



HVIVO PLC
(“hVIVO” or the “Company”)

NIH present partial preliminary results from the Phase I first-in-man study of AGS-v, a Universal mosquito-borne diseases vaccine candidate

- *National Institutes of Health (NIH) presented partial preliminary results for some of the primary endpoint evaluations at the American Society of Tropical Medicine and Hygiene’s sixty-seventh annual conference, New Orleans, US*
- *Based upon currently available data the Phase I study met Primary Objectives and Endpoints with regard to safety and humoral response*
- *The remaining Primary and Secondary endpoints will be evaluated once the full and final data are available*
- *Given favourable safety profile and results so far, the vaccine warrants further development*

London, UK, 30 October 2018: hVIVO plc (AIM: HVO), an industry leading clinical development services business pioneering human disease models based upon viral and allergen challenge, confirms that the National Institutes of Health (NIH), has presented partial preliminary results from the recently completed Phase I study of AGS-v at the American Society of Tropical Medicine and Hygiene’s (ASTMH) sixty-seventh annual conference, New Orleans, US.

The presentation at the conference focused on safety and certain immunogenicity results of AGS-v, a mosquito saliva peptide vaccine in the randomized, double-blind, placebo-controlled Phase I trial.

Certain primary objectives and endpoints met.

- AGS-v did not cause any clinically significant adverse events
- Observed increase in vaccine -specific IgG antibodies with adjuvant present which was long lasting

Additional assays of the immunogenicity response and *in vitro* virus killing are ongoing and will be reported in due course. These will enable determination of the remaining primary endpoint analysis related to immunogenicity, along with the secondary endpoints.

Given the safety profile of the vaccine observed in this study further development of the vaccine will continue.

AGS-v is being developed by Imutex Limited, hVIVO's 49% joint venture with the SEEK Group and the AGS-v Phase I study is being conducted by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH.

Trevor Phillips, Executive Chairman of hVIVO, said: "The presentation of these partial preliminary results by NIH at the ASTMH conference is encouraging regarding safety and immunogenicity responses. We look forward to seeing the full data when the NIH completes the sample analyses in due course, at which point, a full assessment of the trial results will be possible".

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Further details on AGS-v randomized, double blind, placebo-controlled Phase I trial:

Parasites and viruses carried within mosquito saliva appear to initiate or enhance severity of host infection by taking advantage of saliva-human host interactions. This leads to alteration of the cutaneous environment and modulation of the host's innate and adaptive immune responses, thereby providing a rationale for creating vaccines against mosquito salivary proteins rather than the pathogens contained within the saliva, or a combination of both.

AGS-v is a vaccine composed of four salivary peptides isolated from *Anopheles gambiae* salivary glands, but that are common across a number of mosquitoes. This first-in-human study enrolled and randomized 49 healthy adult participants to receive the AGS-v vaccine with and without adjuvant (Montanide ISA 51) versus placebo. Vaccinations occurred at Day 0 and Day 21 followed by an uninfected *Aedes aegypti* mosquito feeding at Day 42. Primary objectives were: 1) to assess safety via incidence of adverse events and 2) to evaluate humoral and cellular immunity by respectively measuring total AGS-v specific immunoglobulins and Th1-associated cytokine release after incubation of peripheral blood mononuclear cells with AGS-v antigens. Secondary objectives are post-mosquito feeding measures of AGS-v specific immunoglobulins and Th1-related cytokine release, mosquito survival and fecundity, as well as the effects of immunized individuals' peripheral blood mononuclear cells on Zika virus after stimulation with *Aedes aegypti* saliva.

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.

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.