Arbutus Announces Additional Robust HBsAg Decline Data with AB-729 in Chronic Hepatitis B Subjects

November 16, 2020

Data released today expands on November 15, 2020 AASLD presentation

Repeat dosing of 60 mg AB-729 every 4 weeks resulted in robust and continuous mean declines in HBsAg decline at week 20 (-1.71 log10IU/mL, N=7) and further reductions continued beyond week 20 (-1.84 log10 IU/mL, N=3)

In HBV DNA positive subjects, a single 90 mg AB-729 dose resulted in robust mean declines in HBsAg (-1.02 log10 IU/mL), HBV DNA (-1.53 log10 IU/mL), HBV RNA and HBcrAg at week 12

Results support advancement into Phase 2 combination clinical trials with AB-729 dosing as infrequently as every 8 or 12 weeks

Conference Call and Webcast Scheduled Today at 8:00 am ET

WARMINSTER, Pa., Nov. 16, 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.

The new data described today expands on the presentation entitled *Safety and pharmacodynamics of the GalNAc-siRNA AB-729 in subjects with chronic hepatitis B infection,* recorded on October 14, 2020 and presented on November 15, 2020 by Professor Man-Fung Yuen, D.Sc., M.D., Ph.D., from the University of Hong Kong at The Liver Meeting Digital Experience™, The American Association for the Study of Liver Diseases (AASLD) Meeting.

The new data summarized below include HBsAg data for the complete 60 mg every 4 weeks multi-dose cohort (N=7) at week 20, and the first results for the AB-729 90 mg single-dose cohort of HBV DNA positive subjects (N=5).

William Collier, President and Chief Executive Officer of Arbutus, stated, “The positive data described today, together with the strong safety and efficacy results presented by Professor Yuen at AASLD yesterday, are encouraging and continue to support our confidence in the therapeutic value of AB-729 as we plan to move into Phase 2 clinical trials.”

Summary of new data

Repeat dosing of AB-729 60 mg every 4 weeks results in continuous declines in mean HBsAg through week 20 (Cohort E)

	Mean (SE) Week 16 N=7	Mean (SE) Week 20 N=7	Mean (SE) Week 24 N=3
Δlog10 HBsAg (IU/mL)	**-1.44 (0.18)**	**-1.71 (0.18)**	**-1.84 (0.10)**

Dr. Gaston Picchio, Chief Development Officer at Arbutus stated, “Further follow up of the 60 mg every 4 weeks multi-dose cohort confirmed continuous reductions in mean HBsAg at week 20 (N=7), and in a subset of subjects (N=3) beyond this time point, while being generally safe and well tolerated. Additionally, the mean HBsAg declines and slopes of declines are similar between single doses and repeat doses of AB-729 up to week 12. Importantly, this suggests that dosing AB-729 as frequently as every 4 weeks may not be necessary, and that AB-729 has the potential to be dosed every 8 weeks or even every 12 weeks. This dosing strategy is being investigated in other cohorts of the trial with results from the 60 mg every 8 week cohort expected before the end of 2020.”

AB-729 90 mg single-dose reduces HBsAg and HBV DNA in HBV DNA positive chronic Hepatitis B (CHB) subjects with mean HBsAg declines similar to those seen in HBV DNA negative subjects (Cohort D)

	Mean (SE) Week 12 N=5
Δlog10 HBsAg (IU/mL)	**-1.02 (0.13)**
Δlog10 HBV DNA (IU/mL)	**-1.53 (0.24)**

Dr. Picchio added, “It is also encouraging to observe that a single 90 mg dose of AB-729 is capable of reducing HBsAg in HBV DNA positive subjects to the same extent achieved in other single-dose HBV DNA negative cohorts. Further, a single 90 mg AB-729 dose substantially reduced HBV DNA as well as HBV RNA and HBcrAg.”

AB-729 was safe and well tolerated after single and repeat doses

- No serious adverse events or discontinuations due to adverse events
- No treatment-related Grade 3 or 4 adverse events

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.

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Monday, November 16, 2020 at 8:00 am Eastern Time to provide an AB-729 clinical update. You can access a live webcast of the call, which will include presentation slides, through the Investors section of Arbutus' website at www.arbutusbio.com or directly at Live Webcast. Alternatively, you can dial (866) 393-1607 or (914) 495-8556 and reference conference ID 7791835.

An archived webcast will be available on the Arbutus website after the event. Alternatively, you may access a replay of the conference call by calling (855) 859-2056 or (404) 537-3406, and reference conference ID 7791835.

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 the Company's expectations to conduct Phase 2 combination studies with AB-729 dosing as infrequently as every 8 or 12 weeks**;** the Company's expectation that AB-729 could be effective at dosing intervals of every 8 or even every 12 weeks; the Company's expectations that additional data results from the AB-729 60 mg 8 week cohort will be available before the end of 2020; and the Company's expectation that AB-729 could be the cornerstone of future combination regimens for the treatment of 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.

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