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hVIVO PLC
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hVIVO plc

("hVIVO", the "Company" or the "Group")

£2.5m Contract for Omicron characterisation study

Highlights

- Characterisation study to establish world's first Omicron BA.5 challenge model
- Study to utilise hVIVO's new state-of-the-art containment level 3 (CL3) quarantine facilities in Canary Wharf
- FluCamp to recruit healthy 18-30 year old seropositive volunteers who have previously completed a course of COVID-19 vaccination
- New quarantine unit in Canary Wharf facilitates the expansion of hVIVO's world leading portfolio of human challenge models

hVIVO plc (AIM & Euronext: HVO), a fast growing specialist contract research organisation (CRO) and world leader in testing infectious and respiratory disease products using human challenge clinical trials, announces that it has signed a £2.5m contract with a mid-sized pharmaceutical company to initiate an Omicron characterisation study (the "Study"). The manufacture of hVIVO's Omicron BA.5 challenge agent was successfully completed in 2023.

The Study aims to identify a dose of hVIVO's Omicron BA.5 challenge agent that establishes a safe, measurable and reproducible disease in healthy volunteers with sufficiently high infection rates to then be able to use the model to test the efficacy of antivirals and vaccines in the future. The Company's dedicated volunteer recruitment arm, FluCamp, will recruit healthy volunteers aged 18-30 years who have previously received a full course of a licenced COVID-19 vaccine. Characterisation studies offer numerous benefits to biopharma clients, including insights into specific pathogens that are more precise, actionable, and relevant to support and refine vaccine or antiviral development. They also provide the necessary data from which to design subsequent antiviral or vaccine efficacy testing studies.

The Study is expected to commence in Q4 2024, with the majority of revenue recognised in 2025, and will take place at the Company's new CL3 quarantine facility at Canary Wharf. hVIVO's facility has been specifically designed to meet the highest hospital isolation suite standards suitable for CL3 pathogens and is equipped with advanced safety features including physical containment barriers, controlled ventilation systems with negative pressure and HEPA filtration, and comprehensive waste management protocols. This is the first COVID-related work that hVIVO will be undertaking since the manufacture of the Omicron BA.5 challenge agent.

Dependent on the successful completion of the characterisation study and receipt of relevant regulatory approvals, the Company expects to conduct multiple Omicron human challenge trials to test the efficacy of medical products from mid-2025. hVIVO successfully conducted the world's first SARS-CoV-2 characterisation study, using the original COVID-19 strain in 2021, with data showing that SARS-CoV-2 human challenge studies are safe in healthy young adults.

Yamin 'Mo' Khan, Chief Executive Officer of hVIVO, said: *"One of our key goals at hVIVO is to further diversify our challenge trial offerings. The establishment of a COVID challenge model is a key step to penetrating a new and expanding market, especially with regards to mucosal and multi-valent COVID vaccine development. This study will take place at our new CL3 quarantine facility in Canary Wharf, which will open shortly. The new site, which was largely funded by a number of key clients, is the largest human challenge trial quarantine clinic in the world and is highly specialised in its design to facilitate the safe conduct of challenge studies. Securing this contract further validates the move to our new facilities and the new opportunities it brings for CL3 category projects."*

Dr Andrew Catchpole, Chief Scientific Officer of hVIVO, said: *"We are excited to begin work on characterising our Omicron challenge agent, which has been made possible by our new CL3 facilities in Canary Wharf. We have leading expertise in characterising SARS-CoV-2 challenge agents, having successfully conducted the world's first COVID-19 characterisation study. The client funding towards this study demonstrates the strong interest and growing pipeline in this indication due to the continued risk that COVID-19, and particularly the Omicron strain, poses to global health and ongoing need for improved vaccines and treatments."*

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Notes to Editors

About hVIVO

hVIVO plc (ticker: HVO) (formerly Open Orphan plc) is a rapidly growing specialist contract research organisation (CRO) and the world leader in testing infectious and respiratory disease vaccines and therapeutics using human challenge clinical trials. The Group provides end-to-end early clinical development services to its large, established and growing repeat client base, which includes four of the top 10 largest global biopharma companies.

The Group's fast-growing services business includes a unique portfolio of 11 human challenge models, with a number of new models under development, to test a broad range of infectious and respiratory disease products. The Group has world class challenge agent manufacturing capabilities, specialist drug development and clinical consultancy services via its Venn Life Sciences brand, and a lab offering via its hLAB brand, which includes virology, immunology biomarker and molecular testing. The Group offers additional clinical field trial services such as patient recruitment and clinical trial site services.

hVIVO runs challenge trials in London with a new 50 quarantine bedroom, state-of-the-art facilities opening in Canary Wharf in 2024, with highly specialised on-site virology and immunology laboratories, and an outpatient unit. To recruit volunteers / patients for its studies, the Group leverages its unique clinical trial recruitment capability via its FluCamp volunteer screening facilities in London and Manchester.

About Omicron

Omicron is a variant of SARS-CoV-2 that was first reported to the World Health Organization in November 2021 and is characterised by its heightened transmissibility compared to previous variants. It is associated with a range of symptoms similar to previous variants, such as fever, cough, and fatigue, with many cases reporting milder symptoms.

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