

October 28, 2015

Arbutus Provides an HBV Pipeline Update

TKM-HBV Progressing to Phase II in HBV Infected Patients by Year-End TKM-HBV Phase II S-Antigen Reduction Data Expected in 2016 Initiation of Proprietary Combination Studies in HBV Infected Patients Expected in 2017 Conference Call Scheduled for 7:30AM Pacific

VANCOUVER, British Columbia and DOYLESTOWN, Pa., Oct. 28, 2015 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading therapeutic solutions company focused on developing a cure for chronic hepatitis B virus infection (HBV), today issued an update on the company's HBV pipeline, including plans to progress lead pipeline candidate TKM-HBV into a multi-dose Phase II study in HBV infected patients by year-end.

TKM-HBV Progressing to Phase II in HBV Infected Patients

TKM-HBV, Arbutus' RNAi product candidate for HBV, is progressing to a Phase II multi-dosing study in HBV infected patients based on results to date from a Phase I single ascending dose study. TKM-HBV, which comprises three RNAi triggers that target all HBV transcripts, has been shown in preclinical studies to reduce all viral antigen levels as well as cccDNA. TKM-HBV's design will target hepatitis B surface antigen (HBsAg) expression regardless of its source. The Phase I clinical trial is a randomized, single-blind, placebo-controlled study, involving single ascending doses of TKM-HBV. The study is assessing the safety, tolerability and pharmacokinetics of intravenous administration of two LNP formulations (third and fourth generation) of TKM-HBV in healthy adult subjects. In order to enable maximum TKM-HBV dose escalation, steroid premedication was added to the Phase I protocol. At this time, a maximum tolerated dose has not yet been reached and evaluation of higher doses is under consideration.

TKM-HBV Phase II Study

Pending confirmation from the relevant regulatory authorities, the Phase II study will evaluate two dose levels of TKM-HBV administered as three monthly doses in chronic HBV infected patients who are on stable background nucleot(s)ide analog therapy. In the proposed protocol, eight subjects will be enrolled in each of the dose cohorts with six subjects receiving TKM-HBV, and two receiving placebo. Dosing in this study is expected to begin by year-end. HBsAg reduction results are expected to be reported in 2016. The TKM-HBV product candidate that will be studied in Phase II will be referred to as ARB-1467.

Status update on other HBV pipeline programs

Arbutus believes that direct-acting antiviral drugs such as TKM-HBV, cccDNA formation inhibitors and core protein/capsid assembly inhibitors represent the most important approaches with the highest probability of contributing to a cure. As a result, Arbutus has prioritized and accelerated development of its direct acting antiviral product candidates including the company's cccDNA formation inhibitors and core protein/capsid assembly inhibitors.

cccDNA formation inhibitors. Arbutus has made significant progress with its discovery of potent and unique small molecule cccDNA formation inhibitors, directly targeting this unique viral reservoir. As presented at the 2015 International Meeting on Molecular Biology of Hepatitis B Viruses earlier this month, Arbutus' cccDNA formation inhibitors demonstrate synergy with approved nucleot(s)ide analogs in preclinical models, which supports the potential for added benefit when combining these agents in HBV infected patients. Arbutus expects to file an IND (or equivalent filing) for a cccDNA formation inhibitor in 2H16, with a plan to include the molecule in combination studies in 2017.

Core protein/capsid assembly inhibitors. HBV core protein, or capsid, is required for viral replication and core protein may have additional roles in cccDNA function. Current nucleot(s)side analog therapy significantly reduces serum HBV DNA levels but HBV continues to replicate in the liver, thereby enabling the infection to persist and progress. Effective therapy for patients requires combinations consisting of new agents that will more effectively block viral replication. Arbutus has identified potent and unique HBV core protein/capsid inhibitors that are expected to enter clinical development in 2H16.

TLR9 agonist CYT003. Arbutus' TLR9 agonist, CYT003, is anticipated to be active in boosting the immune system in HBV patients, and will be used in settings where direct acting antiviral agents have reduced viral replication and antigen production.

Arbutus is planning to start clinical development of CYT003 in 2016, in time to enable inclusion of this molecule in combination studies in 2017.

Cyclophilin inhibitor OCB-030. After extensive preclinical evaluation of OCB-030 and other cyclophilin inhibitors against HBV, Arbutus has concluded that the data do not support further development of OCB-030 as a single agent or in combination with our other drug candidates. As a result, Arbutus is discontinuing development of OCB-030 and has suspended interest in the cyclophilin inhibitor class so the company can focus its resources on higher priority agents that directly target HBV. This decision is based on a significant amount of research and analysis conducted by Dr. Sofia and his team, which will be presented at the HepDart conference in December.

