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

hVIVO landmark asthma stratification initiative, supporting targeted therapy development, is underway

hVIVO plc (AIM: HVO), the pioneer of human disease models, is delighted to announce that the Company's landmark asthma stratification initiative is now underway, with the first volunteer inoculated with human rhinovirus (HRV) at hVIVO's London based clinical research unit. The hVIVO asthma stratification program will characterise asthma patients according to clinical and biomarker phenotypes following HRV challenge to discover a more effective way to differentiate subtypes of asthma patients – enabling the development of targeted therapies, disease biomarkers and more precision medicine-based approaches to asthma care.

Asthma: Urgent Medical Need

Asthma is a heterogeneous disease that affects more than 300 million people, with many people remaining sub-optimally controlled and currently with no cure. More than 80% of asthma attacks or exacerbations are caused by viruses, primarily HRV. With over \$14.7 billion health care-related expenses per year, a third of which are due to hospitalisations from severe asthma attacks alone, there is a critical unmet need for new asthma treatments.

There are currently no simple tests to diagnose asthma or differentiate between various asthma phenotypes, and no easy way to predict when a patient is at risk of an asthma attack or exacerbation, making it difficult to develop targeted therapies today. Historically treated as one condition, up to 10% of asthma patients do not respond well to current treatments and 50% of adult asthma patients in the US have asthma that is uncontrolled – highlighting the urgent need for more personalised therapies.

Dynamic Study of Asthma "in Motion": First Step Towards Precision Medicine

The hVIVO asthma initiative is one of the first dynamic phenotyping projects aiming to characterise asthma not only in the static or baseline state, but also throughout the evolution of an exacerbation following viral infection, the most common cause of exacerbations of asthma. The hVIVO initiative will leverage the hVIVO viral-induced asthma exacerbation disease model to map the underlying biology associated with asthma exacerbations.

This unique phenotyping study involves a total of 500 subjects, including both healthy and asthma patients (GINA 1-5). It aims to define asthma phenotypes and possible endotypes (i.e. underlying disease mechanisms) through HRV-16 challenge induced clinical and biomarker changes, as well as safety and tolerability to HRV-16 challenge in healthy and a broad range of asthma subjects.

Using the hVIVO platform of human disease models, a common cold infection from human rhinovirus (HRV-16) is generated in asthma patients and these patients are then continuously monitored as their condition is exacerbated by the viral infection. This approach is expected to reveal biological causality previously unseen by scientists.

In addition to phenotyping asthma patients, this approach is expected to discover useful biomarkers for predicting and developing more efficacious treatments for exacerbations of asthma – a vital first step to advancing more precision-medicine based treatments. Interim data analysis is expected to be conducted in the third quarter of 2017.

Kym Denny, hVIVO CEO commented, “Even though millions suffer from asthma today, very little is understood about this disease. Even less is known about preventing asthma attacks, where viruses are the predominant cause. After two years in designing, planning and piloting, we are excited to officially kick off the sample collection phase of this exciting project. We believe the hVIVO platform’s capability to provide a window into the disease process and capture exacerbations in action will be a powerful tool in the fight to treat and prevent asthma.”

Sources:

1. http://www.cdc.gov/asthma/asthma_stats/uncontrolled_asthma.htm
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3. Dougherty et al (2009) Acute Exacerbations of Asthma: Epidemiology, Biology, and the Exacerbation-Prone Phenotype, *Clin Exp Allergy*; 39(2):193-202
4. Choy et al, (2015) TH2 and TH17 inflammatory pathways are reciprocally regulated in asthma, *Science Transl Med*, 7(301):301ra129
5. <http://www.ginasthma.org/>

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Notes to Editors:

About hVIVO

hVIVO is a life sciences company pioneering a technology platform of human disease models to accelerate drug discovery and development in respiratory and infectious diseases, including flu, RSV, asthma and common cold. hVIVO has commercialised four disease models, successfully enrolled over 2,000 subjects and conducted over 45 product validation studies for a wide range of industry, government and academic clients and collaborators. For more information, please visit www.hvivo.com, Facebook and Twitter.