Arbutus receives regulatory clearance to initiate Phase 1a/1b Clinical Trial of AB-729

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- AB-729 is a subcutaneously-administered RNAi agent targeting HBV replication and HBsAg antigen production

- Supports corporate objective to combine AB-729 with AB-506, Arbutus' proprietary oral capsid inhibitor

WARMINSTER, Pa., June 20, 2019 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today announced it has received regulatory clearance to initiate a Phase 1a/1b clinical trial of AB-729, Arbutus' subcutaneously-administered RNA interference (RNAi) agent. AB-729 employs a single RNAi trigger that has been shown in preclinical models to span all HBV transcripts, reduce all viral antigens, including hepatitis B surface antigen (HBsAg) expression, and inhibit HBV replication. This RNAi agent uses Arbutus' proprietary covalently conjugated N-acetylgalactosamine (GalNAc) hepatocyte targeting technology which is expected to allow for once-a-month dosing. As previously announced on May 3rd, a regulatory authority requested that Arbutus complete its ongoing 3- and 6-month toxicology studies before commencing the single ascending portion of the Phase 1a/1b clinical trial of AB-729. Based on further interaction with the regulatory authority, a revised protocol was submitted and Arbutus has received clearance to begin the Phase 1a/1b clinical trial.

Dr. Gaston Picchio, Arbutus's Chief Development Officer, said, "The Phase 1a/1b clinical trial of AB-729 is expected to initiate shortly and will initially be evaluated in healthy volunteers followed by chronic hepatitis B patients in single ascending dose cohorts."

Dr. Picchio, added, "We believe the combination of AB-729 and AB-506, our oral capsid inhibitor, has the potential to result in more profound inhibition of HBV replication in conjunction with a reduction in HBsAg levels thus enabling a reawakening of the patient's immune system. We also believe that these combined effects should lead to significantly higher rates of sustained HBsAg loss than the current standard of care after a yet-to-be-established finite dosing period."

About the AB-729 Phase 1a/1b Clinical Trial
AB-729-001 is a single and multiple dose clinical trial to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 administered by subcutaneous injection to healthy subjects and patients with chronic hepatitis B infection.

About AB-729
AB-729 is a RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery and we expect monthly dosing. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen (HBsAg) in preclinical models. Reducing HBsAg is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus.

About AB-506
AB-506 is an oral HBV capsid inhibitor. HBV core protein assembles into a capsid structure, which is required for viral replication. The current standard-of-care therapy for HBV, primarily nucleoside analogues that work by stopping the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids and also by inhibiting the uncoating step of the viral life cycle thus reducing the formation of new covalently closed circular DNA ("cccDNA"), the viral reservoir which resides in the cell nucleus.

About Arbutus
Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic Hepatitis B infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. 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 expectation for once-a-month dosing; our expectation to initiate the Phase 1a/1b clinical trial of AB-729 shortly and the clinical trial design for such clinical trial; our belief that the combination of AB-729 and AB-506 has the potential to result in more profound inhibition of HBV replication in conjunction with a reduction in HBsAg levels thus enabling a reawakening of the patient's immune system; our belief that the combined effects of AB-729 and AB-506 should lead to significantly higher rates of sustained HBsAg loss than the current standard of care after a yet-to-be-established finite dosing period; and the potential for our drug candidates to improve upon the standard of care and contribute to a curative combination regimen.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical 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.

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 not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; and

market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and Arbutus' continuous 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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