Arbutus Biopharma and Vaccitech Announce Clinical Trial Collaboration Agreement to Evaluate RNAi Therapeutic, AB-729, in Combination with Immunotherapeutic, VTP-300, in Subjects with Chronic Hepatitis B Virus Infection

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WARMINSTER, Pa. and OXFORD, United Kingdom, July 06, 2021 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) and Vaccitech plc (Nasdaq: VACC) today announced that the companies have entered into a clinical trial collaboration agreement to evaluate an innovative therapeutic combination for the treatment of subjects with chronic hepatitis B virus (HBV) infection (CHB) who are already receiving standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy.

The multi-center, Phase 2a clinical trial will evaluate the safety, pharmacokinetics, immunogenicity, and antiviral activity of Arbutus's proprietary GalNAc delivered RNAi therapeutic, AB-729, followed by Vaccitech's proprietary immunotherapeutic, VTP-300, in NrtI-suppressed subjects with CHB. The Phase 2a clinical trial is expected to initiate in the second half of this year and will be managed by Arbutus, subject to oversight by a joint development committee comprised of representatives from Arbutus and Vaccitech. The parties retain full rights to their respective product candidates and will split all costs associated with the clinical trial. Pursuant to the agreement, the parties intend to undertake a larger Phase 2b clinical trial depending on the results of the initial Phase 2a clinical trial.

"Based on the positive clinical results we have seen in our ongoing Phase 1a/1b clinical trial for AB-729, including recent data demonstrating increased HBV-specific immune responses, we believe AB-729 has the potential to become a cornerstone therapeutic in multiple future HBV combination regimens," stated Gaston Picchio, Chief Development Officer at Arbutus. "We are looking forward to initiating this proof-of-concept Phase 2a clinical trial, which will allow us to evaluate the combination of two promising clinical candidates with potential complimentary mechanisms of action. We believe combining AB-729, which is designed to reduce HBsAg resulting in increased HBV immune responses with VTP-300, an immunotherapeutic designed to elicit an HBV specific immune response, may offer patients with CHB a much needed and durable functional cure."

"CHB is characterized by T cell exhaustion, driven primarily by HBsAg, that may require immune modulation," said Tom Evans, MD, Vaccitech's Chief Scientific Officer. "Current treatments can control viral replication but do not cure the disease. We believe that a combination of immunotherapy, such as VTP-300, with agents that reduce hepatitis B surface antigen is a promising approach toward a functional cure. This clinical trial will be evaluating that hypothesis. If successful, we believe that VTP-300, along with siRNA, such as AB-729, could be a foundation for CHB combination therapy."

About the Phase 2a Clinical Trial

Pending regulatory approval, the trial is expected to enroll 40 NrtI-suppressed, Hepatitis B e-antigen negative or positive, non-cirrhotic CHB subjects. Subjects are expected to receive AB-729 + NrtI for 24 weeks. At Week 24, subjects will be randomized 1:1 to receive either NrtI + VTP-300 or NrtI + VTP-300 sham. At Week 48, all subjects are expected to be evaluated for eligibility to either discontinue all treatments or remain on their NrtI only. Subjects are expected to be followed for an additional 48 weeks.

About AB-729

AB-729 is an 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. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About VTP-300

VTP-300 utilizes Vaccitech's ChAdOx1-HBV/MVA-HBV prime-boost combination to elicit an immune response against HBV. The HBV DNA sequence contained in the viral vectors is derived from a genotype C sequence, which is the most common genotype circulating worldwide. Vaccitech's proprietary platform has demonstrated robust activation of cytotoxic CD8+ T cells (immune cells associated with clearance of HBV infected cells), which are believed to have the potential to lead to a functional cure for patients with CHB, a life-threatening disease that affects more than 250 million people worldwide. VTP-300 is currently being evaluated in ongoing Phase 1/2a clinical trial in healthy volunteers and CHB patients and a Phase 1b/2a clinical trial in CHB patients in combination with a low-dose checkpoint inhibitor.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. CHB represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective prophylactic vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct

mechanisms of action that it believes have the potential to provide a new 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, visit www.arbutusbio.com.

About Vaccitech

Vaccitech plc is a publicly traded (Nasdaq: VACC) clinical-stage biopharmaceutical company engaged in the discovery and development of novel immunotherapeutics and vaccines for the treatment and prevention of infectious diseases and cancer. The company's proprietary platform comprises proprietary modified simian adenoviral vectors, known as ChAdOx1 and ChAdOx2, as well as the well-validated Modified Vaccinia Ankara, or MVA, boost vector, both with demonstrable tolerability profiles and without the ability to replicate in humans. The combination of a ChAdOx prime treatment with subsequent MVA boost has consistently generated significantly higher magnitudes of CD8+ T cells compared with other technologies and approaches. The company has a broad pipeline of both clinical and preclinical stage therapeutic programs in solid tumors and viral infections and 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 the milestones and royalty income received by OUI from AstraZeneca.

Arbutus 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 expectations for the collaboration, including Arbutus' belief that combining the ability of AB-729 to reduce HBsAg with VTP-300, an immunotherapeutic that elicits an HBV specific immune response, may offer patients with chronic hepatitis B a much needed and durable functional cure; the timing and expected trial design of the Phase 2a clinical trial to be initiated by the parties pursuant to the agreement; Arbutus' belief that AB-729 has the potential to become a cornerstone therapeutic in multiple future HBV combination regimens; and the parties' plans for future collaboration clinical trials depending on the results of the initial Phase 2a clinical trial.

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: the parties may never realize the expected benefits of the collaboration; anticipated 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 candidate; Arbutus may elect to change its 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 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.

Vaccitech plc Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding risks and uncertainties related to Vaccitech's expectations regarding the benefits of this collaboration, including the potential benefits of using VTP-300 in triple combination with AB-729 and an NrtI, the timing and expected trial design of the Phase 2a clinical trial to be initiated by the parties pursuant to the agreement and Vaccitech's expectations that, if the clinical trial is successful, VTP-300 together with AB-729, could be a foundation for CHB combination therapy. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to numerous risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to timing and advancement of the planned clinical trial and other risks identified in Vaccitech's SEC filings, including its Quarterly Report on Form 10-Q for the first quarter of 2021 and subsequent filings with the SEC. Existing and prospective investors are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Vaccitech expressly disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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