Arbutus and Vaccitech Dose First Patient in Phase 2a Clinical Trial Combining Therapies for the Treatment of Chronic Hepatitis B Virus

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Trial will evaluate AB-729, an RNAi therapy in combination with VTP-300, an immunotherapeutic, and NA therapy

WARMINSTER, Pa. and OXFORD, United Kingdom, June 06, 2022 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, and Vaccitech plc (Nasdaq: VACC), a clinical-stage biopharmaceutical company engaged in the discovery and development of novel immunotherapeutics and vaccines, today announced the first patient dosed in a Phase 2a clinical trial. This trial will evaluate Arbutus' RNAi therapeutic candidate, AB-729, in combination with Vaccitech's T-cell stimulating immunotherapeutic, VTP-300, and standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NA) therapy for the treatment of patients with virologically-suppressed chronic HBV infection (cHBV).

Dr. Gaston Picchio, Chief Development Officer of Arbutus, stated, "To-date, we believe AB-729 is the only RNAi to show evidence of HBV-specific immune re-awakening. Through this collaboration, we have a unique opportunity to assess if the triple combination of AB-729, Vaccitech's immunotherapeutic VTP-300 and NA therapy further enhances HBV-specific immune T-cell responses resulting in an incremental and sustainable reduction in HBsAg beyond what we have already seen with AB-729 and NA therapy alone. We are excited to explore these compounds in combination and we look forward to seeing results from this promising study."

Dr. Tom Evans, Chief Scientific Officer for Vaccitech added, "Patients with HBV have high levels of HBsAg which can exhaust the immune system and prevent the clearance of HBV. By combining AB-729 with VTP-300, we are hoping to boost the immune system to manage the virus on its own by both reducing HBsAg levels and stimulating CD4+ and CD8+ T-cell responses in the liver."

The randomized, multi-center, blinded, Phase 2a clinical trial will evaluate the safety, antiviral activity and immunogenicity of VTP-300 administered after AB-729 in virologically-suppressed cHBV patients. The trial is designed to enroll 40 cHBV patients. All patients will receive AB-729 (60mg every 8 weeks) plus NA therapy for 24 weeks. At week 24, treatment with AB-729 will stop. Patients will continue only their NA therapy and will be randomized to receive either VTP-300 or placebo for an additional 24 weeks. At week 48 all participants will be evaluated for eligibility to either discontinue or remain on NA therapy.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens, including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated *N*-Acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

About VTP-300

VTP-300 is a novel immunotherapy, dosed in a prime-boost regimen, whereby the immune system is primed with an adenovirus (ChAdOx1) and boosted with a pox virus (MVA). Both vectors have been modified to improve safety, enhance the immune response they induce and include HBV specific antigens including core, polymerase and surface antigen. Clinical data generated to date has demonstrated this regimen to be generally safe and well-tolerated, that antigen specific T cell responses are stimulated to each antigen and there were meaningful reductions in hepatitis B surface antigen when this regimen is given alone or when given in combination with a low dose of nivolimab at the boost.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. In HBV, we are developing an RNAi therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine with the aim of providing a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729, is the only RNAi therapeutic with evidence of immune re-awakening. It is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). In addition, we are exploring oncology applications for our internal PD-L1 portfolio. For more information, visit www.arbutusbio.com.

About Vaccitech

Vaccitech ("the Company") is a clinical-stage biopharmaceutical company engaged in the discovery and development primarily of novel immunotherapies for the treatment of chronic infectious diseases, cancer, autoimmunity and diseases where the T cell arm of the immune system is believed to play an important role. The company's proprietary platforms include modified simian adenoviral vectors (ChAdOx1 and ChAdOx2), other viral vectors including the well-validated Modified Vaccinia Ankara (MVA) and synthetic nano-particle technologies (SNAPvax™ and Syntholytic™) The combination of different technologies in a mix and match approach (heterologous prime-boost) consistently generates significantly higher magnitudes of T cells compared with other technologies and approaches. The company has a broad pipeline of both clinical and preclinical stage therapeutic programs to treat solid tumors, chronic viral infections, as well as a few prophylactic viral vaccine programs. Vaccitech co-invented a COVID-19 vaccine with the University of Oxford, now approved for use in many territories and exclusively licensed worldwide to AstraZeneca through Oxford University Innovation, or OUI. Vaccitech is entitled to receive a share of all milestones and royalty income received by OUI from AstraZeneca.

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 future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations and goals for our collaboration with Vaccitech and any potential benefits related thereto; and the potential for our product candidates to achieve success in clinical trials.

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 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 product candidate; Arbutus or Vaccitech may elect to change its 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; Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' or Vaccitech's 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.

Arbutus Contact Information

Investors and Media

William H. Collier
President and CEO
Phone: 267-469-0914
Email: ir@arbutusbio.com

Lisa M. Caperelli
Vice President, Investor Relations
Phone: 215-206-1822
Email: lcaperelli@arbutusbio.com

Vaccitech Contact Information

Media:

Katja Stout, Scius Communications (EU)
Direct: +44 (0) 7789435990
Email: katja@sciuscommunications.com

Katie Larch / Robert Flamm, Ph.D., Burns McClellan, Inc. (U.S.)
Email: klarch@burnsmc.com / rflamm@burnsmc.com

Investors:

Georgy Egorov, Vaccitech
Email: IR@vaccitech.co.uk