Proprietary combination timelines. Importantly, the development timelines for Arbutus' HBV pipeline should enable the start of combination studies in 2017 that include TKM-HBV, an approved nucleot(s)ide analog, and one or more of: a cccDNA formation inhibitor, a core protein/capsid assembly inhibitor, or CYT-003. Arbutus' current cash balance is expected to fund operations into late 2018, well beyond the anticipated timeline for initial combination data.

"We are very excited to be advancing TKM-HBV into Phase II and look forward to reporting HBsAg reduction data from this multi-dose study in HBV patients in 2016," said Dr. Mark J. Murray, Arbutus' President and CEO. "I am also delighted with the progress our scientific team is making in advancing our oral direct acting antiviral programs targeting cccDNA formation and core protein/capsid assembly. We believe that our diverse and differentiated pipeline will enable us to initiate important proprietary drug combinations in 2017, on our way to developing curative combination regimens for HBV."

Updated 2016 Goals and Expected Milestones

Arbutus is revising its previously issued pipeline guidance. The company expects to have four HBV products in clinical development by the end of 2016, including the two INDs (or IND equivalents) expected to be filed for the cccDNA formation inhibitor program and the core protein/capsid inhibitor program.

Conference Call Today

Arbutus will hold a conference call and webcast today, Wednesday October 28, 2015, at 7:30 a.m. Pacific Time (10:30 a.m. Eastern Time) to provide a corporate update. A live webcast of the call can be accessed through the Investor section of Arbutus' website at <u>www.arbutusbio.com</u>. Or, alternatively, to access the conference call, please dial 1-914-495-8556 or 1-866-393-1607.

An archived webcast will be available on the Arbutus website approximately two hours after the event. Alternatively, you may access a replay of the conference call by calling 1-404-537-3406 or 1-855-859-2056 and referencing conference ID 69450867.

About Arbutus

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic HBV infection. Our strategy is to target the three pillars necessary to develop a curative regimen for HBV: suppressing HBV replication within liver cells, stimulating and reactivating the body's immune system so that it can mount an effective defense against the virus and, eliminating the reservoir of viral genomic material known as covalently closed circular DNA, or cccDNA that is the source of HBV persistence. Our portfolio of assets includes a broad pipeline of drug candidates for use in combination to develop a cure for HBV. To support continuous discovery of potential novel drug candidates and technologies, Arbutus has a research collaboration agreement with the Baruch S. Blumberg Institute that provides exclusive rights to in-license any intellectual property generated through the relationship. The Baruch S. Blumberg Institute was established in 2003 by the Hepatitis B Foundation.

Arbutus is headquartered in Vancouver, BC, Canada with offices in Doylestown, PA, USA. For more information, visit <u>www.arbutusbio.com</u>.

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 plans to progress lead pipeline candidate TKM-HBV into a multi-dose Phase II study in HBV infected patients by year-end, pending confirmation from the relevant regulatory authorities, with HBsAg reduction results expected to be reported in 2016; the ability of TKM-HBV to target hepatitis B surface antigen (HBsAg) expression regardless of its source; expectations to file an IND (or equivalent filing) for a cccDNA formation inhibitor in 2H16, with a plan to include the molecule in combination studies in 2017; expectations for potent and unique HBV core protein/capsid inhibitors to enter clinical development in 2H16; the

anticipation for Arbutus' TLR9 agonist, CYT003, to be active in boosting the immune system in HBV patients, and to be used in settings where direct acting antiviral agents have reduced viral replication and antigen production; plans to start clinical development of CYT003 in 2016, in time to enable inclusion of the molecule in combination studies in 2017; discontinuing development of OCB-030 and suspending interest in the cyclophilin inhibitor class; the start of combination studies in 2017 that include TKM-HBV, an approved nucleot(s)ide analog, and one or more of a cccDNA formation inhibitor, a core protein/capsid assembly inhibitor, and CYT-003; the expectation that Arbutus' current cash balance will fund operations into late 2018, well beyond the anticipated timeline for initial combination data; initiating important proprietary drug combinations in 2017, on the way to developing curative combination regimens for HBV; the expectation to have four HBV products in clinical development by the end of 2016, including the two INDs (or IND equivalents) expected to be filed for the cccDNA formation inhibitor program and the core protein/capsid inhibitor program; and a strategy to target the three pillars necessary to develop a curative regimen for HBV.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness 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 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 <u>www.sedar.com</u> and at <u>www.sec.gov</u>. 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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