Arbutus Completes Enrollment in its Phase 2a Clinical Trial Combining AB-729 with NA Therapy and Peginterferon alfa-2a in Patients with Chronic Hepatitis B Virus Infection

December 13, 2022

Preliminary data from lead-in phase further validates AB-729's capacity to reduce HBsAg

Initial data from IFN phase expected in the first half of 2023

WARMINSTER, Pa., Dec. 13, 2022 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today announced preliminary data from the AB-729 lead-in portion of its Phase 2a clinical trial combining AB-729 with nucleos(t)ide analogue (NA) therapy and Peginterferon alfa-2a (IFN). The data reinforces AB-729's surface antigen reducing-capacity, while continuing to exhibit a generally safe and well-tolerated profile in patients with chronic Hepatitis B virus (cHBV). Given that only a few patients are in the early weeks of the IFN phase of the clinical trial, the Company intends to provide additional updated data in the first half of next year which will include preliminary results of the IFN portion of the trial.

Enrollment is complete in the clinical trial with 43 patients having received at least one dose of AB-729. For the first 15 patients who reached week 16 of treatment and received two doses of AB-729 plus NA therapy, the mean (SE) HBsAg decline was 1.51 log (0.12), comparable to the decline observed at the same timepoint in the completed Phase 1b clinical trial AB-729-001 (1.56 log (0.1)). As the trial progresses, patients will be randomized into various treatment arms which include the combination of AB-729, NA therapy and short courses of IFN for either 12 or 24 weeks.

Gaston Picchio, Ph.D., Chief Development Officer at Arbutus, commented, "These preliminary Phase 2a data are reassuring since they confirm previous Phase 1b results showing that AB-729 is capable of consistently reducing HBsAg while maintaining a safe and well-tolerated profile. We look forward to seeing the effects of different courses of IFN in combination with AB-729 to reduce HBsAg throughout 2023."

The randomized, open label, multicenter Phase 2a proof-of-concept clinical trial is designed to investigate the safety and antiviral activity of AB-729 in combination with ongoing NA therapy and short courses of IFN. The trial enrolled NA-suppressed, HBeAg negative, non-cirrhotic patients with cHBV. Patients are predominantly of Asian descent. The mean baseline HBsAg was 3.0 logs. All patients receive 60 mg of AB-729 every 8 weeks for 24 weeks after which they are randomized into one of four arms to receive NA therapy plus IFN for 12 or 24 weeks with or without additional doses of AB-729.

After completion of the assigned IFN treatment period, all patients will remain on NA therapy for an additional 24-weeks and will then discontinue NA treatment provided they meet pre-defined stopping criteria. Patients who stop NA therapy will enter an intensive follow-up period of 48 weeks.

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 enabling subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated, while also 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. It 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 coronavirus (including SARS-CoV-2). In addition, we are 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 the ongoing COVID-19 pandemic and 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; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' clinical development programs.

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
William H. Collier
President and CEO
Phone: 267-469-0914
Email: ir@arbutusbio.com

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