Arbutus Presents Preliminary AB-729 and Pegylated Interferon Alfa-2a Combination Data at the EASL Congress 2023

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Treatment was generally well tolerated with continued HBsAg declines in some patients

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 preliminary data from its on-going Phase 2a clinical trial evaluating the safety, tolerability and antiviral activity of the combination of AB-729, the Company's lead RNAi therapeutic, and pegylated interferon alfa-2a (IFN) in patients with chronic hepatitis B virus (cHBV) was presented today at the European Association for the Study of the Liver (EASL) Congress. The preliminary data suggests that the addition of IFN to AB-729 treatment was generally well tolerated and appears to result in continued HBsAg declines in some patients.

William Collier, President and Chief Executive Officer of Arbutus, commented, "These data continue to support our strategy of utilizing AB-729 as a cornerstone in a combination therapeutic for patients with cHBV. In this trial, some patients that received 12 weeks or more of IFN after AB-729 treatment saw promising declines in surface antigen, which continues to reinforce our confidence in AB-729's ability to effectively suppress HBsAg. While this is a small sample size and additional follow-up is needed, we believe that the combination of AB-729 and IFN is both safe and lowers surface antigen, which in turn, may allow the patient's immune system to control the virus. We look forward to providing more data as patients continue to receive treatment."

Forty-three virally suppressed, HBeAg negative cHBV patients were enrolled in the clinical trial and received a lead-in of AB-729 (60mg every 8 weeks) plus nucleos(t)ide analog (NA) therapy for 24 weeks followed by 12 or 24 weeks of IFN with or without additional AB-729 doses. The preliminary data showed the following:

- The mean HBsAg decline from baseline during the lead-in phase was 1.6 $\log_{10}$ at week 24 of treatment which is comparable to what was previously seen in other clinical trials with AB-729.
- HBsAg levels <100 IU/mL were noted during the treatment period in 93% (38 of 41 randomized) of the patients.
- Four patients have reached HBsAg below the lower limit of quantitation (LLOQ) during IFN treatment, however, none of the patients have achieved sustained seroclearance to date.
- AB-729 treatment alone or in combination with IFN was generally well tolerated. There were no serious adverse events (SAEs), discontinuations or AB-729 treatment discontinuations. IFN-related treatment emergent adverse events (TEAEs) were consistent with the known safety profile. Five patients required IFN dose modifications due to laboratory abnormalities.

The clinical trial remains ongoing with most patients still in the early IFN treatment period continuing to be followed for on-treatment responses. After completion of the IFN treatment period, patients are followed for an additional 24 weeks on NA therapy alone, then assessed for NA discontinuation. Three patients have been evaluated to stop NA treatment to date, with one meeting the protocol-defined criteria to stop NA treatment.

The posters that were presented at EASL 2023 can be accessed through the Investors section of Arbutus' website under Publications at https://www.arbutusbio.com/publications/.

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 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.

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