

Arbutus Provides Update on HBV Development Programs and Announces Appointment of Dr. Gaston Picchio as Chief Development Officer

October 9, 2018

Dr. Mark Murray, Arbutus President & Chief Executive Officer, to participate in a fireside chat at Chardan's Genetic Medicines Conference at 2:45 pm ET today

WARMINSTER, Pa., Oct. 09, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today announced a change to its executive leadership team and provided an update on its key HBV development programs. These updates include:

- The progression of AB-506, the Company's second-generation capsid inhibitor, which is poised to be dosed in HBV patients this month, following successful execution of the healthy volunteer portion of the ongoing phase 1 clinical study;
- The decision to delay the initiation of the Phase 1 clinical trial for AB-452, its novel HBV RNA de-stabilizer that was planned in Q4;
- An update on the status of ARB-1467, an RNAi agent targeting HBV, currently in a Phase 2 combination study;
- An update on AB-729, a second-generation subcutaneously administered RNAi agent, expected to enter clinical studies in Q2 2019; and
- The addition of Dr. Picchio, formerly Janssen's Infectious Diseases & Vaccines VP Hepatitis Disease Area Leader, adds Antiviral Drug Development Expertise to Executive Leadership

Small Molecule Programs

AB-506

AB-506, the Company's second generation capsid inhibitor, has progressed through the healthy volunteer portion of a multi-component phase 1a/1b study in which it was demonstrated to be generally safe and well-tolerated after 10 days of dosing. This month, AB-506 will enter the 28-day HBV patient portion of the trial, where it will be evaluated both with and without a nucleoside analog. The Company expects to complete this segment of the trial in Q2 2019. AB-506 exhibits dual anti-HBV activities, both inhibiting HBV DNA replication and preventing the establishment and replenishment of cccDNA through inhibition of capsid uncoating.

AB-452

AB-452 is a novel, orally available RNA-destabilizer that has shown compelling anti-viral effects in multiple preclinical models. AB-452 is a new chemical entity acting via a novel mechanism and the Company is taking the time needed to further characterize the compound following emerging nonclinical safety findings before initiating clinical studies. At present, this is expected to delay the initiation of the phase 1 program while the Company completes the ongoing nonclinical studies.

RNA Interference Programs

ARB-1467

ARB-1467, an RNAi agent targeting HBV replication and antigen production, is currently in a 30-week study in HBV patients, in combination with tenofovir and PEG-IFN. To date, six HBV patients have enrolled and been treated. Three patients did not meet the predetermined response criteria at week 6 to proceed to PEG-IFN treatment as per protocol. Two patients have not yet progressed to the six-week analysis point to determine if the addition of PEG-IFN is warranted. One patient has responded strongly, with a 3.17 log reduction in HBsAg level at treatment week 14 of under 4 IU/mL having started with a baseline level of greater than 6000 IU/mL, indicating that this regimen may drive HBsAg levels to undetectable in some patients. The study remains open to enrollment and the Company will provide periodic updates.

AB-729

Arbutus is developing a second-generation RNAi agent, AB-729, a subcutaneously-administered GalNAc conjugate, targeting HBV. In preclinical models AB-729 exhibits potent and durable reductions in HBsAg. This agent is expected to enter clinical studies in Q2 2019 and may be combined with AB-506 in a clinical study in 2H 2019.

New Chief Development Officer Dr. Gaston Picchio

Dr. Picchio has joined Arbutus from Janssen R&D, bringing with him over thirty years of basic and clinical experience in the field of human virology, and sixteen years of industry experience dedicated to the development of antiviral drugs including drug approvals for the treatment of HIV (etravirine and rilpivirine) and HCV (telaprevir and simeprevir).

"I am thrilled to be joining the Arbutus team after working on the development and approval of transformational therapies for chronic HCV infection. Chronic HBV remains a major unmet need globally. I believe Arbutus is uniquely positioned to lead this effort and it is a privilege to have the opportunity to take on this challenge as part of a remarkably talented and accomplished team," said Dr. Picchio.

Prior to joining Arbutus, Dr. Picchio served in various senior management positions at Janssen R&D, including Vice President – Scientific Innovation Infectious Diseases & Vaccines, Vice President – Hepatitis Disease Area Leader and Vice President – Clinical Virology Infectious Diseases & Vaccines. Dr. Picchio received a Masters in Molecular Biology from University Centro de Altos Estudios en Ciencias Exactas, Buenos Aires, and a PhD degree from University of Buenos Aires, Argentina.

Webcast Information

A live webcast of the fireside chat with Dr. Murray, scheduled for 2:45 pm ET, during the Chardan conference can be accessed through the Investors section of Arbutus' website at www.arbutusbio.com. A replay of the webcast will be available for 90 days following the live presentation.

About Arbutus

Arbutus Biopharma Corporation is a publicly-traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing, and commercializing a cure for patients suffering from chronic Hepatitis B infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. For more information, visit www.arbutusbio.com.

Forward-Looking Statements

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 inclusion of AB-506, AB-452, ARB-1467 and AB-729 in future drug combination regimens; further clinical evaluation of our clinical assets, including AB-506, AB-452, ARB-1467 and AB-729, and eventual testing of a proprietary combination; Arbutus' expectations regarding the initiation, timing and completion of preclinical studies and clinical trials; and discovering, developing, and commercializing a cure for patients suffering from chronic HBV 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 and clinical trials, and the usefulness of the data; 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: 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 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 and Arbutus' continuous 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

Mark Murray
President and CEO
Phone: 604-419-3200
Email: ir@arbutusbio.com

Pam Murphy

Investor Relations Consultant Phone: 604-419-3200 Email: ir@arbutusbio.com

Arbutus

Source: Arbutus Biopharma Corporation