



hVIVO plc
("hVIVO" or the "Company")

HVIVO reports that the Phase IIb viral challenge Study for FLU-v (FLU-v004) achieved the primary endpoint of a statistically significant reduction in Mild to Moderate Influenza

Update to results announced 26 March 2018

Completes a compelling Phase II FLU-v data package around this first-in-class 'universal', broad spectrum, standalone, influenza vaccine candidate

- *Primary endpoint achieved*
- *Additional endpoint achieved statistical significance and is identified as potential primary endpoint for future Phase III trials*

London, UK 10 January 2019: hVIVO plc (AIM: HVO), an industry leading clinical development services business pioneering human disease models based upon viral and allergen challenge, today announces positive result for the primary endpoint, following completion of analysis of samples by NIAID and additional results from the Phase IIb viral challenge study of FLU-v, (Study 004, NCT03180801). FLU-v is being developed by Imutex Limited, hVIVO's 49% joint venture with the SEEK Group.

- *Following additional analysis of the samples from the study by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health, hVIVO reports that the study's primary endpoint achieved a statistically significant result*
 - *One dose of FLU-v produced a highly statistically significant reduction in the primary endpoint of Mild to Moderate Influenza Disease (MMID), comprising a positive signal of influenza infection and at least one influenza symptom, compared with placebo ($p=0.035$)*
- *A statistically significant additional endpoint has been achieved ($p=0.006$) from further data analysed by the NIAID from FLU-v 004, which confirmed the result for the primary endpoint and has the potential to become the primary regulatory endpoint for Phase III*
- *These results together with the previously reported highly statistically significant reduction in symptoms endpoint ($p=0.023$) and performing better than placebo in a number of other key endpoints is evidence of the vaccine's protective effect*

Trevor Phillips, Executive Chairman of hVIVO, said: "We are pleased to finally be in a position to report a positive primary endpoint outcome for this Phase IIb challenge study resulting from the NIAID's additional analysis of samples taken during the study. These results follow an announcement in March 2018 confirming that key secondary endpoints in symptom reduction had achieved statistical significance and indicating that the NIAID would be conducting further sample analyses to assess the primary endpoint outcome, as the initial analysis, using results from a less sensitive assay for the presence of influenza virus, had showed the primary endpoint only trended to statistical significance. The more sensitive assay, routinely utilised by NIAID to assess the presence of virus, identified more cases of influenza infection than had originally been determined, resulting in the achievement of statistical significance. These final results are further verification that FLU-v is achieving measures of clinical efficacy and is now positioned to enter Phase III. The successful achievement of statistical significance in the primary endpoints from two Phase II studies confirms that FLU-v has clinical impact in establishing immunity and disease, symptom and viral load reduction. The exploratory design of -004 has also enabled us

to determine, what we believe to be the most appropriate clinical efficacy endpoint, relating to confirmed influenza infection, for application in the Phase III programme and we look forward to discussing this with the regulatory authorities at our next meetings

We continue to endeavour to progress strategic discussions with regards to our joint venture, Imutex, and to maximise the strategic options available to both companies as we now await publication of the data from the UNISEC and NIAID FLU-v studies in peer reviewed journals.”

Gregory Stoloff, Chief Executive Officer of SEEK, said: *“NIAID has been conducting further and a more sensitive viral detection analysis on the FLU-v challenge study results as previously communicated. Our FLU-v vaccine has now demonstrated in two different Phase IIb studies, a statistically enhanced immune response which has translated into a statistical reduction in the number of people getting sick and severity of influenza symptoms which remains a significant burden to public health globally.”*

Further details on Phase IIb challenge study of FLU-v (FLU-v 004)

A challenge study conducted by hVIVO using the NIAID virus, methods and analysis as a result of a collaboration between SEEK and NIAID.

A randomised, double-blind, placebo-controlled single-centre trial in collaboration with to assess the efficacy and safety of two different formulation and dosing regimens of FLU-v vaccine administered in healthy adults. In this trial, 123 subjects (aged 18-60 years) were assigned to either placebo or treatment arms.

- The primary endpoint was to assess the incidence of MMID which is defined as evidence of viral shedding in nasopharyngeal swab samples and the presence of at least one symptom.

