Vaccitech reports promising interim efficacy analysis in Phase 1b/2a clinical study in chronic HBV

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Interim data from 27 patients, who had completed 3 months in the HBV002 study in chronic Hepatitis B (CHB) patients, demonstrated noted changes in surface antigen (HBsAg) levels, especially in the group receiving low-dose nivolumab with the heterologous boost (VTP-300).

The HBV002 study is enrolling 4 groups to explore prime-boost vector combinations, either MVA-HBV (prime) + MVA-HBV (boost), ChAdOx1-HBV (prime) + MVA-HBV (boost) (VTP-300), VTP-300 with low-dose nivolumab given at the boost, and VTP-300 with low-dose nivolumab given at both the prime and the boost.

The HBV002 study is designed to evaluate the different regimens and investigators will now look to focus enrollment on Group 2 which involves dosing of VTP-300 without nivolumab and Group 3, which involves dosing of VTP-300 with nivolumab administered with the MVA boost, due to the encouraging surface antigen (HBsAg) decrease measured in these study groups.

OXFORD, United Kingdom, Dec. 07, 2021 (GLOBE NEWSWIRE) -- Vaccitech plc (NASDAQ: VACC), a clinical-stage biopharmaceutical company engaged in the discovery and development of novel immunotherapeutics and vaccines, today announced a promising interim analysis of safety and efficacy data from the HBV002 study, including a review of surface antigen (HBsAg) levels in CHB patients.

Data from an interim analysis of immunogenicity and safety in Groups 1 and 2 were recently reported at the 2021 AASLD The Liver Meeting®, and a broader efficacy data set has now been analyzed, including patients receiving VTP-300 in combination with low-dose nivolumab (Groups 3 and 4).

The company has concluded that the results support a protocol change that will lead to a focus on enrolling patients into Groups 2 and 3.

The analysis of Group 3, patients on antivirals for at least 12 months with undetectable HBV DNA and a mean starting HBsAg level of 441 IU/ml, showed:

- *Mean of greater than one log decrease (-1.04) and a greater than one log decrease in HBsAg in 3/6 patients at 3 months.*
- *HBsAg in one patient was undetectable 3 months after starting the immunotherapy regimen.*
- *One patient with a decrease experienced a transaminase flare after the MVA boost plus nivolumab that resolved over 3 weeks.*
- *Despite the very small patient numbers the difference in mean HBsAg between Group 3 and the other groups was highly significant ($p < 0.01$).*

In addition, in the VTP-300 group without nivolumab (Group 2), one patient had a 1.29 log and one patient had a 0.70 log decrease at month 3 (2/6).

Enrollment into HBV002 will continue into 2022 and a further interim analysis, including more HBsAg level data, is anticipated during the first half of 2022.

“These interim efficacy results of the ongoing HBV002 study are very promising and build upon recent safety and T cell immunogenicity data from Groups 1 and 2 that were presented at AASLD this year,” said Thomas Evans, M.D., Chief Scientific Officer of Vaccitech. “The new analysis showed that some patients on chronic antivirals receiving VTP-300 alone, as well as in combination with a low-dose checkpoint inhibitor, experienced meaningful decreases in HBsAg levels.”

HBsAg is a hallmark of chronic HBV infection. Fewer than 10% of patients on current standard of care HBV therapies ever achieve distinct, sustained HBsAg decrease or loss, a state associated with functional cure of the disease.

Data from a previous interim analysis of HBV002 showed that VTP-300 was well-tolerated in CHB patients and that induced T cells were shown to be cross-reactive to two major HBV genotypes (C and D).

About HBV002

HBV002 is an open-label trial to determine the safety, immunogenicity and preliminary efficacy of ChAdOx1-HBV and MVA-HBV (VTP-300), with or without low-dose nivolumab, in patients with chronic HBV with supressed HBV DNA on nucleos(t)ide therapy.

As of December 6th, 2021, 33 patients had been enrolled, and no concerning safety signals or Serious Adverse Reactions have been reported.

Data presented at the AASLD The Liver Meeting® in October 2021 showed that VTP-300 induced antigen specific T cell responses to all antigens, with elevated responses to core and polymerase, as compared to healthy controls dosed with ChAdOx1-HBV alone in HBV001, who exhibited a greater response to surface antigen. As in the HBV001 results, T cell responses cross-reactive to Genotype D specific peptides were measured in the majority of patients.

About Vaccitech plc.

Vaccitech is a 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.

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, express or implied statements regarding: the clinical trials of ChAdOx1-HBV and the ChAdOx1-HBV/MVA-HBV (VTP-300) and low-dose nivolumab combination, the continued development of VTP-300 and the potential therapeutic effects and expected patient population of VTP-300. 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: 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, the Company's ability to fund its operations and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and preclinical studies and other risks identified in the Company's filings with the Securities and Exchange Commission (the "SEC"), including its Quarterly Report on Form 10-Q for the first quarter of 2021 and subsequent filings with the SEC. 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.

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