Arbutus Announces Pipeline Updates and Dosing of the First Subject in the Phase 1a/1b Clinical Trial with AB-101; Cash Runway Extended

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Progressing development of hepatitis B virus (HBV) compounds imdusiran (AB-729) and AB-101, an oral PD-L1 inhibitor

Discontinuing all coronavirus and oral RNA destabilizer programs, including AB-343 and AB-161

Extending cash runway through Q3 2025

WARMINSTER, Pa., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, today announced pipeline updates including its continued focus on its hepatitis B virus (HBV) assets, imdusiran (AB-729) as a cornerstone therapy in a functional cure treatment regimen for patients with chronic hepatitis B virus (cHBV), as well as its oral PD-L1 inhibitor, AB-101. In addition, the Company is discontinuing development of its oral RNA destabilizer, AB-161, due to a pre-clinical toxicology finding not related to peripheral neuropathy. There were no safety issues reported in the healthy subjects that received single doses of AB-161 in the Phase 1 clinical trial. The company is also discontinuing its efforts to identify and develop a coronavirus combination therapy that included AB-343 its M^{pro} candidate, due to an unfavorable PK profile noted in the IND-enabling studies, and a potential nsp12 polymerase inhibitor. These pipeline changes are expected to extend the Company's cash runway through Q3 2025.

The Company remains on track to report preliminary data in the fourth quarter of this year from the Phase 2a clinical trial with imdusiran and Vaccitech's VTP-300 in patients with cHBV. In addition, the Company has dosed the first subject in its Phase 1a/1b clinical trial with its oral PD-L1 inhibitor, AB-101, for HBV and expects preliminary data in the first half of 2024.

"We are confident that our current clinical focus on HBV and our most advanced clinical stage compounds, imdusiran and AB-101, will best position us for success in our mission to achieve a functional cure for HBV," commented William Collier, Arbutus President and Chief Executive Officer. "Imdusiran has a strong foundation of safety and efficacy data, and we are actively advancing multiple ongoing Phase 2a combination clinical trials. We are also making progress on advancing AB-101, our oral PD-L1 Inhibitor for HBV, which is highly potent with demonstrated activity against PD-L1 in cells from chronic HBV subjects. We recently dosed the first subject in our Phase 1a/1b clinical trial for AB-101 and continue to believe that checkpoint inhibitors may play a role in antiviral immune tolerance in cHBV."

The AB-101-001 Phase 1a/1b double-blind, randomized, placebo-controlled, clinical trial is designed to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single and multiple oral doses of AB-101 for up to 28 days in healthy subjects and patients with cHBV. The trial will be conducted in three parts starting with single ascending doses in up to 64 healthy subjects, followed by multiple ascending doses in up to 40 healthy subjects and culminating with multiple doses in up to 60 patients with cHBV. Safety and PK/PD assessments will be performed prior to dose escalation in all study parts. Initial data from part one of the clinical trial are expected in the first half of 2024.

These pipeline updates will not impact the Company's pending litigations. Arbutus will continue to protect and defend its intellectual property, which is the subject of the on-going lawsuits against Moderna and Pfizer/BioNTech. The Company is seeking fair compensation for Moderna's and Pfizer/BioNTech's use of its patented LNP technology that was developed with great effort and at a great expense, without which Moderna and Pfizer/BioNTech's COVID-19 vaccines would not have been successful. Document production is currently on-going in the lawsuit against Moderna with the claim construction hearing scheduled for February 7, 2024. There are no updates to the status of the Pfizer/BioNTech lawsuit at this time.

About imdusiran (AB-729)

Imdusiran is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Imdusiran targets hepatocytes using Arbutus' novel covalently conjugated N-Acetylgalactosamine (GalNAc) delivery technology enabling subcutaneous delivery. Clinical data generated thus far has shown single and multiple doses of imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. Imdusiran is currently in multiple Phase 2a clinical trials.

About AB-101

AB-101 is our oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade while minimizing the systemic safety issues typically seen with checkpoint antibody therapies. Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. Preclinical data generated thus far indicates that AB-101 mediates re-activation of exhausted HBV-specific T-cells from cHBV patients. We believe AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in patients chronically infected with HBV. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. We have identified compounds in our internal PD-L1 portfolio that could also be used in oncology indications.

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 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 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 leveraging its extensive virology expertise to identify and develop novel therapeutics with distinct mechanisms of action, which can be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). We believe the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Our pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729) and an oral PD-L1 inhibitor, AB-101. Imdusiran is the only RNAi that has generated meaningful clinical data demonstrating an impact on both surface antigen reduction and reawakening of the HBV-specific immune response. Imdusiran is currently in two Phase 2a combination clinical trials. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. We are also exploring oncology applications for our internal PD-L1 portfolio. 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; our program updates; our belief that checkpoint inhibitors may play a key role in antiviral immune tolerance in cHBV; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to clinical trial design and the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital.

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 patent litigation matters.

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: the risk that the program updates may not materially extend the cash runway and may create a distraction or uncertainty that may adversely affect our operating results, business, or investor perceptions; 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 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; uncertainties associated with litigation generally and patent litigation specifically; it may take considerable time and expense to resolve the clinical hold that has been placed on AB-101 by the FDA, and no assurance can be given that the FDA will remove the clinical hold; Arbutus and its collaborators may never realize the expected benefits of the collaborations; and market shifts may require a change in strategic focus; and risks related to the sufficiency of Arbutus' cash resources and its ability to obtain adequate financing in the future for its foreseeable and unforeseeable operating expenses and capital expenditures.

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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