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hVIVO PLC
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hVIVO plc

("hVIVO" or the "Company")

Positive topline results from client Phase 2b field study

hVIVO recruited participants and performed the virology and immunology laboratory services for the study

hVIVO plc (AIM: HVO), a full-service Contract Research Organisation (CRO) and the world leader in human challenge clinical trials, congratulates Cidara Therapeutics (Cidara: Nasdaq CDTX) on the positive topline results from their Phase 2b field study, for which hVIVO recruited participants and performed the virology and immunology laboratory services. The study was to determine the efficacy of Cidara's drug-Fc conjugate, CD388, which is designed as a non-vaccine preventative of seasonal influenza.

As part of the randomised, double-blind, placebo-controlled, multicenter dose selection study hVIVO enrolled 817 healthy participants via the Company's dedicated volunteer recruitment arm, FluCamp. Participants were administered with either a dose of CD388 or a placebo at hVIVO's Plumbers Row site and then free to leave the facilities, where they were monitored over the following months, with regular clinical check-ups, to collect samples and data used to assess the efficacy and safety of the candidate.

hVIVO's laboratory, hLAB, was selected as the sole virology laboratory for this international, multi-site Phase 2b field study to conduct the comprehensive virology and immunology analysis for the 61 study sites and approximately 5,000 participants worldwide. hLABs' responsibilities on the study include the conduct of ~60,000 antibody assays on serum samples and approximately 450 PCR assays on respiratory swabs to detect and quantify influenza virus levels in the participant's samples. In addition, the contract includes more extensive analysis on the virus detected in participant samples via genotypic and phenotypic analyses -all carried out at hVIVO's state-of-the-art laboratory facility in Canary Wharf.

The study met its primary endpoint with a statistically significant prevention efficacy (PE), p <0.0001. Furthermore, the primary efficacy analysis showed a statistically significant PE for each of three dose groups in individuals who received a single dose of CD388 at the beginning of the flu season and were evaluated for laboratory and clinically confirmed influenza over 24 weeks. 0.7% of the subjects who were given a single 450 mg dose came down with an influenza-like illness (ILI) over the course of the flu season. This was statistically significant versus the 2.8% of placebo subjects who experienced ILI. The study also met all its secondary endpoints, including efficacy in participants with temperatures of 37.8 and 37.2 degrees Celsius, as well as maintenance of efficacy for another month after the end of the trial.

Upon the success of these results, the client has submitted an end of Phase 2 meeting request to the FDA to review the Phase 2b results and further discuss the Phase 3 trial design and start time.

Yamin 'Mo' Khan, Chief Executive Officer of hVIVO, said:*"This has been our largest field study clinical conduct and hLAB laboratory support contract to date, and we are pleased to have worked with Cidara to assess the efficacy and safety of their candidate for the prevention of seasonal influenza. We were selected as the sole UK site in this multicentre study, which is a testament to the professionalism and high standards that we uphold on behalf of our clients. The success of this trial also illustrates hVIVO's ability to run sizeable field trials in addition to those that take place in its facilities in Canary Wharf and Germany.*

"It is very pleasing to see positive results from this study which was supported by our newly introduced tiered participant recruitment offering, and this is a good example of the successful delivery of our diversified hVIVO revenue streams."

Dr. Andrew Catchpole, Chief Scientific Officer of hVIVO, said: *"These are extremely impressive results, with influenza prevention efficacy having been demonstrated in all CD388 dose levels tested and with statistical significance achieved not only in the primary efficacy analysis but also for all the secondary efficacy endpoints. This product previously demonstrated influenza illness prevention efficacy in a challenge study conducted by hVIVO, so we are delighted to now see the product demonstrate*

such excellent results in this phase 2b field study. At hVIVO, we are pleased to have been able to continue to help in the clinical development of this important and novel non-vaccine preventative of influenza".

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Notes to Editors

hVIVO plc(Ticker: HVO) is full-service early-phase Contract Research Organisation (CRO) and the global leader in human challenge trials. The company delivers end-to-end clinical development services to a diverse and expanding client base, including seven of the world's ten largest biopharma companies.

hVIVO specialises in conducting human challenge trials across multiple infectious and respiratory indications, leveraging its state-of-the-art quarantine facility in London-the largest of its kind worldwide. The company also offers comprehensive virology and immunology laboratory services under the **hLAB** brand.

Through its German subsidiary, **CRS**, hVIVO operates a 120-bed capacity across Mannheim and Kiel, providing early-phase clinical trial services, including first-in-human and proof-of-concept studies. Its second subsidiary, **Venn Life Sciences** offers Early Drug Development Consulting and Biometry services to the biopharma sector.

The Group provides fully integrated drug development solutions from preclinical stages through Phase II trials, alongside patient recruitment via **FluCamp**. Additionally, its five clinical sites support outpatient Phase II and III trials, ensuring a seamless and efficient pathway from discovery to late-stage development.

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