Arbutus Announces Robust HBsAg Decline Data with AB-729 Dosed at 60 mg Every 8 Weeks in Chronic Hepatitis B Subjects

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Repeat dosing of 60 mg AB-729 every 8 weeks resulted in mean HBsAg declines of –1.37 log10 (N=6) comparable to AB-729 dosed every 4 weeks (–1.44 log10, N=7, p<0.7)

AB-729 remains generally safe and well tolerated with no SAEs or treatment discontinuations in any cohort

WARMINSTER, Pa., Dec. 10, 2020 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company primarily focused on developing a cure for people with chronic hepatitis B virus (HBV) infection as well as therapies to treat coronaviruses (including COVID-19), today announced additional clinical data from an ongoing Phase 1a/1b clinical trial (AB-729-001) with AB-729, its proprietary GalNAc delivered RNAi compound.

William Collier, President and Chief Executive Officer of Arbutus, stated, “Throughout 2020, Arbutus has reported data that demonstrate the robust safety and efficacy of AB-729 in multiple patient cohorts. These data support advancing AB-729 into phase 2a clinical studies in 2021 and further support our confidence in its potential to become a cornerstone drug in future combination regimens to cure chronic hepatitis B.”

Summary of new data

Repeat dosing of AB-729 60 mg every 4 and 8 weeks results in comparable declines in mean HBsAg through week 16

Δlog10 HBsAg/(SE) (IU/mL)	Mean (SE) Week 12	Mean (SE) Week 16	Mean (SE) Week 24
Cohort E Q4W (N=7)	-1.10 (0.15)	-1.44 (0.18)	-1.84 (0.16)
Cohort F Q8W (N=7)	-1.02 (0.11)	-1.37* (0.08)	N/A**

*Mean determined based on N=6 since one subject has not reached week 16.
**Data not yet available since none of the subjects have reached week 24.

Dr. Gaston Picchio, Chief Development Officer of Arbutus, commented, “The mean reduction in HBsAg seen at week 16 in Cohort F suggests that AB-729 could offer patients the advantage of being dosed every 8 weeks versus every 4 weeks. Further dosing should allow us to confirm this finding.”

Dr. Picchio added, “Importantly, safety continues to be unremarkable. We have not seen any related Grade 3/4 AEs or treatment-related discontinuations in any cohorts to date. In Cohort F, two subjects had asymptomatic ALT elevations not considered AEs; one subject with Grade 1 ALT elevations prior to trial entry has had intermittent Grade 2 elevations, while another subject had a transient Grade 1 elevation which resolved with continued treatment.

Further, in Cohort E, the two subjects previously reported with Grade 2 and two subjects with Grade 1 ALT elevations have improved to Grade 1 and Grade 0, respectively, after week 24. All seven subjects in the cohort have consented to continue dosing with AB-729 for an additional 6 months.”

Summary of clinical trial design

AB-729-001 is an ongoing first-in-human clinical trial consisting of three parts:
In Part 1, three cohorts of healthy subjects were randomized 4:2 to receive single-doses (60 mg, 180 mg or 360 mg) of AB-729 or placebo.

In Part 2, non-cirrhotic, HBeAg positive or negative, chronic HBV subjects (N=6) on a background of nucleos(t)ide therapy with HBV DNA below the limit of quantitation received single-doses (60 mg to 180 mg) of AB-729. An additional cohort in Part 2 included 90 mg single-dose of AB-729 in HBV DNA positive chronic HBV subjects.

In Part 3, chronic HBV subjects, HBV DNA negative first and HBV DNA positive later, are receiving multi-doses of AB-729 for up to six months.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus’ novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient’s immune system to respond to the virus. In an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About HBV

Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily dedicated to discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, please 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 advancing AB-729 into phase 2a clinical studies in 2021; the Company's suggestion that suggests that AB-729 could offer patients the advantage of being dosed every 8 weeks versus every 4 weeks, which could be confirmed via further dosing; and the potential that AB-729 could be a cornerstone drug in future combination regimens to cure chronic hepatitis B infection.

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, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug 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; 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.

Contact Information

Investors and Media

William H. Collier
President and CEO
Phone: 267-469-0914
Email: ir@arbutusbio.com

Pam Murphy
Investor Relations Consultant
Phone: 267-469-0914
Email: ir@arbutusbio.com