Barinthus Bio Announces Topline Data from Phase 1b/2 APOLLO Trial of VTP-200 in Persistent High-Risk Human Papillomavirus (HPV) Infections

Apr 18, 2024

- *Primary safety endpoint met; VTP-200 was generally well-tolerated, with no treatment-related grade 3 or higher adverse events (AEs) or serious AEs (SAEs).*
- *Positive trends in clearance rate for both high-risk (hr)HPV (60%, Group 2) and cervical lesions (67%,Groups 2 and 5), were observed in the groups receiving the highest ChAdOx dose.*
- *Pooled data from the five different active dose groups demonstrated no statistically significant improvement in either hrHPV or cervical lesion clearance in comparison to the placebo group.*

OXFORD, United Kingdom, April 18, 2024 (GLOBE NEWSWIRE) -- Barinthus Biotherapeutics plc (NASDAQ: BRNS), formerly Vaccitech plc, a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer, today announced topline final data from the APOLLO trial (also known as HPV001), a completed randomized, placebo-controlled Phase 1b/2 dose-ranging trial of VTP-200 in women with low-grade cervical lesions associated with persistent hrHPV infection.

“This was our first in-human, dose-ranging trial of VTP-200 in women with hrHPV-associated low-grade cervical lesions, who currently don’t have any treatment option until progression to high-grade lesions,” said Bill Enright, Chief Executive Officer of Barinthus Bio. “While we didn’t observe a significant improvement from VTP-200 in the overall pooled results, we did observe positive trends in the highest dose cohorts.”

APOLLO (NCT04607850) was a randomized, placebo-controlled Phase 1b/2 multi-center trial of 108 participants across the UK and EU evaluating the safety, tolerability and immunogenicity of VTP-200 in women aged 25-55 with persistent hrHPV infection and low-grade cervical lesions. The primary objective was to evaluate the safety and tolerability of VTP-200. The trial was also designed to assess the effect of VTP-200 on clearance of hrHPV infection and cervical lesion(s), as well as select appropriate doses for further development.

The APOLLO study met its primary safety endpoint, demonstrating that VTP-200 was generally well-tolerated and was administered with no treatment-related grade 3 or higher unsolicited AEs and no treatment-related SAEs.

The highest hrHPV clearance rate of 60% at Month 12 was observed in group 2, which included the highest dose of ChAdOx, compared to a 33% clearance rate in the placebo group. Groups 1, 3, 4 and 5 showed 12%, 11%, 33% and 36% hrHPV clearance rates, respectively.

The study also evaluated cervical lesion clearance rates in participants with both reported lesions at screening and visualization of the cervical transformation zone at 12 months (n=57). The highest cervical lesion clearance rate of 67% was observed in group 2 and group 5, both received the highest dose of ChAdOx, compared to 39% in the placebo group. Groups 1, 3 and 4 showed 40%, 20% and 33% cervical lesion clearance rates, respectively.

Pooled data from the five active dose groups showed no significant improvement in hrHPV clearance or cervical lesion clearance rates in comparison to the placebo group. Future development options for the VTP-200 program are currently being evaluated with further analyses ongoing.

“We were pleased to see that VTP-200 was generally well-tolerated, meeting the primary safety endpoint in this study. The most promising hrHPV and cervical lesion clearance data were observed in the highest ChAdOx-HPV dosing groups which is informative for future development,” said Nadege Pelletier, Chief Scientific Officer of Barinthus Bio. “However, these differences compared to placebo were not statistically significant given that the trial was not powered for individual dose group comparisons. Further analyses are ongoing, mostly focusing on immunological responses and we plan to share the detailed results in due course.”

About the APOLLO trial
APOLLO (NCT04607850) was a randomized, placebo-controlled Phase 1b/2 multi-center trial of 108 participants across the UK and EU evaluating the safety, tolerability and immunogenicity of VTP-200 in women aged 25-55 with persistent high-risk (hr) HPV infection and low-grade cervical lesions. The primary objective was to evaluate the safety and tolerability of VTP-200. The trial was also designed to assess the effect of VTP-200 on clearance of hrHPV infection and cervical lesion(s), as well as select the appropriate doses for further development. The study consisted of an open label, non-randomized, dose escalation lead-in phase (n=9), followed by a blinded, randomized main phase (n=99; 67 randomized to VTP-200 and 32 to placebo). Participant groups were dosed sequentially with ChAdOx and MVA 28 days apart, as follows: Group 1, ChAdOx $2x10^9$ viral particles (vp), MVA $1x10^7$ plaque-forming units (pfu); Group 2, ChAdOx $2x10^{10}$ vp, MVA $1x10^7$ pfu; Group 3, ChAdOx $2x10^8$ vp, MVA $1x10^8$ pfu; Group 4, ChAdOx $2x10^9$ vp, MVA $1x10^8$ pfu; Group 5, ChAdOx $2x10^{10}$ vp, MVA $1x10^8$ pfu.

