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HVIVO PLC
("hVIVO" or the "Company")

hVIVO announces initial results from a Phase IIb study of FLU-v, a first-in-class universal flu vaccine candidate

hVIVO plc (AIM: HVO) today announces encouraging initial results from a Phase IIb study examining FLU-v as a potential universal vaccine against influenza (flu). Preliminary analysis of the primary endpoint revealed a trend to statistical significance, with further testing of samples ongoing that could affect the final outcome. In addition, the study demonstrated a statistically significant reduction in overt flu symptoms in treated subjects in one arm of the trial (p=.02). Importantly, this vaccine candidate is designed to minimise the impact of the virus by reducing symptoms - potentially relegating flu to a much milder disease - through stimulating an immune response mediated through T-cells, in contrast to seasonal flu vaccines, that prevent infection through antibody protection. The Company believe this is the first time that any universal flu vaccine candidate has demonstrated a statistically significant reduction in a symptom measure for flu in humans in a controlled clinical study.

FLU-v is being developed by Imutex Limited, hVIVO's 49% joint venture with PepTcell Limited, trading as the SEEK Group ("SEEK").

The FLU-v Challenge Study
The FLU-v Phase IIb flu challenge study (ClinicalTrials.gov Identifier: NCT03180801) was part of the collaboration between PepTcell Limited and the National Institute of Allergy and Infectious Diseases, part of the US National Institute of Health (NIH). In this double-blind placebo-controlled single-site study, conducted at hVIVO's quarantine facilities, 123 volunteers were randomised to one of two FLU-v plus adjuvant dosing regimen arms[1] or a placebo plus adjuvant arm. Given the novel putative mechanism of action of FLU-v, the study employed a panel of study endpoints allowing the Company and the NIH to explore broadly the most relevant efficacy endpoints for future clinical development. These included composite endpoints involving symptom scores and lab-determined biomarkers, such as viral load, as well as symptom-based endpoints that are suited to FLU-v's mechanism of action.

The primary endpoint, a novel composite score combining the occurrence of one symptom of flu-like illness and changes in viral load, trended to statistical significance in the single FLU-v dose arm versus placebo when using qPCR to determine viral load. The NIH is currently independently evaluating, as a prespecified part of this study, this primary endpoint using the more multifaceted Luminex platform (the platform on which the study powering was derived) to determine viral load. Results of these tests could impact the final result. This data will be presented in due course. Encouragingly, a key secondary endpoint, a reduction in at least two symptoms, achieved statistical significance (p=.02) in the single dose plus adjuvant cohort when compared to placebo. Furthermore, in most endpoints analysed to date, there was a statistical trend for the single dose FLU-v arm performing better than placebo. These endpoints included a reduction in the number and severity of symptoms and the length of time subjects shed virus.

Interestingly, no signals of efficacy were seen in any of the endpoints on comparing the double FLU-v plus adjuvant arm to placebo. However, this was not unexpected as it is known that the relationship between vaccine peptide dose and T-cell response is complex[2].

FLU-v was well tolerated in this study. The profile of adverse events was similar between both FLU-v dosing arms and placebo.

Kym Denny, CEO of hVIVO, commented:
"While we note the preliminary determination that the primary endpoint only trended to statistical significance, we are mindful of the prespecified additional analysis being conducted by the NIH, that may have an impact, before opining conclusively. That said, the symptom reduction data we have seen in this study with FLU-v is incredibly exciting and consistent with this universal flu vaccine candidate's putative mechanism of action. In the real world, ultimately, it is symptom reduction that is a clinically meaningful outcome if it can reduce the more severe flu disease, which is the concern and significant burden of healthcare systems across the world. This is, to our knowledge, the first time a universal flu vaccine candidate has demonstrated statistically significant reduction in a symptom score in humans. As a result, we believe FLU-v could be the most advanced universal flu vaccine candidate in development. With its potential for significant disease efficacy, broad protection against all flu strains, simplified manufacturing and the ability to be administered as a stand-alone vaccine - rather than in combination with traditional seasonal flu vaccine - FLU-v could help provide relief from flu to people across the globe."

FLU-v, a universal flu vaccine candidate
FLU-v is a synthetic polypeptide-based vaccine candidate designed to protect against all strains of the virus. This includes both human flu A and B strains of influenza as well as animal strains, which when mutated and transmitted in man can lead to pandemic outbreaks of influenza.

Published data to date has shown that FLU-v is safe and induces a vaccine specific cellular immunity. Cellular immune responses are historically known to control and mitigate infection and illness during natural infection.

[1] The two FLU-v arms were (i) a single FLU-v dose plus adjuvant arm (one dose FLU-V plus adjuvant followed by one dose placebo plus adjuvant) (ii) a double FLU-v dose plus adjuvant arm (one dose FLU-v plus adjuvant followed by another dose of FLU-v plus adjuvant)

[2] See Leggatt, GR *Vaccines* **2014**, *2*, 537-548

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Notes to Editors:

About hVIVO plc

hVIVO plc ("hVIVO") is pioneering a human-based analytical platform to accelerate drug discovery and development in respiratory and infectious diseases. Leveraging human disease models in flu, RSV and asthma exacerbation, the hVIVO platform captures disease in motion, illuminating the entire disease life cycle from healthy to sick and back to health. Based in the UK, market leader hVIVO has conducted more than 50 clinical studies, inoculated over 2500 volunteers and has three first-in-class therapies currently in development with a growing pre-clinical pipeline.