Supportive regulatory and academic environment

The development of a universal influenza vaccine has become a worldwide public health priority in both industrialised and low-and middle-income countries. A large number of government, academic, public and private organisations (such as, for example, WHO, BARDA, NIH, FDA and EMA) are supportive of development of such a vaccine. These global stakeholders have indicated the benefits of vaccines that induce broad immunity so as to prime the population against newly emerging influenza viruses or other respiratory viruses of pandemic potential.

Significant unmet need

FLU-v is intended to address a number of key issues associated with current annual influenza vaccines whose effectiveness varies from year to year, which need to be redesigned every year, are available in limited quantities due to manufacturing cost, complexity and lead times and which offer limited protection over pandemic influenza. A synthetic universal flu vaccine offering long lasting protection across a broad spectrum of influenza which could be given to a much broader population would be a significant step forward, and a potential future blockbuster in terms of sales.

- Ends -

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This announcement is released by hVIVO plc and contains inside information for the purposes of the Market Abuse Regulation (EU) 596/2014 ("MAR") and is disclosed in accordance with the Company's obligations under Article 17 of MAR. The person who arranged for the release of this announcement on behalf of hVIVO plc was Trevor Phillips, Executive Chairman.

Notes to Editors:

About FLU-v – a Phase III enabled, broad spectrum stand-alone, universal influenza vaccine candidate

FLU-v is a novel first-in-class, broad spectrum, true stand-alone, influenza vaccine candidate. FLU-v is designed to provide broad spectrum cover against multiple influenza strains and does not require annual immunisation alongside an annual influenza vaccine to confer immunity. It is also designed to minimise the impact of the influenza virus by reducing symptoms, potentially relegating influenza to a much milder disease by stimulating an immune response mediated through T-cells and B-cells to the internal proteins, in contrast to seasonal influenza vaccines that prevent infection through antibody protection against external proteins. In 2017, there were two FLU-v Phase IIb studies conducted– 003 (field study) and 004 (human viral challenge study).

FLU-v is a synthetic polypeptide vaccine which means that it is not reliant on traditional manufacturing techniques with inherent risks, in particular the potential of a miss-match of virus particularly relevant for a pandemic strain. FLU-v is designed to protect against a broad range of influenza viral strains and this includes unexpected seasonal strains or a potentially devastating pandemic strain.

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

About Influenza

Influenza is one of the major person-to-person transmittable respiratory viral infections in humans. Globally, seasonal influenza epidemics cause 3 million hospitalisations and 290,000 – 650,000 deaths annually¹. The annual global economic burden associated with seasonal influenza globally is \$260 billion and the impact of a severe pandemic can result in millions of deaths, and even the most conservative estimates suggest that pandemics destroy up to 1% of the global GDP². The current strategy to prevent influenza-associated health risks is annual immunisation of risk populations. Yet, current vaccines need to be adjusted each year and even then it is not guaranteed that they will match the circulating epidemic virus. Moreover, current vaccines are not effective against newly emerging influenza virus strains as demonstrated during the H1N1 influenza pandemic in 2009. Universal influenza vaccines which would be capable of providing protection against a broad spectrum of influenza virus strains are thus urgently needed. Such vaccines need to be based on conserved constituents of the virus and should raise humoral as well as cellular immunity that effectively protect against influenza-associated disease symptoms.

About hVIVO:

hVIVO plc ("hVIVO") is pioneering a human-based clinical trial platform to accelerate drug and vaccine development in respiratory and infectious diseases. Leveraging human disease models in flu, RSV, HRV and respiratory indications, 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 and inoculated over 2500 volunteers.

¹ <http://www.endfluenza.com>

² CDC, WHO

About SEEK Group (PepTCell Limited, trading as SEEK Group)

SEEK's strategy is to bring safe, effective and low-cost medicines to patients as quickly as possible, to radically improve human health in major disease areas.

We do this by:

- Modifying existing medicines to improve their efficacy
- Using existing medicines in new indications
- Creating new chemical entities

Working in these different ways allows us to optimise the regulatory approval pathway to ensure that we bring safe and effective products to patients in the shortest possible time.

Forward-looking statements

This announcement includes statements that are, or may be deemed to be, forward-looking statements. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms anticipates, believes, estimates, expects, intends, may, plans, projects, should or will, or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements include all matters that are not historical facts. Any forward-looking statements in this announcement reflect the Group's (or, as the case may be, the hVIVO directors') current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's operations, results of operations and growth strategy. Investors should specifically consider the factors identified in this announcement which could cause actual results to differ before making an investment decision.