



Arbutus Announces FDA Clinical Hold is Lifted on IND Application for AB-101, an Oral PD-L1 Inhibitor

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WARMINSTER, Pa., Oct. 22, 2026 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company focused on infectious disease, today announced that the Company was notified by the U.S. Food and Drug Administration ("FDA") that the clinical hold on the Investigational New Drug ("IND") application for AB-101 has been removed and that the Company may engage in additional clinical development for AB-101 in the United States. Arbutus is evaluating next steps for the continued development of AB-101.

AB-101 is a proprietary oral PD-L1 inhibitor that has the potential to activate patients' hepatitis B virus ("HBV")-specific immune response by inhibiting PD-L1. AB-101 has completed a Phase 1a/1b clinical trial (AB-101-001) evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of single- and multiple-ascending oral doses in healthy subjects and patients with chronic HBV ("cHBV") infection. The data from healthy subjects in Parts 1 and 2 and cHBV patients in Part 3 of this clinical trial have shown that AB-101 was generally well-tolerated with evidence of high receptor occupancy in seven cHBV patients and hepatitis B surface antigen decline in two cHBV patients at the 30mg dose.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company focused on infectious disease. The Company is currently developing imdusiran (AB-729) and an oral PD-L1 inhibitor (AB-101) for the treatment of cHBV infection. The Company is also consulting closely with and supporting its exclusive licensee, Genevant Sciences, to protect and defend its intellectual property, which is the subject of on-going lawsuits against Pfizer Inc., BioNTech SE, and certain of their affiliates, for use of Arbutus' patented LNP technology in their COVID-19 vaccines. For more information, visit www.arbutusbio.com.

About AB-101

AB-101 is an oral PD-L1 inhibitor candidate that is designed to 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, for example against HBV. In Arbutus' Phase 1a/1b clinical trial, AB-101 was generally well-tolerated with evidence of high receptor occupancy.

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. cHBV infection represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from cHBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from cHBV infection. Approximately 1.1 million people die every year from complications related to cHBV infection despite the availability of effective vaccines and current treatment options.

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 plans for the development of AB-101; the potential to lead to a functional cure for HBV; the potential for Arbutus' product candidates to achieve success in clinical trials; and Arbutus' pipeline and development plans for its cHBV programs.

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 clinical trials, and the usefulness of the data; 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: ongoing and anticipated 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' product candidates; 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.sec.gov and at www.sedarplus.ca. 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.

