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hVIVO PLC
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hVIVO plc

("hVIVO" or the "Company")

£11.5 million RSV contract signed with existing top-tier global pharmaceutical client

Notice of trading update

hVIVO plc (AIM: 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 an £11.5 million contract with an existing top-tier global pharmaceutical client to test its antiviral candidate using hVIVO's Respiratory Syncytial Virus ("RSV") Human Challenge Study Model.

The Phase 2a randomised, double-blinded placebo-controlled human challenge trial will evaluate the safety, pharmacokinetics and antiviral activity of the drug candidate. hVIVO will leverage its in-house volunteer recruitment arm, FluCamp, to enrol healthy volunteers into the study. The study is scheduled to commence in H2 2025 at hVIVO's state-of-the-art quarantine facilities in Canary Wharf, with revenue expected to be recognised across 2025 and 2026.

This repeat contract with an existing client highlights the value that global pharma place on hVIVO's human challenge trials. hVIVO's trials offer a time-efficient and cost-effective way to generate early human efficacy data and inform later stage trial design, which can accelerate the path to market for new therapies.

RSV remains a leading cause of childhood lower respiratory infections and is responsible for a significant burden of disease in the elderly and in adults with chronic medical problems, such as COPD. Globally RSV affects an estimated 33 million people annually, leading to approximately 4 million hospitalisations and approximately 101,000 RSV attributable deaths in children under five years.[1] Even with a number of RSV vaccines approved in recent years, there remains a considerable unmet need for effective antivirals that address acute disease which continues to have a major impact on vulnerable populations globally.

To date, hVIVO has inoculated c.2,000 healthy volunteers across 30 RSV challenge trials which has successfully expedited the development of several RSV drug and vaccine candidates for a number of biopharmaceutical companies. Use of hVIVO's RSV challenge model has provided compelling, pivotal, proof of concept data that has directly led to product acquisitions as well as some products receiving FDA Fast Track and / or Breakthrough Designations. The model has also been used for an RSV product that has now been launched to market. hVIVO's challenge trials continue to be a key drug development tool helping companies to develop products to combat RSV as well as other infectious and respiratory diseases.

Yamin 'Mo' Khan, Chief Executive Officer of hVIVO, said: *"This contract further demonstrates the trust and confidence that leading pharmaceutical companies place in hVIVO's human challenge study models. We are proud to work with four of the top 10 global pharmaceutical companies to address unmet medical need in infectious and respiratory diseases. Our unique and established RSV model can provide valuable data on a candidate's safety, pharmacokinetics, and efficacy, reducing the risks associated with later-stage clinical development and accelerating the pathway to market."*

Dr Andrew Catchpole, Chief Scientific Officer of hVIVO, said: *"While the recent approvals of the world's first RSV vaccines represent a major step forward, the virus continues to pose a substantial risk to public health, especially among vulnerable populations. The need for effective antiviral treatments that can counteract severe illness remains urgent, and human challenge trials can play a pivotal role in the development of these therapeutics."*

Confirmation of FY 2024 guidance and notice of trading update

The Company reaffirms its FY 2024 revenue guidance of £62 million, with full year EBITDA margins anticipated to be at the upper end of market expectations.*

Consistent with the Company's usual timetable for providing forward guidance the Company expects to announce a trading update for the year ended 31 December 2024 before the end of February 2025, which will include the outlook for 2025.

**Consensus market expectations for FY24 EBITDA margins are 22.7%, within a range of 22-24%.*

[1] Li Y et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet. 2022 May 28;399(10340):2047-2064. doi: 10.1016/S0140-6736(22)00478-0. Epub 2022 May 19. PMID: 35598608; PMCID: PMC7613574.

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation ("MAR") EU no.596/2014. Upon the publication of this announcement via Regulatory Information Service *("RIS"), this inside information is now considered to be in the public domain.*

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Notes to Editors

About hVIVO

hVIVO plc (ticker: HVO) is a fast-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 also offers additional clinical field trial services such as patient recruitment and clinical trial site services.

hVIVO runs challenge trials in London - its new state-of-the-art facilities in Canary Wharf opened in 2024 and is the world's largest commercial human challenge trial unit, 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.

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