



Arbutus Announces Topline Results for ARB-1467 Phase II Cohort 4

September 25, 2017

Detailed Data to be Presented at AASLD in October

VANCOUVER, British Columbia and WARMINSTER, Pa., Sept. 25, 2017 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, announced topline results of the bi-weekly dosing segment of Cohort 4 of the Phase II study of its RNAi agent, ARB-1467.

In the bi-weekly dosing segment of Cohort 4, twelve HBeAg negative chronically infected HBV patients on stable nucleotide therapy were given five doses of ARB-1467 on a bi-weekly dosing schedule. All twelve patients in Cohort 4 experienced reductions in serum HBsAg levels, with an average reduction in serum HBsAg of 1.4 log₁₀, which was greater than that observed with monthly dosing in Cohorts 1-3. Seven of the twelve patients met the predefined response criteria (at least 1 log₁₀ reduction in serum HBsAg level and a serum HBsAg level below 1000 IU/mL) at or before day 71. Five of the seven patients who met the response criteria had their serum HBsAg reduced to low absolute levels (below 50 IU/mL) during the bi-weekly dosing period. Initial results for the monthly dosing extension suggest that monthly dosing is not sufficient to maintain or improve upon these reductions in s-antigen levels. Dosing with ARB-1467 in Cohort 4 has been generally well tolerated, with no serious adverse events. Eleven of the twelve patients received all five bi-weekly doses. ALT values remained normal throughout treatment. Detailed results of Cohort 4 are expected to be presented at AASLD in October.

"The new Phase II results for ARB-1467 show greater reduction in serum HBsAg levels with a favorable safety profile. We look forward to presenting detailed bi-weekly dosing results at AASLD," said Dr. Mark J. Murray, Arbutus' President and CEO. "Furthermore, we are planning to initiate a new study of ARB-1467 in 4Q17 to evaluate longer dosing of ARB-1467 combined with interferon. The design of the study is informed by the findings in Cohort 4 and has the potential to create a late stage development and possible approval pathway for ARB-1467."

ARB-1467 Phase 2 Trial Design

The Phase II trial is a multi-dose study in chronic HBV patients who are also receiving stable nucleot(s)ide analog therapy. The trial consists of four cohorts, the first three of which enrolled eight subjects each (six receiving three monthly doses of ARB-1467 and two receiving placebo) and the fourth enrolled twelve patients (all of whom were to receive 5 bi-weekly doses of ARB-1467, followed by monthly dosing for patients who met predefined response criteria). Cohorts 1, 2, and 4 included HBeAg- patients and Cohort 3 included HBeAg+ patients.

Next Steps for ARB-1467

Arbutus will initiate a new study in 4Q17 to study longer term bi-weekly dosing of ARB-1467 in combination with tenofovir followed by the addition of pegylated interferon for patients who meet a predefined response criteria. This study will explore the effect of driving HBsAg to very low levels with ARB-1467 along with an immune modulating mechanism.

About ARB-1467

Arbutus' RNAi candidate ARB-1467 comprises three RNAi triggers that target all four HBV transcripts, and has been shown in preclinical studies to reduce all viral antigen levels as well as cccDNA and HBV DNA. ARB-1467 utilizes Arbutus' proprietary lipid nanoparticle (LNP) platform, a clinically validated delivery technology, which has been tested in hundreds of patients.

About Arbutus

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic HBV infection. Arbutus is headquartered in Vancouver, BC, and has facilities in Warminster, PA. 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 presenting detailed bi-weekly dosing results at AASLD; initiating a new study of ARB-1467 in 4Q17 to evaluate longer dosing of ARB-1467 combined with interferon; creating a late stage development and possible approval pathway for ARB-1467; and discovering, developing and commercializing a cure for chronic hepatitis B virus (HBV) infection.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: continued and timely positive preclinical and clinical efficacy data; the continued demand for Arbutus' assets, including its LNP technology; 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: continued positive clinical results for ARB-1467 may not be realized on a timely basis, or at all; demand for Arbutus' assets may lower; 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

Adam Cutler
Senior Vice President, Corporate Affairs
Phone: 604-419-3200
Email: acutler@arbutusbio.com

Tiffany Tolmie
Manager, Investor Relations
Phone: 604-419-3200
Email: ttolmie@arbutusbio.com

Media

David Schull
Russo Partners
Phone: 858-717-2310
Email: david.schull@russopartnersllc.com

[Primary Logo](#)

Source: Arbutus Biopharma Corporation