Arbutus Presents Clinical Trial Data from its Two HBV Assets, Imdusiran and AB-101, at the European Association for the Study of the Liver (EASL) Congress 2025

May 7, 2025

Data highlighted in late-breaker poster presentation shows that imdusiran achieves functional cure in chronic hepatitis B (cHBV) patients when combined with VTP-300 and low dose nivolumab

In a Phase 1a/1b clinical trial, AB-101, an oral PD-L1 inhibitor, has shown to be generally safe and well-tolerated with evidence of high receptor occupancy and no liver dysfunction in cHBV patients

WARMINSTER, Pa., May 07, 2025 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus" or the "Company"), a clinical-stage biopharmaceutical company focused on infectious disease, today announced the presentation of five posters, including one late-breaker, highlighting imdusiran, its RNAi therapeutic and AB-101, its oral PD-L1 inhibitor, at the European Association for the Study of the Liver (EASL) Congress 2025.

In a late-breaker poster presentation, the following select key end-of-study data were reported from the Phase 2a clinical trial (IM-PROVE II, AB-729-202) evaluating stable nucleos(t)ide analogue (NA) therapy throughout the treatment period with imdusiran (60mg every 8 weeks) for 24 weeks and either Barinthus Biotherapeutic's T-cell stimulating immunotherapeutic VTP-300 without nivolumab (Group A, n=20) or with low dose nivolumab (Group C, n=22; 13 received nivolumab) or placebo (Group B, n=20):

- Three patients in Group C with the addition of nivolumab had HBsAg loss (HBsAg <LLOQ) at the end of the treatment period (week 48) and seroconverted. All 3 patients had baseline HBsAg <1000 IU/mL.
- 25% (2/8) of Group C patients with baseline HBsAg <1000 IU/mL who received nivolumab reached functional cure with an overall functional cure rate in Group C of 15.3% (2/13).
- Most patients treated with imdusiran maintained quantitative HBsAg levels that were consistently lower than pre-treatment HBsAg levels during the post-treatment follow-up period.
- Compared to placebo (Group B) more patients treated with imdusiran and VTP-300 (Group A) were able to remain off NA therapy even without achieving functional cure.
- Treatment with imdusiran, VTP-300 and lose dose nivolumab was well tolerated with no serious adverse events, deaths or early treatment discontinuations. In addition, there were no immune related adverse events, including thyroid abnormalities.

Dr. Grace Lai-Hung Wong, Professor of The Chinese University of Hong Kong, commented, "Throughout this clinical trial we saw a benefit in first lowering HBsAg with imdusiran prior to adding any additional therapies to promote HBV-specific immune reawakening. These data show that adding a low dose of nivolumab to the imdusiran and VTP-300 treatment regimen, with ongoing NA therapy in CHB patients, is well-tolerated and leads to more patients achieving HBsAg loss and reaching a functional cure."

As previously reported, patients with HBsAg levels less than 1000 IU/mL represent a significant portion of the cHBV population. To date, across all Phase 2a clinical trials (IM-PROVE I and IM-PROVE II) conducted with imdusiran, Arbutus has reported a total of 8 patients who have been functionally cured, 7 of whom had baseline HBsAg less than 1000 IU/mL.

Also at EASL, Arbutus presented posters with pre-clinical and clinical data on AB-101, including Part 3 data from its Phase 1a/1b clinical trial, AB-101-001. Data from the first cohort of cHBV patients in Part 3 showed that once daily dosing of 10mg of AB-101 for 28 days was well tolerated, with PD-L1 receptor occupancy similar to that observed in healthy volunteers who received multiple doses of AB-101 10mg once daily. Importantly, there were no immune related adverse events reported in healthy volunteers or patients thus far, and no evidence of liver dysfunction.

All the poster presentations from EASL 2025 can be accessed through the Arbutus website under Publications.

IM-PROVE II Trial Details

The IM-PROVE II Phase 2a clinical trial initially enrolled 40 non-cirrhotic, virally suppressed cHBV patients that were on stable NA therapy. The patients initially received imdusiran (60mg every 8 weeks) for 24 weeks with on-going NA therapy and were then randomized to receive either VTP-300 or placebo at Weeks 26 and 30 (and conditionally at Week 38 if they experienced a >0.5 $\log_{10}$ decline in HBsAg between Weeks 26 and 34). After completion of the treatment period at Week 48, those patients who met the following criteria: ALT levels less than two times the upper level of normal, HBV DNA less than the lower limit of quantitation, HBsAg <100 IU/mL, and HBeAg negative, discontinued NA therapy and were followed for an additional 48 weeks. Those who did not meet the criteria continued on NA therapy for an additional 24 weeks of follow-up.

This trial was amended to include an additional cohort of 20 patients that received imdusiran plus NA therapy for 24 weeks followed by VTP-300 plus up to two low doses of nivolumab, an anti-PD-1 monoclonal antibody.

About Imdusiran (AB-729)

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 control the virus. Imdusiran targets hepatocytes using Arbutus' novel covalently conjugated *N*-Acetylgalactosamine (GalNAc) delivery technology enabling subcutaneous delivery. To date, Arbutus has reported a

total of eight patients with cHBV who have achieved functional cure following treatment with imdusiran and NA therapy in combination with either IFN or low dose nivolumab plus an immunotherapeutic. 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 virus DNA.

About AB-101

AB-101 is an oral PD-L1 inhibitor candidate that is designed to allow for controlled immune checkpoint blockade while minimizing the systemic safety issues typically seen with immune checkpoint protein antibody therapies. Immune checkpoints proteins such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. In Arbutus' ongoing Phase 1a/1b clinical trial, AB-101 was generally safe and well-tolerated with evidence of high receptor occupancy.

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 focused on infectious disease. The company is currently developing imdusiran (AB-729) and an oral PD-1 inhibitor (AB-101) for the treatment of chronic HBV 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 Moderna and Pfizer/BioNTech for use of Arbutus's patented LNP technology in their COVID-19 vaccines. 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 and the potential for Arbutus' product candidates to achieve success in clinical trials.

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; 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.

Arbutus Biopharma Corporation / ir@arbutusbio.com