Vaccitech Announces Positive Topline Final Data for HBV002 Study in People with Chronic Hepatitis B

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- *Completed Phase 1b/2a trial of VTP-300 met its primary and secondary endpoints*
- *VTP-300 is the first antigen-specific immunotherapy shown to induce sustained reductions in Hepatitis B surface antigen (HBsAg)*
- *Results will be presented at the upcoming European Association for the Study of the Liver (EASL) Congress in June*

OXFORD, United Kingdom, March 28, 2023 (GLOBE NEWSWIRE) -- Vaccitech plc (NASDAQ: VACC), a clinical-stage biopharmaceutical company focused on the development of novel T cell immunotherapeutics designed to use the power of the immune system to potentially treat and cure chronic infectious diseases, autoimmune diseases and cancer, today announced positive topline final data from the HBV002 study (NCT04778904), a Phase 1b/2a clinical trial of VTP-300 in people with chronic Hepatitis B (HBV) infection.

The completed trial, which included 55 patients with chronic hepatitis B, supported the generally favorable tolerability profile previously reported with VTP-300, with no incidents of VTP-300-related Grade 3 adverse events or product-related serious adverse events following study dosing. VTP-300 was observed to induce meaningful, sustained reductions of Hepatitis B surface antigen (HBsAg) in patients with chronic HBV. Declines were most prominent in patients with lower baseline HBsAg. The final results of the immunology assays are currently being analyzed and the full data, including tolerability and immunogenicity results, will be presented at the upcoming EASL Congress, June 21-24, 2023.

“The safety data and HBsAg reductions in the HBV002 study are very encouraging and we look forward to sharing the full data set, including immune responses, at the EASL conference,” said Bill Enright, CEO of Vaccitech. “Less than 10% of people with chronic HBV reach a functional cure with current therapies. We believe VTP-300 has the potential to be a critical component of functional cure for HBV, potentially eliminating the need for chronic treatment. Our ongoing trials are exploring dosing, including an additional booster, and combination approaches with readouts expected towards the end of the year.”

Topline Study Results
HBV002 was an open-label study to evaluate the safety, tolerability and immunogenicity of VTP-300, with or without low-dose nivolumab, in people with chronic HBV who are virally suppressed with oral anti-viral therapies. In the HBV002 study, 55 participants were randomized into four groups to receive combinations of VTP-300 and low-dose nivolumab, with follow-up for nine months after the first dose.

In the VTP-300 monotherapy group (Group 2; N=18), five patients had baseline HBsAg under 100 IU/mL. Of those five patients, three showed meaningful and durable reductions of HBsAg of 0.9-1.4 $\log_{10}$ at five and eight months after the last dose of VTP-300.

Group 3 (N=18) patients received VTP-300 in combination with a single low dose of nivolumab at the time of the booster dose. The mean $\log_{10}$ reduction in HBsAg was 0.8 at 3, 6, and 9 months (n=18, 18, and 17, respectively), with more prominent declines observed in patients with baseline HBsAg lower than 1,000 IU/mL (mean $\log_{10}$ reduction of 1.0 at 3, 6, and 9 months [n=13 at each timepoint]). Five patients in this group had baseline HBsAg lower than 100 IU/mL, of which three had persistent declines ranging from 1.4 to 3.4 $\log_{10}$ at 9 months. Moreover, two of these patients developed non-detectable HBsAg at 3 months, which persisted in both patients at eight months after the last dose, as assessed in a post-hoc analysis.

T cell immune responses to the HBV antigens encoded in VTP-300, as measured by ELISpot assay, were observed in the majority of individuals in Groups 2 and 3. In some responders, decreases in viral replication (measured via pre-genomic RNA) were noted and consistent with declines in HBsAg (viral load). Immune responses were seen across both virus genotypes B and C, which is consistent with studies of cross reactivity to the HBV core protein in healthy controls, where almost complete immunologic cross reactivity was seen to Hepatitis B virus genotypes A-E.

While there were no incidents of Grade 3 adverse events or serious adverse events related to VTP-300, transaminase flares occurred in two patients. Both of these incidents occurred in patients with HBsAg declines, but not in any of the patients who cleared HBsAg (<0.05 IU/mL).

