Arbutus Receives Regulatory Approval to Initiate a Phase 1a/1b Clinical Trial with AB-836, an Oral Capsid Inhibitor for the Treatment of Chronic Hepatitis B Infection

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WARMINSTER, Pa., March 16, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on developing a cure for people with chronic hepatitis B virus (HBV) infection, as well as therapies to treat coronaviruses (including COVID-19), today announced that it has received regulatory approval to initiate a Phase 1a/1b clinical trial with AB-836, its proprietary oral capsid inhibitor for the treatment of HBV infection.

"We are pleased that we have received regulatory approval to proceed with our Phase 1a/1b clinical trial for AB-836, and we expect to begin dosing shortly. Initiation of this trial is an important step towards potential future proprietary combinations with AB-729 and other mechanisms," said William Collier, President and Chief Executive Officer of Arbutus.

Dr. Michael Sofia, Chief Scientific Officer of Arbutus, added, "Based on pre-clinical studies with AB-836, which is derived from a novel chemical series in this class, we believe it has the potential for improved clinical efficacy and safety as well as a favorable resistance profile relative to earlier generation capsid inhibitors. In addition, we believe that the strong potency of AB-836 as shown in *in vitro* testing should allow active engagement of the second mechanism of inhibiting cccDNA replenishment at clinically relevant doses."

About AB-836

AB-836 is an oral capsid inhibitor for the treatment of chronic hepatitis B infection. It is from a novel chemical series that is differentiated from competitor compounds and has the potential for increased efficacy and an enhanced resistance profile. AB-836 binds to a novel site within the core protein dimer-dimer interface and has shown in *in vitro* testing to be active against nucleotide analog resistant variants and also has the potential to address certain known capsid resistant variants. AB-836 has been shown in *in vitro* studies to be active against nucleoside resistant variants and therapeutically relevant activity against key core protein resistant variants I105T and T33N. AB-836 is anticipated to be combinable with other drugs having different mechanisms of action for treating HBV, including AB-729, and is also anticipated to be dosed once daily.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by 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 is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily dedicated to discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, please 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 the Company's expectation to begin dosing in a Phase 1a/1b clinical trial for AB-836 shortly; the Company's belief that AB-836 has the potential for improved clinical efficacy and safety as well as a favorable resistance profile relative to earlier generation capsid inhibitors; the Company's belief regarding the strong potency of AB-836 and its ability to allow active engagement of the second mechanism of inhibiting cccDNA replenishment at clinically relevant doses; AB-836's potential to address certain known capsid resistant variants; and the Company's anticipation for AB-836 to be combinable with other drugs having different mechanisms of action for treating HBV and to be dosed once daily.

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, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug 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; 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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