’s plans and strategy with respect to its pipeline and product candidates, including VTP-300 and the HBV003 clinical trial, and the potential benefits of VTP-300 for the treatment of chronic HBV. Any forward-looking statements in this press release are based on Barinthus Bio 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 Barinthus Bio’s pipeline development activities and planned and ongoing clinical trials, Barinthus Bio’s ability to execute on its strategy, regulatory developments, the risk that Barinthus Bio may not realize the benefits related to its rebranding and name change, Barinthus Bio’s ability to fund its operations and access capital, global economic uncertainty, including disruptions in the banking industry, the conflict in Ukraine, and the conflict in Israel and Gaza, and other risks identified in Barinthus Bio’s filings with the Securities and Exchange Commission (the “SEC”), including its Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Reports on Form 10-Q and subsequent filings with the SEC. Barinthus Bio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Barinthus Bio expressly disclaims 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.

Arbutus' Forward-Looking Statements

This press release contains forward-looking statements regarding Arbutus within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, forward-looking statements). Forward-looking statements in this press release include statements about Arbutus' belief that the key to success in developing a functional cure for CHB involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses; Arbutus' future development plans for Arbutus' product candidates; Arbutus' program updates; the expected cost, timing and results of Arbutus' clinical development plans and clinical trials with respect to Arbutus' product candidates; Arbutus' expectations with respect to clinical trial design and the release of data from Arbutus' clinical trials and the expected timing thereof; Arbutus' expectations and goals for Arbutus' collaborations with third parties and any potential benefits related thereto, including with respect to the Phase 2a clinical trial combining imdusiran with VTP-300; and the potential for Arbutus' product candidates to achieve success in clinical trials.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to the ongoing patent litigation matters.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: the risk that anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested product candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; uncertainties associated with litigation generally and patent litigation specifically; Arbutus and its collaborators may never realize the expected benefits of the collaborations, including with Barinthus Bio; and market shifts may require a change in strategic focus; and risks related to the sufficiency of Arbutus' cash resources and its ability to obtain adequate financing in the future for its foreseeable and unforeseeable operating expenses and capital expenditures.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic disclosure filings, which are available at www.sedar.com and at www.sec.gov. All forward-looking statements herein with respect to Arbutus are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein with respect to Arbutus to reflect future results, events or developments, except as required by law.

Barinthus Bio - Contacts:
Investor Contacts:
Christopher M. Calabrese
Managing Director
LifeSci Advisors
+1 917-680-5608
ccalabrese@lifesciadvisors.com

Kevin Gardner
Managing Director
LifeSci Advisors
+1 617-283-2856
kgardner@lifesciadvisors.com

Media contact:
Audra Friis
Sam Brown, Inc.
+1 917-519-9577
audrafriis@sambrown.com

Company contact:
Jonothan Blackbourn
IR & PR Manager
Barinthus Biotherapeutics
ir@barinthusbio.com

Arbutus - Investors and Media
Lisa M. Caperelli
Vice President, Investor Relations
Phone: 215-206-1822
Email: lcaperelli@arbutusbio.com