Arbutus Doses First Patient in Additional Treatment Arm of Phase 2a Triple Combination Clinical Trial that Includes a PD-1 Monoclonal Antibody

June 21, 2023

Evaluating safety and efficacy of combining AB-729, VTP-300, nucleos(t)ide analogues and nivolumab (Opdivo®)

WARMINSTER, Pa., June 21, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today announced that the first patient has been dosed in the additional treatment arm of the AB-729 Phase 2a triple combination clinical trial that has been expanded to include a PD-1 monoclonal antibody, nivolumab. Nivolumab is approved for a number of types of cancer under the brand name, Opdivo®. The objective of the additional treatment arm is to assess if a low dose of nivolumab, in combination with the booster dose(s) of Vaccitech plc's (Nasdaq: VACC) VTP-300, will further stimulate immune mediated reduction of HBsAg after the initial treatment with AB-729 and ongoing nucleos(t)ide analogue (NA) therapy in patients with chronic hepatitis B infection (cHBV).

"We are excited to explore the addition of low dose nivolumab to our existing combination of AB-729 and VTP-300, and assess if this will further stimulate HBsAg reduction," said Dr. Karen Sims, Vice President of Clinical Development at Arbutus Biopharma. "We are hopeful that if we can lower HBsAg and stimulate the immune system with the combination of AB-729 and the first dose of VTP-300 and further enhance this stimulation by administering a low dose of a PD-1 monoclonal antibody with the subsequent dose or doses of VTP-300, we may enhance the ability of the immune system to fully suppress the virus and in turn achieve functional cure. We look forward to reporting preliminary data from this additional treatment arm in 2024."

AB-729 was 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. The Phase 2a triple combination clinical trial, AB-729-202, has been expanded to evaluate the safety, antiviral activity and immunogenicity of nivolumab plus Vaccitech's VTP-300, an antigen-specific immunotherapeutic encoding multiple hepatitis B antigens, following treatment with AB-729 and ongoing NA therapy. Approximately 20 virologically-suppressed chronic hepatitis B (cHBV) patients will be enrolled in the open-label arm to receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks. Patients will then receive a course of VTP-300 which consists of a single dose of ChAdOx-HBV at week 26 and an initial dose of MVA-HBV plus low dose nivolumab at week 30. Patients with HBsAg levels ≥10 IU/mL at Week 34 will receive a second dose of MVA-HBV plus low dose nivolumab at week 38. Patients will remain on their NA therapy throughout the VTP-300 administration period through week 48. At week 48, all patients will be evaluated for eligibility to discontinue their NA therapy.

Enrollment is complete in the original portion of the clinical trial, which is currently evaluating the triple combination of AB-729, NA therapy and VTP-300 or placebo. Preliminary data from the original portion of the trial is expected in the second half of 2023.

About AB-729

AB-729 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. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated N-Acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

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 develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. To address HBV, we are developing a RNAi therapeutic, an oral PD-L1 inhibitor, and an oral RNA destabilizer to potentially identify a combination regimen with the aim of providing a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening. AB-729 is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses, (including SARS-CoV-2), for which we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are also exploring oncology applications for our internal PD-L1 portfolio. For more information, visit www.arbutusbio.com.

Forward-Looking Statements and Information

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 future development plans for our product candidates; 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 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; 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 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: 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; and market shifts may require a change in strategic focus.

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.

Contact Information

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