Arbutus Provides 2025 Corporate and Financial Update

January 13, 2025

Initiating Phase 2b clinical trial in first half of 2025 after achieving a meaningful functional cure rate in cHBV patients treated with imdusiran and interferon

WARMINSTER, Pa., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop a functional cure for people with chronic hepatitis B virus (cHBV) infection, today announced its 2025 corporate objectives and provided a financial update.

"We enter 2025 with solid financial footing and strong momentum in achieving our mission of developing a functional cure for cHBV, a disease that affects more than 250 million people worldwide and is a leading cause of liver cancer," said Michael J. McElhaugh, Interim President and Chief Executive Officer of Arbutus. "The data we reported late last year from our IM-PROVE I Phase 2a clinical trial showed a meaningful functional cure rate and immune activation in cHBV patients that were treated with our RNAi therapeutic, imdusiran, interferon and nucleos(t)ide analogue (NA) therapy. These data support our belief that imdusiran is differentiated from other RNAi therapeutics in development for HBV. Therefore, we plan to initiate a Phase 2b clinical trial combining imdusiran, interferon and NA therapy in the first half of 2025."

Imdusiran (RNAi therapeutic)

- At the American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® in November 2024, the Company presented new data from its IM-PROVE I Phase 2a clinical trial showing that six doses of imdusiran and 24 weeks of pegylated interferon alfa-2α (IFN), a standard-of-care immunomodulator, added to ongoing NA therapy led to a functional cure rate of 50% (3/6) in HBeAg-negative patients with baseline HBsAg levels less than 1000 IU/mL, and an overall functional cure rate of 25% (3/12). Those patients that achieved a functional cure also seroconverted with high anti-HBs antibody levels. The combination of imdusiran, IFN and NA therapy was generally safe and well-tolerated.
- Based on this data, the Company is planning to initiate a placebo-controlled Phase 2b clinical trial with this treatment regimen in the first half of 2025. Subject to regulatory approval, the clinical trial is anticipated to enroll approximately 170 HBeAg-negative cHBV patients with baseline HBsAg ≤1000 IU/mL. Additional details will be provided by the Company after regulatory approval.
- The Company also presented data from its IM-PROVE II Phase 2a clinical trial showing that the addition of low dose nivolumab increased rates of HBsAg loss in cHBV patients that were first treated with imdusiran, ongoing NA therapy and Barinthus Biotherapeutics' VTP-300. In this clinical trial, 23% (3/13) of patients that received imdusiran, VTP-300, NA therapy and nivolumab achieved HBsAg loss by week 48. The Company is evaluating functional cure in these patients and anticipates reporting data in the first half of 2025.

AB-101 (oral PD-L1 inhibitor)

- AB-101-001 is a Phase 1a/1b double-blind, randomized, placebo-controlled clinical trial designed to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single- and multiple-ascending doses of AB-101, the Company's oral PD-L1 inhibitor, in healthy subjects and patients with cHBV.
- Based on data from Part 2 of this clinical trial reported in November 2024 showing that AB-101 was generally well-tolerated with evidence of dose-dependent receptor occupancy, Arbutus has moved into Part 3 which evaluates repeat doses of AB-101 for 28 days in patients with cHBV. Data from the 10 mg cohort is expected in the first half of 2025. Next steps for AB-101 will be determined after Arbutus evaluates data from Part 3 of this clinical trial.

LNP Litigation

- 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's and Pfizer/BioNTech's COVID-19 vaccines would not have been successful.
- The claim construction hearing for the lawsuit against Pfizer/BioNTech occurred on December 18, 2024. The court is expected to provide its ruling on the claim construction and issue the scheduling order in the first half of 2025.
- The Moderna trial date is scheduled for September 24, 2025, and is subject to the court's availability. Expert reports and expert depositions continue in this lawsuit.

Financial Update:

- The Company had cash, cash equivalents and investments in marketable securities totaling approximately $123 million as

of December 31, 2024 (unaudited).

- The Company expects to significantly reduce its net cash burn in 2025 when compared to 2024. Net cash burn is expected to range from $47 to $50 million in 2025 versus a 2024 net cash burn of approximately $65 million (unaudited). The Company believes its cash, cash equivalents, investments in marketable securities and anticipated contractual milestones from Qilu Pharmaceutical, its strategic partner in Greater China, are sufficient to fund its operations through the first quarter of 2028. This includes fully funding the imdusiran Phase 2b clinical trial.
- The preliminary cash, cash equivalents and investments as of December 31, 2024 and the estimated 2024 net cash burn were calculated prior to the completion of an audit by Arbutus' independent registered public accounting firm and are therefore subject to adjustment.
- With its current cash balance and anticipated 2025 net cash burn, the Company does not anticipate utilizing its "at-the-market" program (ATM) this year.

About Imdusiran

Imdusiran is an 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. In a Phase 2a clinical trial, imdusiran achieved meaningful functional cure rates in patients with cHBV when combined with pegylated interferon (IFN) alfa-2α and nucleos(t)ide analogue (NA) therapy. Clinical data generated thus far has shown imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. In the first half of 2025, the Company is planning to initiate a Phase 2b clinical trial of imdusiran combined with IFN and NA therapy.

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.

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 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 1.1 million 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 develop novel therapeutics with distinct mechanisms of action, which can potentially be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). Arbutus believes the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Arbutus' pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729), and an oral PD-L1 inhibitor, AB-101. Imdusiran has achieved meaningful functional cure rates in patients with cHBV when administered as combination therapy. In the first half of 2025, Arbutus is planning to initiate a Phase 2b clinical trial with imdusiran. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. 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: the potential to lead to a functional cure for HBV; Arbutus' future development plans for its product candidates; the expected timing, cost and results of Arbutus' clinical development plans and clinical trials with respect to its product candidates; Arbutus' expectations with respect to the cost, initiation and the release of data from its clinical trials and the expected timing thereof; the potential for Arbutus' product candidates to achieve success in clinical trials; Arbutus' expectations with respect to utilizing its ATM program; Arbutus' plans with respect to the ongoing patent litigation matters; and Arbutus' expected financial condition, including the anticipated duration of its cash runway, its expectations regarding its 2025 cash burn and the timing and need 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 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: 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' products; uncertainties associated with litigation generally and patent litigation specifically; economic and market conditions may worsen; market shifts may require a change in strategic focus; Arbutus and its collaborators may never realize the expected benefits of the collaborations; Arbutus may need to utilize its ATM program based on changes in its business; Arbutus' plans to reduce its net cash burn may not materially extend the cash runway and may create a distraction or uncertainty that may adversely affect its operating results, business, or investor

perceptions; 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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