Arbutus Announces New Data on AB-729 in Late Breaker Poster Presentation at AASLD - The Liver Meeting®

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Arbutus' Lead Compound AB-729 Continues to be Safe and Effective at Reducing HBsAg in Patients with Chronic Hepatitis B

HBsAg remains suppressed up to 28 weeks after discontinuation of AB-729

Repeat dosing of both 60 mg and 90 mg of AB-729 results in comparable HBsAg reductions

WARMINSTER, Pa., Nov. 10, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on discovering, developing and commercializing a broad portfolio of wholly-owned assets with different modes of action to provide a cure for people with chronic hepatitis B virus (HBV) infection and to treat coronaviruses (including COVID-19), today announced new AB-729 safety and efficacy data, as well as long-term data from HBV patients following discontinuation of treatment with AB-729. The data are from part 3 of the Company's ongoing Phase 1a/1b clinical trial with 60 mg or 90 mg of AB-729 dosed every four, eight or 12 weeks. The data will be presented at AASLD in a poster entitled, "Low HBsAg levels maintained following cessation of the GalNAc-siRNA, AB-729, in chronic hepatitis B subjects on nucleos(t)ide analogue therapy".

Data from the poster presentation include long-term follow-up data for patients in cohort E (60 mg every four weeks) and cohort F (60 mg every eight weeks) who had been off AB-729 treatment for six months. Suppression of HBsAg to levels <100 IU/mL were maintained up to 24 weeks off-treatment in 3 of 7 patients in cohort E and 1 of 3 patients with available data in cohort F. Patients who remain below this clinically relevant threshold for six months after stopping AB-729 treatment could consider discontinuing their nucleos(t)ide analogue ("NA") therapy to assess the potential for functional cure.

Professor Man-Fung Yuen, D.Sc., M.D., Ph.D., Deputy Head of Department Medicine and Chief of Division of Gastroenterology and Hepatology, University of Hong Kong, and lead investigator of Arbutus' Phase 1a/1b clinical trial, stated, "I find this long-term off-treatment data very encouraging. Albeit small patient numbers, these data give us confidence that AB-729 is capable of reducing and maintaining suppression of HBsAg even after its discontinuation. We look forward to providing additional long-term follow up data on these patients, especially as some of them may elect to discontinue their NA therapy."

Also included in the poster presentation are data showing that robust mean declines (ranging from 1.8-2.0 $\log_{10}$ at week 40) in HBsAg were sustained with repeat dosing of AB-729 up to 48 weeks, with no statistically significant differences observed to date between the 60 mg and 90 mg dose and/or dosing intervals.

Mean (SE) Baseline Change in HBsAg with Repeat Dosing of AB-729

Nominal Visit	HBV DNA-				HBV DNA+
	Cohort E 60 mg Q4W (n=7)	Cohort F 60 mg Q8W (n=7)	Cohort I 90 mg Q8W (n=6)	Cohort J 90 mg Q12W (n=7)	Cohort G 90 mg Q8W (n=7)
Baseline (IU/mL)	3.51 (0.20)	3.53 (0.17)	3.36 (0.23)	3.37 (0.28)	3.14 (0.14)
Week 12	-1.10 (0.15)	-1.02 (0.11)	-1.30 (0.19)	-1.06 (0.31)	-1.56 (0.32)
Week 24	-1.84 (0.16)	-1.57 (0.09)	-1.79 (0.22)	-1.56 (0.25)	-1.82# (0.29)
Week 40	-1.84 (0.19)	-1.78 (0.10)	-1.93 (0.25)	-1.89^ (0.35)	-2.03+ (0.33)
Week 44	-1.81 (0.17)	-1.88 (0.13)	-2.16 (0.31)	-1.86^ (0.38)	---
Week 48	-1.89 (0.18)	-1.90 (0.14)	---	---	---
Week 16 Post Last Dose	-1.74 (0.20)	-1.76 (0.19)	---	---	---
Week 20 Post Last Dose	-1.61 (0.20)	-1.55* (0.28)	---	---	---
Week 24 Post Last Dose	-1.54 (0.19)	---	---	---	---

NOTE: Mean (SE) values presented only if n>3; there are no statistically significant differences between cohorts (data not shown); *n=5; ^n=6, one patient in Cohort J chose not to extend treatment; #6 of 7 patients had HBV DNA <LLOQ by Week 8, the 7th patient became <LLOQ at Week 16; +n=6.

Repeat dosing of both the 60 mg and 90 mg doses of AB-729 continues to be generally safe and well- tolerated. There were no treatment related serious adverse events or discontinuations. The most common treatment emergent adverse events were injection site related of which all were grade one and did not appear to be dose or interval dependent. ALT and AST elevations were asymptomatic and not considered adverse events by the study investigators.

Gaston Picchio, Ph.D., Chief Development Officer at Arbutus, commented, “AB-729 consistently delivers impressive efficacy and safety data at both the 60 mg and 90 mg doses at all dosing intervals. AB-729 represents a therapeutic option with a consistent profile that can suppress HBsAg and has the potential to be a cornerstone agent in combination with other agents to cure HBV. I look forward to continuing to evaluate AB-729 in future clinical trials.”

A total of 34 patients were enrolled in cohorts E, F, G, I, and J, all of which met the eligibility criteria (>0.5 $\log_{10}$ HBsAg reduction at week 20) to participate in the treatment extension and 33 of which agreed to continue treatment. HBV DNA negative patients on stable NA therapy were enrolled in part 3 of this trial to receive 60 mg of AB-729 every 4 weeks (cohort E) or 8 weeks (cohort F) or 90 mg of AB-729 every 8 weeks (cohort I) or 12 weeks (cohort J). HBV DNA positive patients received 90 mg of AB-729 every 8 weeks in addition to current standard of care treatment, tenofovir disoproxil fumarate (cohort G). HBV DNA negative/HBeAg positive patients are continuing to be dosed with 90 mg of AB-729 every 8 weeks (cohort K).

The meeting platform with posters is now open and the e-poster is also available through the Investors section under Events & Presentations of Arbutus’ website at www.arbutusbio.com.

About AB-729

AB-729 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. AB-729 targets hepatocytes using Arbutus’ novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA.

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 900,000 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 primarily focused on discovering, developing and commercializing a broad portfolio of wholly-owned assets with different modes of action to provide a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that suppress viral replication, reduce surface antigen and reawaken the immune system. Arbutus believes this three-prong approach is key to transforming the treatment and developing a potential cure for chronic HBV infection. Arbutus’ HBV product pipeline includes RNA interference (RNAi) therapeutics, oral capsid inhibitors, oral compounds that inhibit PD-L1 and oral HBV RNA destabilizers. In addition, Arbutus has an ongoing drug discovery and development program directed to identifying orally active agents for treating coronaviruses (including COVID-19). 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; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; 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; our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital; and our expectations regarding the impact of the COVID-19 pandemic on our business and 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 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 COVID-19 pandemic.

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: anticipated pre-clinical studies and clinical trials may be more costly or take longer to complete than anticipated, 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; Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus’ clinical development programs.

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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