Arbutus Biopharma and Barinthus Bio Present Preliminary Data from Phase 2a Clinical Trial Combining Imdusiran with VTP-300 at AASLD - The Liver Meeting®

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The combination of imdusiran and VTP-300 provides a meaningful reduction of HBsAg levels that are maintained well below baseline

Preliminary data in subset of patients given imdusiran and then VTP-300 show early signs of immune activation

WARMINSTER, Pa. and OXFORD, United Kingdom, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop a cure for people with chronic hepatitis B virus (cHBV) infection, and Barinthus Biotherapeutics plc (Nasdaq: BRNS), formerly Vaccitech plc, 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, today announced a late breaking poster presentation at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023. The poster contains preliminary data from the Phase 2a clinical trial (AB-729-202) combining Arbutus' RNAi therapeutic, imdusiran (AB-729), with Barinthus Bio's T-cell stimulating immunotherapeutic, VTP-300, and standard-of-care nucleos(t)ide analogue (NA) therapy.

Professor Man-Fung Yuen, D.Sc., M.D., Ph.D., Chief of the Division of Gastroenterology and Hepatology, University of Hong Kong, and a lead investigator of this Phase 2a clinical trial, stated, “These preliminary data are very encouraging and we look forward to additional follow-up of these patients which will provide insight into the possibility of a functional cure with this combination treatment regimen. It is well accepted that a combination therapy that can both reduce HBV surface antigen and stimulate an HBV-specific host immune response will be needed to provide a functional cure for patients with chronic HBV. These promising initial data show that the combination of imdusiran followed by VTP-300 reduces surface antigen from baseline and, importantly, the reduced levels are maintained compared to placebo controls. Although the patient numbers are small and the data are early to see the expected clinical effect of VTP-300 on surface antigen, it is impressive to see that some patients have more robust immune activation post-VTP-300 treatment compared to controls.”

Clinical trial AB-729-202 enrolled 40 non-cirrhotic, virally suppressed cHBV patients that were on stable NA 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 NA 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 $\log_{10}$ 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 appears 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 ~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 NA therapy.
- Preliminary immunology data suggests HBV-specific T cell IFN-γ production is 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 safe and 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 with 24 weeks of imdusiran plus NA 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 NA therapy can have on achieving a functional cure for patients with cHBV.”

Bill Enright, Chief Executive Officer of Barinthus Bio, added, “Although these are preliminary data, we can already see that VTP-300 appears to show a meaningful impact on 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 NA therapy, which really highlights VTP-300’s potential as an important component of a functional cure regimen.”

The above poster presentation can be accessed through the Publications section of the Arbutus Biopharma website at https://www.arbutusbio.com/publications/ or via Barinthus Bio website here https://investors.barinthusbio.com/events-presentations.

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 Barinthus Bio's VTP-300

VTP-300 is an immunotherapeutic candidate consisting of an initial dose using the ChAdOx platform and a secondary dose(s) using MVA, 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 HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

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). We believe the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Our 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, we have identified compounds in our internal PD-L1 portfolio that could also be used in oncology indications. For more information, visit www.arbutusbio.com.

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. The company stands apart through its 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 hepatitis B viral (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; 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, high-value portfolio and focus on product development uniquely positions the company to navigate towards delivering treatments for patients with infectious diseases, autoimmunity and cancers that have a significant impact on their lives every day. For more information, visit www.barinthusbio.com.

Arbutus' Forward-Looking Statements

This press release contains forward-looking statements 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 our belief that the key to success in developing a functional cure for cHBV involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses; our future development plans for our product candidates; our program updates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to clinical trial design and the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our 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 our 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 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 to reflect

future results, events or developments, except as required by law.

Barinthus Bio's Forward-Looking Statements

This press release contains forward-looking statements, 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: the company'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 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 the Company's pipeline development activities and planned and ongoing clinical trials, the company's ability to execute on its strategy, regulatory developments, the risk that the company may not realize the benefits related to its rebranding and name change, the company's ability to fund its operations and access capital, global economic uncertainty, the conflict in Ukraine, and the conflict in Israel and Gaza, including disruptions in the banking industry, and other risks identified in the company'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. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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.

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