Arbutus Announces Single-Dose Week 12 Data in Chronic Hepatitis B Subjects with 60 mg AB-729 Demonstrating a Significant and Continuous Reduction in HBsAg

May 18, 2020

Mean 60 mg HBsAg reduction of 0.99 log10 IU/mL at week 12, with normal ALT and AST values throughout the follow-up period

90 mg single-dose and 60 mg multi-dose cohorts initiated with data expected in the second half of 2020

Conference Call and Webcast Scheduled Today at 4:30 PM ET

WARMINSTER, Pa., May 18, 2020 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company focused on developing a cure for people with chronic hepatitis B virus (HBV) infection, today reports positive follow-up data from a Phase 1a/1b clinical trial (AB-729-001) in chronic HBV subjects on nucleos(t)ide therapy who received a single subcutaneous injection of 60 mg of AB-729, a proprietary GalNAc delivered RNAi compound.

William Collier, President and Chief Executive Officer of Arbutus, stated, “These new data further demonstrate the robust activity of AB-729. At week 12, the 60 mg single-dose achieved equivalent reductions in HBsAg as the 180 mg single-dose. We are currently dosing chronic HBV subjects in a multi-dose cohort with 60 mg of AB-729. These data keep us on track for achieving our goal of delivering a combination therapy that includes HBsAg reduction in chronic hepatitis B subjects.”

Mean HBsAg changes from baseline:

	60 mg Single-Dose Cohort (N=6)	180 mg Single-Dose Cohort (N=4)
Day 29 mean log10 IU/mL (Standard Error of the Mean)	-0.24 (0.13)	-0.8 (0.38)
Week 12 (day 84) mean log10 IU/mL (Standard Error of the Mean)	-0.99 (0.24)	-0.98 (0.22)

Dr. Gaston Picchio, Chief Development Officer of Arbutus, stated, “Importantly, throughout the 12 week period, not only does AB-729 demonstrate robust HBsAg reduction, it does so while remaining generally safe and well tolerated with no abnormal transaminase values in any of the six subjects.”

Dr. Picchio added, “We are impressed by both the magnitude and continuous reduction in HBsAg achieved with a single 60 mg dose. We believe that these features could provide a competitive advantage with a low dose and reduced frequency of injections. To this end, we are currently dosing chronic HBV subjects in a multi-dose cohort with 60 mg at 4 week intervals and also intend to evaluate 60 mg at 8 week intervals, which will begin as soon as possible. As we previously announced we are also exploring an additional 90 mg single-dose cohort. We expect data from both the 60 mg multi-dose cohorts in the second half of the year. We also expect week 12 90 mg single-dose data in the second half of 2020.”

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 or 180 mg) of AB-729. An additional cohort in Part 2 is designed to include 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, will receive multi-doses of AB-729 for up to six months.

COVID-19

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will negatively impact our plans and timelines in the future.

Conference Call and Webcast Today

Arbutus will hold a conference call and webcast today, Monday, May 18, 2020 at 4:30 pm Eastern Time to provide a corporate 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 8186276.

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 8186276.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for people with chronic Hepatitis B (HBV) infection. The Company is advancing multiple drug product candidates that may be combined into a potentially curative regimen for chronic HBV infection. 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 expectations regarding the timing and clinical development of our product candidates; our expectation that certain data from the 60 mg multi-dose and 90 mg single-dose cohorts will be available in the second half of 2020; our plans to evaluate 60 mg at 8 week intervals as soon as possible; and our expectations regarding the effect of the COVID-19 pandemic on our business.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; 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; changes in Arbutus' 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; and the ongoing COVID-19 pandemic could significantly disrupt our 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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Source: Arbutus Biopharma Corporation