About VTP-200
VTP-200 is an investigational immunotherapeutic combination regimen consisting of an initial dose using the ChAdOx vector and a second dose using MVA vector, both encoding the same HPV antigens, designed to elicit an antigen-specific T cell immune response to HPV. VTP-200 is being developed as a potential non-invasive treatment for persistent high-risk HPV infections and associated pre-cancerous cervical lesions.

About HPV
It is estimated that approximately 291 million women worldwide are carriers of human papillomavirus DNA.[2] Persistent genital HPV infection is responsible for almost all cases of cervical pre-cancerous lesions, which can lead to cervical carcinoma.[3] Over 95% of cervical cancers are caused by HPV infection.[3] Cervical cancer was the fourth most common cancer in women in 2022, with approximately 660,000 cases and 350,000 deaths from the disease worldwide.[3] The American Cancer Society predicted that in 2023, approximately 13,960 new cases of invasive cervical cancer would be diagnosed in the US with over 4,310 women dying from the disease.[4]

About Barinthus Biotherapeutics

Barinthus Bio is a clinical-stage biopharmaceutical company developing novel T cell immunotherapeutic candidates designed to guide the immune system to overcome chronic infectious diseases, autoimmunity and cancer. Helping people living with serious diseases and their families is the guiding principle at the heart of Barinthus Bio. With a broad pipeline, built around three proprietary platform technologies: ChAdOx, MVA and SNAP, Barinthus Bio is advancing a pipeline of five product candidates across a diverse range of therapeutic areas, including: VTP-300, an immunotherapeutic candidate designed as a potential component of a functional cure for chronic HBV infection; VTP-200, a non-surgical product candidate for persistent high-risk human papillomavirus (HPV); VTP-1000, an autoimmune candidate designed to utilize the SNAP-Tolerance Immunotherapy (TI) platform to treat patients with celiac disease; and VTP-850, a second-generation immunotherapeutic candidate designed to treat recurrent prostate cancer. Barinthus Bio's proven scientific expertise, diverse portfolio and focus on pipeline development uniquely positions the company to navigate towards delivering treatments for people with infectious diseases, autoimmunity and cancers that have a significant impact on their everyday lives. For more information, visit www.barinthusbio.com.

Forward Looking Statements
This press release contains forward-looking statements regarding Barinthus Bio 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 "may," "will," "plan," "forward," "encouraging," "believe," "potential," 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 our product development activities and clinical trials, including timing for readouts of any interim data or next steps for any of our programs, including VTP-200 and the APOLLO trial, the tolerability or potential benefits of VTP-200, and our ability to develop and advance our current and future product candidates and programs. Any forward-looking statements in this press release are based on our 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 our pipeline development activities and planned and ongoing clinical trials, our ability to execute on our strategy, regulatory developments, our ability to fund our operations and access capital, the risk that interim or topline data may not reflect final data or results, global economic uncertainty, including disruptions in the banking industry, the conflict in Ukraine, the conflict in Israel and Gaza, and other risks identified in our filings with the Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We expressly disclaim 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

1. Womens Health (Lond). 2021; 17: 17455065211020702. doi: 10.1177/17455065211020702
2. Lancet Infect Dis. 2007 Jul;7(7):453-9. doi: 10.1016/S1473-3099(07)70158-5
3. WHO, Cervical Cancer, 2024.
4. American Cancer Society, Key Statistics for Cervical Cancer, 2022.

IR contacts:
Christopher M. Calabrese
Managing Director
LifeSci Advisors
+1 917-680-5608
ccalabrese@lifesciadvisors.com

Kevin Gardner
Managing Director
LifeSci Advisors
+1 617-283-2856
kgardner@lifesciadvisors.com

Media contact:
Audra Friis
Sam Brown, Inc.
+1 917-519-9577
audrafriis@sambrown.com

Company contact:
Jonothan Blackbourn
IR & PR Manager
Barinthus Bio
ir@barinthusbio.com