First patients entered into Phase II trial of VHsquared's lead Vorabody product V565

HARBOR study of novel anti-TNFα oral domain antibody taking place in North America & Europe

Cambridge, UK, February 20 2017 – VHsquared, the oral domain antibody company, is pleased to announce that the first patients have entered the international Phase II trial of its lead product, V565, in Crohn's disease. The aim of the HARBOR study[1] is to show the efficacy of the anti-TNFα oral domain antibody as measured by changes in clinical symptoms, markers of inflammation and endoscopic appearance. It is randomised, double-blind and placebo-controlled, involving over 100 patients with moderately to severely active Crohn's disease. VHsquared is developing a portfolio of complementary oral domain antibodies (Vorabodies) which engage validated biological targets with the potential to transform the treatment of inflammatory bowel disease (IBD).

HARBOR follows on from a recently completed successful Phase I trial which emphasised the clinical potential of V565. The product was shown to be safe and well tolerated at high single and multiple doses, with minimal systemic exposure and no drug-induced antibodies. In addition, the trial confirmed that high concentrations of active V565 were delivered throughout the gastro-intestinal tract in volunteers and Crohn's patients.

V565, an orally administered protease-resistant domain antibody, has been designed to achieve optimum local concentrations directly at the site of disease in the GI tract. It is therefore expected to combine the dramatic clinical impact of injectable systemic anti-TNFα antibodies in IBD with the benefits of oral administration, resulting in activity targeted to the site of inflammation, negligible systemic exposure and minimal immunogenicity.

Arthur Kaser MD, PD Professor of Gastroenterology at the University of Cambridge, UK, said, 'Inflammatory bowel diseases are debilitating conditions in clear need of new therapeutic approaches, so I'm delighted to be involved in this exciting trial. The profile of V565 offers a step change in approach to IBD management, potentially resulting in substantial disease modification early in its course, reducing progression, improving quality of life and bringing significant benefits to patients.'

Rod Richards, CEO of VHsquared said, 'Following on from the successful Phase I trial of our lead product, V565, we are pleased to have progressed rapidly to Phase II trial enrolment. We believe that V565 offers a transformational approach to the treatment of IBD, with oral delivery of the Vorabody achieving a highly desirable clinical impact.'

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[1] A Six Week Efficacy, Safety and Tolerability Study of V565 in Crohn's Disease, NCT02976129