Preliminary Data Shows that Arbutus' Capsid Inhibitor, AB-836 is Generally Safe and Well-Tolerated and Provides Robust Antiviral Activity

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WARMINSTER, Pa., Dec. 01, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of assets with different modes of action to provide a cure for people with chronic hepatitis B virus (cHBV) infection and to treat coronaviruses (including COVID-19), today announced preliminary data from its on-going Phase 1a/1b clinical trial demonstrating that its next generation capsid inhibitor, AB-836, is generally safe and well-tolerated in both healthy subjects and patients with cHBV and provides robust antiviral activity.

Gaston Picchio, Ph.D., Chief Development Officer at Arbutus, commented, "These preliminary results demonstrate that AB-836 is generally safe and well-tolerated in both single- and multiple-doses in healthy subjects and at doses up to 100mg administered once daily for 28 days in cHBV patients. In addition, the mean Day 28 drop in HBV DNA observed to date with a relatively low dose suggests that AB-836 is a very potent inhibitor of HBV replication making it an ideal candidate to potentially completely suppress viral replication. We look forward to continuing to evaluate the safety and efficacy of AB-836 in Part 3 of this trial."

The Phase 1a/1b clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of single and multiple doses of AB-836 in healthy subjects and patients with cHBV. The trial consists of three parts. Part 1 evaluated alternating single doses of AB-836 or placebo ranging from 10mg to 175mg in a fasted or fed state in healthy subjects. Part 2 evaluated multiple ascending doses of 50mg, 100mg or 150mg of AB-836 or placebo once daily for 10 days in healthy volunteers. Part 3, which is still on-going, is currently randomizing HBV DNA positive cHBV patients who are HBeAg positive or negative to receive either 50mg or 100mg of AB-836 or placebo once daily for 28 days.

In Parts 1 and 2, a total of 47 healthy subjects were enrolled and dosed. There were no deaths or serious adverse events (SAEs) observed. One healthy subject that received 50mg once daily discontinued after treatment on day 13 due to an adverse event (AE) of agitation. All but three AEs were mild (Grade 2 headache, agitation and bronchitis), and only one was assessed as related to AB-836 (Grade 1 rash). There were no clinically significant abnormalities in clinical laboratory tests, ECGs, vital signs or physical exams noted.

In Part 3, 16 cHBV patients have been dosed thus far with enrollment continuing. Among those who received 100mg once daily for the full 28 days (n=4), robust antiviral activity was observed at Day 28 of treatment with a mean (SE) $\log_{10}$ change from baseline of -3.1 (0.5). There have been no deaths or AEs. One cHBV patient that received 100mg of AB-836 had a transient increase in ALT from baseline Grade 1 to Grade 3 at a single visit that resolved with continued dosing and had no associated symptoms. There were no clinically significant abnormalities in ECGs, vital signs or physical exams noted.

Arbutus is continuing to enroll and dose cHBV patients in Part 3 of the clinical trial and anticipates presenting additional data at a medical conference in 2022.

About AB-836

AB-836 is a next generation oral hepatitis B virus (HBV) capsid inhibitor that interacts with HBV core protein, which in turn is required for viral replication. The current standard-of-care therapy for HBV is primarily nucleos(t)ide analogues that inhibit the viral polymerase and significantly reduce, but do not eliminate viral replication. AB-836 in combination with nucleos(t)ide analogues is designed to completely eliminate viral replication in infected cells by preventing the assembly of functional viral capsids. In addition, AB-836 has been shown to inhibit the replenishment of covalently closed circular DNA (cccDNA), the viral genetic reservoir which the virus needs to replicate itself.

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 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 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 primarily focused on discovering, developing and commercializing a broad portfolio of assets with different modes of action to provide a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that suppress viral replication, reduce surface antigen and reawaken the immune system. Arbutus believes this three-prong approach is key to transforming the treatment and developing a potential cure for chronic HBV infection. Arbutus' HBV product pipeline includes RNA interference (RNAi) therapeutics, oral capsid inhibitors, oral compounds that inhibit PD-L1 and oral HBV RNA destabilizers. In addition, Arbutus has an ongoing drug discovery and development program directed to identifying orally active agents for treating coronaviruses (including COVID-19). 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 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.

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, 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; 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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