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

hVIVO reports positive results from the Phase IIb field study of FLU-v (FLU-v 003) representing a significant advance in the management of influenza disease

- *Primary and secondary endpoints achieved - induction of long-lasting T and B cell immunological responses*
- *Reduction in influenza infection rates and severity and duration of symptoms observed*
- *Treatment with FLU-v was well tolerated with an adverse event profile consistent with earlier studies*
- *Based on the results of two Phase IIb trials and previous studies, FLU-v is now ready for Phase III development*
- *FLU-v product profile is a broad spectrum (A, B and Pandemic strains), stand-alone, single injection influenza vaccine providing long-lasting protection and significant reduction in influenza symptoms and their severity*
- *By overcoming a number of key issues with current annual influenza vaccines it has the potential to address a much larger patient population and therefore has future blockbuster sales potential*

Webcast and conference call for analysts at 1pm BST today – see details below

London, UK, 18 June 2018: hVIVO plc (AIM: HVO), a pioneer of human disease models and an industry leading clinical development services business, today announces positive results from a second Phase IIb study of FLU-v, (Study 003, NCT02962908).

FLU-v is being developed by Imutex Limited, hVIVO's 49% joint venture with the SEEK Group.

Trevor Phillips, Executive Chairman of hVIVO, said*: "We are pleased that a second Phase IIb study has reported positive results for FLU-v. It is our view that FLU-v is now positioned to enter Phase III, with clear disease and symptom-based endpoints identified.*

The market potential for a broad spectrum universal influenza vaccine is significant. Along with our joint venture partner SEEK, and with a differentiated data-package, we will endeavour to maximise the strategic options available to the Company from FLU-v while still focusing on our other revenue streams."

Gregory Stoloff, Chief Executive Officer of SEEK, said: *"The disease and symptom reduction seen with this "universal" influenza vaccine candidate is achieved by stimulating an immune response mediated through T&B-cells to internal conserved influenza proteins, in contrast to seasonal influenza vaccines that prevent infection through antibody protection against external variable proteins. 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."*

Dr. P.H.P. Groeneveld, Principal Investigator for FLU-003 study, Isala Hospitals, The Netherlands, said: "*The broad spectrum late stage-development FLU-v vaccine is a promising step in the battle against influenza. It has shown to induce very potent Th1 immune response to influenza proteins that could reduce infections and severe symptoms".*

Webcast and conference call for analysts at 1pm BST today

Trevor Phillips, Executive Chairman, Tim Sharpington, Managing Director R&D joined by Greg Stoloff, Chief Executive Officer of SEEK Group, will host a live conference call and webcast for analysts at 1pm BST today, 18 June 2018, to discuss this announcement. Please visit hVIVO's website approximately 10 minutes before the conference call to download the presentation slides.

The presentation and access to the live webcast will be on hVIVO's website at www.hvivo.com. An audio replay file will be made available shortly afterwards via hVIVO's website.

Further details on Phase IIb field study of FLU-v (FLU-v 003)
UNISEC consortium EU-funded

A randomised, double-blind, placebo-controlled, single-centre trial part of the EU-funded European Universal Influenza Vaccines Secured Consortium ("UNISEC") project, to assess the immunogenicity, safety and exploratory efficacy of two different formulations and dosing regimens of FLU-v vaccine administered in healthy adults. In this trial, 176 subjects (aged 18-60 years) were assigned to either placebo or treatment arms.

- The primary endpoint was to assess the immunogenicity responses of different formulations and regimens versus placebo at 42 and 180 days post vaccination in healthy volunteers
    - The primary endpoint of enhancing T-cell responses was met demonstrating a statistically significant enhancement of the number of responders positive for interferon gamma (IFNγ) producing T-cells ($p<0.001$), at both 42 days and 180 days after single vaccination. IFNγ is one of the most important markers of T-cell mediated immunity effective against influenza infection
- The secondary immunogenicity related endpoint was to assess the FLU-v specific antibody, immunoglobulin (IgG) responses at both 42 and 180 days after single vaccination compared to placebo
    - The secondary endpoint achieved a statistically significant increase in antibody titers of 100% of vaccinated subjects ($p<0.001$) and is one of the most important markers of B cell mediated immunity against influenza infection
- The reduction in the number of people getting disease and severity of symptoms observed in this study was consistent with the top-line FLU-v 004 challenge study results. In this (003) study a single dose of FLU-v was shown to induce the strongest immunological response rates and this group also experienced a 60% reduction in influenza confirmed infections and an 83% reduction in the number of influenza confirmed cases with severe symptoms compared to placebo
- Importantly for a broad-spectrum vaccine, the combined Phase IIa and IIb FLU-v studies showed disease and symptom improvement following infection by A strains (H3N2 Wisconsin 002 Challenge Study, H1N1 in 004 Challenge Study and H3N2 Hong Kong confirmed infections in 003 Field Study) and B strains (Phuket/3073/2013 and Brisbane/60/2008 confirmed infections in 003 Field Study). Previously it had also been shown that immune cells from vaccinated people recognise a whole range of different unrelated influenza strains, of human and animal origin, *in vitro*
- Overall, FLU-v was safe and well tolerated with the majority of adverse effects being reported as mild to moderate and related to reaction at the site of injection that resolved in time
- The most immunological and efficient dosing regimen seen over the numerous studies was a single dose of adjuvanted FLU-v. A single dose will simplify the logistics of future vaccination campaigns. The extended duration of response offers the promise of long lasting protection

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 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 would prefer a standalone vaccine over a booster to the annual vaccine and have therefore prioritised support for 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 shortcomings 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.

Study FLU-v 003 data consistent with results from FLU-v 004 a Phase IIb clinical human challenge study of FLU-v
Further results will be released on this very shortly.

- 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 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 12,000 – 56,000 deaths annually[1]. 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 GDP[2]. 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 Mexican Flu 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 UNISEC
UNISEC is a European consortium consisting of 3 academic partners, 5 National Health Institutes and SMEs, all with leading expertise in influenza vaccine research and development. The expertise present in the consortium spans the entire range from vaccine design via vaccine formulation to vaccine production, pre-clinical and clinical testing and regulatory issues.

This project received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 602012.
The consortium is supported by an advisory board consisting of representatives from the influenza vaccine industry, public health institutions, the World Health Organization (WHO), the European Centre for Disease Control (ECDC), and the Biomedical Advanced Research and Development Authority (BARDA). UNISEC is coordinated by Prof. Dr. Henderik W. Frijlink, Pharmaceutical Technology and Biopharmacy, Department of Pharmacy, University of Groningen, The Netherlands, and started its activities in October 2013.
The UNISEC consortium is unique in being devoted to comparative evaluation of a panel of universal influenza vaccine candidates. Thus, rather than focusing on a single vaccine, UNISEC harbours a variety of vaccine concepts and these are tested in head-to-head comparison or in standardised animal or clinical tests. This approach allows comparison of the pros and cons of the different vaccine candidates and facilitates selection of the most promising vaccine candidates for further development. http://uniseccconsortium.eu/

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.

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.

[1] http://www.endfluenza.com
[2] CDC, WHO

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.