



Assembly Biosciences and Arbutus Biopharma Announce Clinical Collaboration Agreement to Evaluate the Combination of Core Inhibitor ABI-H0731 with RNAi Therapeutic AB-729 in Patients with Chronic Hepatitis B Virus Infection

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SOUTH SAN FRANCISCO, Calif. and WARMINSTER, Pa., Aug. 27, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB) and Arbutus Biopharma Corporation (Nasdaq: ABUS), today announced that the companies have entered into a clinical collaboration agreement to evaluate Assembly's lead hepatitis B virus (HBV) core inhibitor candidate ABI-H0731 in combination with Arbutus' proprietary GalNAc delivered RNAi therapeutic AB-729 and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (Nrtl) therapy for the treatment of patients with chronic HBV infection.

A randomized, multi-center, open-label Phase 2 clinical trial will explore the safety, pharmacokinetics, and antiviral activity of the triple combination of HBV core inhibitor ABI-H0731, RNAi therapeutic AB-729 and an Nrtl compared to the double combinations of ABI-H0731 with an Nrtl and AB-729 with an Nrtl. This clinical trial is projected to initiate in the first half of 2021 and enroll approximately 60 virologically-suppressed patients with HBeAg negative or positive chronic HBV infection. Patients will be dosed for 48 weeks, with a 24 week follow-up period. As part of the collaboration, the companies may add cohorts in the future, to evaluate other patient populations and/or combinations.

"Our team at Assembly is committed to driving the field of HBV research toward the ultimate goals of finite therapy and cure," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. "One of our key priorities for this year has been to execute a clinical collaboration to initiate a new combination therapy trial, as we believe that multi-drug combinations with non-overlapping mechanisms may result in higher response rates and potentially shorten the duration of treatment. We are excited to combine what we view as the most advanced core inhibitor with a promising RNAi therapeutic in this new trial as we continue to work to advance novel treatment options for patients living with this chronic disease."

William Collier, President and Chief Executive Officer of Arbutus, stated, "Arbutus is focused on discovering and developing a cure for chronic hepatitis B. We maintain this can best be accomplished through a combination of agents with different mechanisms of action that target distinct parts of the virus lifecycle. To this end, we are advancing a proprietary portfolio of compounds at various stages of clinical and preclinical development that have the potential to lead to a functional cure with a finite treatment duration."

Mr. Collier added, "This clinical collaboration in which both companies share expertise and costs has the potential to provide proof of concept data regarding the safety and efficacy of combining some of the most promising drug candidates and expedite efforts to advance a much needed HBV treatment regimen."

About ABI-H0731, Assembly's Lead HBV Core Inhibitor

Assembly's HBV portfolio includes three clinical-stage small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV lifecycle. In Phase 2 clinical trials, first-generation core inhibitor ABI-H0731 administered with nucleos(t)ide analogue reverse transcriptase inhibitor (Nrtl) therapy has been well-tolerated, has shown statistically superior antiviral activity in HBV DNA suppression compared to Nrtl therapy alone, and has demonstrated significant declines in HBV pgRNA that may indicate decreased cccDNA levels. In the ongoing Phase 2 open-label extension trial, Assembly has begun transitioning patients off combination therapy, to then monitor for sustained virologic response (SVR).

About Arbutus' AB-729 (Gal-Nac-RNAi)

AB-729 is a 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 preliminary 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.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL[®] technology. For more information, visit assemblybio.com.

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 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.

Assembly's Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ from those projected or implied. These risks and uncertainties include: Assembly and Arbutus' ability to initiate and complete clinical trials for ABI-H0731, AB-729, and Nrtl in the currently anticipated timeframes; whether the contemplated clinical trials meet their primary endpoint(s); safety and efficacy data from clinical trials may not warrant further development of ABI-H0731 or the combination of ABI-H0731 with AB-729 and Nrtl; clinical data with respect to the ABI-H0731, AB-729 and Nrtl combination, may not be differentiated from other companies' clinical data; Assembly may not observe sustained virologic response (SVR) in patients who are treated with its core inhibitors; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on initiation and continuation of the clinical trials under the collaboration; and other risks identified from time to time in Assembly's reports filed with the U.S. Securities and Exchange Commission (the SEC). All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Readers are cautioned not to rely on these forward-looking statements. Assembly intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether resulting from new information, future events or otherwise.

Arbutus' 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 Assembly and Arbutus' ability to initiate and complete clinical trials for AB-729, ABI-H0731 and an Nrtl in the currently anticipated timeframes; expectations regarding the timing and number of patients enrolled in the Phase 2 clinical trial; the expected dosing of the Phase 2 clinical trial; the possibility of including additional cohorts under the collaboration agreement; the potential for multi-drug combinations with non-overlapping mechanisms to result in higher response rates and shorten the duration of treatment; and expectations regarding the safety and efficacy of Arbutus' and Assembly's product candidates.

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 clinical trials for AB-729, ABI-H0731 and an Nrtl, and the usefulness of the data; the continued demand for Arbutus' and Assembly's 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 clinical trials for AB-729, ABI-H0731 and an Nrtl 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 AB-729, ABI-H0731, and an Nrtl; changes in Arbutus' or Assembly's strategy regarding its product candidates and clinical development activities; economic and market conditions may worsen; 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

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