Arbutus Announces Decision to Discontinue AB-452 and to Pursue Development of a Next Generation HBV Specific Oral RNA-Destabilizer

February 10, 2020

Arbutus expects to announce AB-729 Preliminary Phase 1a/1b Data late Q12020

WARMINSTER, Pa., Feb. 10, 2020 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), announced today its decision to discontinue AB-452, its first generation orally available hepatitis B (HBV) specific RNA-destabilizer, and to continue research and development of a next generation oral HBV RNA-destabilizer. In October 2018, Arbutus announced its decision to delay the initiation of a planned 28-day Phase 1a/1b clinical trial for AB-452 in order to further evaluate the safety of the compound. This decision was based on findings in 90-day preclinical safety studies in two species. Since that time Arbutus has extensively reviewed and further characterized these preclinical findings, including repeating the 90-day safety studies.

Michael J. Sofia, Ph.D., Chief Scientific Officer of Arbutus, added, “After reviewing all the data from the preclinical studies, and in consultation with external regulatory and pre-clinical experts, we have decided to not move AB-452 forward. We continue to believe, however, that the HBV RNA destabilizer mechanism of action is very compelling and has the potential to lead to an oral therapy. We intend to vigorously pursue next generation compounds in this area.”

Arbutus also reiterated its earlier guidance for both AB-729 and AB-836. AB-729 is a subcutaneously delivered RNAi agent which has been shown in preclinical models to reduce viral antigens, including hepatitis B surface antigen (HBsAg) expression, and to inhibit HBV replication. In July 2019, the Company initiated a single and multiple dose Phase 1a/1b clinical trial for AB-729, designed to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB-729 in healthy volunteers and in subjects with chronic hepatitis B (CHB) infection. Preliminary safety data in single-dose cohorts of healthy subjects and safety and efficacy data in single-dose cohorts of subjects with CHB infection are expected late this quarter. For AB-836, Arbutus’ next generation capsid inhibitor, the Company expects to complete investigational new drug enabling studies by the end of the year.

The Company believes that this compound has the potential for increased efficacy and an enhanced resistance profile relative to its previous generation capsid inhibitor, AB-506.

William H. Collier, President and Chief Executive Officer of Arbutus, stated, “Arbutus remains committed to developing a range of medicines with differing mechanisms of action that can be used in combination for treatment of chronic HBV infection. The Company is on track to deliver on its key pipeline objectives for 2020; we look forward to announcing our preliminary safety and efficacy data for AB-729 later this quarter and to completing IND enabling studies for AB-836 by the end of the year.”

About Oral RNA-Destabilizers

Small molecule HBV RNA destabilizers are orally active agents that cause the destabilization and ultimate degradation of HBV RNAs. These agents result in the reduction of HBsAg, HBeAg, pgRNA, and core protein in both whole cell systems and animal models. They have the potential to selectively impact HBV versus other RNA or DNA viruses and demonstrate pangenotypic characteristics. HBV RNA destabilizers have demonstrated additive effects in combination with other mechanism of action anti-HBV agents.

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. 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-836

AB-836 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 inhibiting the viral polymerase, significantly reduce virus replication, but not completely. Capsid inhibitors inhibit replication by preventing the assembly of functional viral capsids. They also have been shown to inhibit 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 (HBV) 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 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 expectations regarding the timing and clinical

development of our product candidates; our expectation to announce AB-729 preliminary Phase 1a/1b data late in the first quarter of 2020; our belief that the HBV RNA destabilizer mechanism of action is very compelling and has the potential to lead to an oral therapy; our intention to vigorously pursue additional next generation compounds; our guidance for AB-729 and AB-836, including our expectation to complete investigational new drug enabling studies by the end of the year; our belief that AB-836 has the potential for increased efficacy and an enhanced resistance profile relative to AB-506; and our belief that we are on track to deliver on our key pipeline objectives for 2020.

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 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: delays in the selection of and the advancement of an additional capsid inhibitor compound into lead optimization, 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, 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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