A Phase 2b clinical trial to evaluate timing of low dose nivolumab and additional doses of the MVA boost component of VTP-300 (HBV003; NCT05343481) has been initiated in multiple countries within the Asia-Pacific region, with interim data expected in Q4 2023. In addition, a Phase 2a clinical trial, in collaboration with Arbutus Biopharma Corporation (NASDAQ: ABUS), is evaluating the safety, antiviral activity and immunogenicity of VTP-300 administered after Arbutus’ AB-729 in 40 virologically-suppressed chronic HBV patients, with interim data expected in Q4 2023.

About VTP-300
VTP-300 is a heterologous immunotherapy candidate consisting of an initial dose using the ChAdOx platform and a secondary dose(s) using MVA encoding multiple hepatitis B antigens, including full-length surface, modified polymerase and core antigens. VTP-300 is the first antigen-specific immunotherapy that has been shown to induce sustained reductions in Hepatitis B surface antigen. Vaccitech is studying VTP-300 in combination with other agents, including siRNA and low-dose anti-PD-1 antibodies, to control the infection and counterbalance the immune suppression and T cell exhaustion in the liver caused by chronic HBV.

About Hepatitis B
Globally it is estimated that there are more than 300 million people, including up to 2.4 million in the U.S. and 14 million in Europe, living with chronic HBV infection.[1,2] Prevalence is highest in East Asia and Africa.[3] Fewer than 10% of patients with chronic HBV infection will achieve a functional cure by using existing therapies.[4] Approximately 820,000 people die each year from hepatitis B and related complications, such as liver cirrhosis and hepatocellular carcinoma (HCC).[2] Hepatitis B diagnosis rates remain low, and as of 2019, only an estimated 10.5% of all those infected were aware of their infection.[2] As a result of low diagnosis rates and strict treatment eligibility guidelines, in 2019 only an estimated 6.6 million of the people with chronic HBV were on treatment.[2]

About Vaccitech
Vaccitech is a clinical-stage biopharmaceutical company focused on the development of novel T cell immunotherapeutics designed to utilize the power of the immune system to treat and cure chronic infectious diseases, autoimmune diseases, and cancer. The company stands apart through a proprietary, multi-platform approach that has shown the ability to induce higher magnitudes of T cells compared with other technologies. Vaccitech is uniquely positioned to address the needs of large, underserved patient populations through a diverse clinical-stage pipeline of investigational therapies targeting life-threatening diseases that pose significant public health risk and have limited treatment options. The company's lead product candidates include VTP-300, an immunotherapy candidate designed as a component of a potential functional cure for chronic hepatitis B viral (HBV) infection; VTP-200, a non-invasive, early-stage investigational treatment for persistent, high-risk human papillomavirus (HPV); VTP-850, a novel T cell investigational therapy for prostate cancer; and VTP-1000, a preclinical T cell therapeutic candidate for immune tolerance in celiac disease. Vaccitech has proven drug development and scientific expertise in the field of immunization, co-inventing a COVID-19 vaccine with the University of Oxford, which is now approved and exclusively licensed worldwide to AstraZeneca. For more information, visit www.vaccitech.co.uk.

Forward Looking Statements
This press release contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, which can generally be identified as such by use of the words "will," "forward," "believe," "potential," "expected," and similar expressions, although not all forward-looking statements contain these identifying words. These forward looking statements include, without limitation, express or implied statements regarding the Company's plans and strategy with respect to the HBV002 study, the timing for completion and reporting of results or additional data for the HBV003 study and the Phase 2a study in collaboration with Arbutus Biopharma Corporation, and the potential benefits of VTP-300 for the treatment of chronic HBV infections. 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 the success, cost and timing of the Company's product development activities and planned and ongoing clinical trials, the Company's ability to execute on its strategy, regulatory developments, approval of the Company's product candidates, the Company's ability to fund its operations, global economic uncertainty, including disruptions in the banking industry, and the impact that the COVID-19 pandemic may have on the Company's clinical trials, preclinical studies and access to capital and other risks identified in the Company's filings with the Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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.

References

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