Arbutus Receives Authorization to Proceed with an Investigational New Drug Application (IND) for AB-729, its Proprietary Subcutaneously-Delivered RNAi Agent

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Phase 2a trial to investigate the safety and anti-viral activity of AB-729 in combination with ongoing nucleos(t)ide analog (NA) therapy and short courses of Peg-IFNα-2a in subjects with chronic hepatitis B virus infection (CHB)

WARMINSTER, Pa., July 07, 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 (CHB), as well as therapies to treat coronaviruses (including COVID-19), today announced it has received authorization from the U.S. Food and Drug Administration to proceed with its Investigational New Drug (IND) application for AB-729 in a Phase 2a clinical trial. The Phase 2a proof-of-concept clinical trial will evaluate the safety and efficacy of AB-729 in combination with ongoing nucleos(t)ide analog (NA) therapy and short courses of Peg-IFNα-2a in subjects with CHB.

William Collier, President and Chief Executive Officer of Arbutus, stated, “The acceptance of our IND application is an important step forward for AB-729 and supports our objective to establish its value as a cornerstone therapy for patients with CHB. We look forward to the initiation of this proof-of-concept Phase 2a clinical trial in this quarter.”

Gaston Picchio, PhD, Chief Development Officer at Arbutus, stated, “We are gratified that our IND submission for AB-729, in combination with Peg-IFN, in subjects with chronic hepatitis B viral infection has been deemed safe to proceed. This Phase 2a trial will allow us to investigate if short courses of Peg-IFN, following a pronounced HBsAg suppression and potential immune reactivation by AB-729, could contribute to achieving a functional cure in HBeAg negative chronic hepatitis B subjects.”

About the Phase 2a Clinical Trial

This is a randomized, open label, multicenter Phase 2a trial investigating the safety and antiviral activity of AB-729 in combination with ongoing NA therapy and short courses of Peg-IFNα-2a in subjects with CHB. Pending protocol finalization, the trial is expected to enroll 40 stably NA-suppressed, HBeAg negative, non-cirrhotic CHB subjects. After a 24-week dosing period of AB-729 (60 mg SC every 8 weeks (Q8W)), subjects will be randomized into one of 4 groups:

- A1: AB-729 + NA + weekly Peg-IFNα-2a for 24 weeks (N = 12)
- A2: NA + weekly Peg-IFNα-2a for 24 weeks (N = 12)
- B1: AB-729 + NA + weekly Peg-IFNα-2a for 12 weeks (N = 8)
- B2: NA + weekly Peg-IFNα-2a for 12 weeks (N = 8)

After completion of the assigned Peg-IFNα-2a treatment period, all subjects will remain on NA therapy for the initial 24-week follow up period, and then will discontinue NA treatment if treatment stopping criteria are met. If subjects stop NA therapy, they will enter an intensive follow-up period for 48 weeks.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus’ novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens tested, including hepatitis B surface antigen, in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient’s immune system so as allow it to respond to the virus. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

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 focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that it believes have the potential to provide a new 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, 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, but may not be limited to, statements about Arbutus’ development plans for AB-729, including the expected trial design of the Phase 2a clinical trial, the expected number and type of subject to be enrolled in the trial and the expected dosing schedule of the clinical trial; and Arbutus’ expectations regarding the potential for its product candidates to provide a curative regimen for chronic HBV infection.

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 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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