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Company Announcements Office
Australian Securities Exchange

Vectus Announces Completion of Phase Ia for VB0004

Vectus Biosystems Limited (Vectus or the Company) is pleased to announce the completion of the third and last of the three planned cohorts in the Multiple Ascending Dose (M.A.D.) segment of its first-in-human trial: "A phase I/Ib, first-time-in-human, single centre, double-blind, randomized, placebo-controlled, dose escalating study of the safety, tolerability and pharmacokinetics of single and repeat doses of VB0004 administered orally to healthy volunteers; and to patients with mild to moderate hypertension with low cardiovascular risk", which has been reviewed by the Trial Safety Review Committee (Committee).

In this cohort of normal healthy subjects who received a 100mg dose of VB0004 for 14 consecutive days no significant adverse events were reported. This study group has further enhanced the impressive safety record of VB0004. The interim pharmacokinetics (PK) analysis confirms again that the time to achieve the maximal concentration (T_{max}) of VB0004 occurred six to eight hours after dosing and that the plasma half-life (the time taken for the plasma concentration of VB0004 to decrease by 50%) was 10 to 15 hours on both Days 1 and 14. The data also suggests that little to no accumulation of VB0004 occurred with time in normal individuals. This data reinforces the previous evidence that VB0004 will be amenable to once daily dosing, a desirable feature in medications for chronic conditions such as hypertension, heart failure, kidney failure and pulmonary fibrosis.

To-date the Committee has reviewed data from all five planned Single Ascending Dose (S.A.D.) cohorts as well as all three planned M.A.D. cohorts. This Phase Ia trial has established an impressive safety profile for VB0004 with a maximum tolerated single dose of 300mg and no significant adverse events seen in M.A.D. studies at 10mg, 30mg or 100mg administered daily over a 14-day period. Also established are consistent PK of six to eight hours to achieve maximal plasma concentration and a half life in excess of 10 hours.

The Committee has now given permission for the Phase Ib section of the trial to commence. In this section of the clinical trial patients with uncomplicated hypertension will be treated for 28 days at a dose of 30mg of VB0004 per day.

The trial is registered on the Clinical Trials Protocol Registration and Results Systems (ClinicalTrials.gov) and has been provided with the identifier NCT04925050. Protocol details may be found using this number on the ClinicalTrials.gov public website.

Vectus Chairman, Dr Ronald Shnier said: "This is a significant milestone in proving the safety of our antifibrotic / antihypertensive drug. This is particularly pleasing as we move towards the next phase of testing of a compound that can have a significant and widespread global positive impact on disease, the pathology of which has many aetiologies."

Vectus Biosystems Limited

Karen Duggan MD FRACP
Chief Executive Officer and Executive Director

This Vectus announcement was authorised by the Board of Directors.

About Vectus Biosystems Limited

Vectus Biosystems Limited is developing a treatment for fibrosis and high blood pressure, which includes the treatment for three of the largest diseases in the fibrotic market, namely heart, kidney and liver diseases. Vectus successfully completed its Initial Public Offering (IPO) on the Australian Securities Exchange (ASX:VBS) and commenced trading on ASX on 23 February 2016, after raising A$5.1 million. Funds from the IPO were predominantly used to develop the Company's lead compound, VB0004, which aims to treat the hardening of functional tissue and high blood pressure. Vectus has conducted a range of successful pre-clinical trials, which have shown that VB0004 slows down the advances of fibrosis, potentially repairs damaged cell tissue and reduces high blood pressure. VB0004 is now progressing through a number of important milestones, including pharmaceutical scale-up and additional toxicity studies. Following successful results, the late 2019 convertible note fundraising and the late 2020 share placement, the Company has funding for its Human Phase I trial. Vectus' strategy is to develop and perform early validation of its drug candidates to the point where they may become commercially attractive to potential pharmaceutical partners.

The Company has also developed technology aimed at improving the speed and accuracy of measuring the amount of DNA and RNA in samples tested in laboratories. The technology, called Accugen, is owned by Vectus' wholly-owned subsidiary Accugen Pty Limited. The technology offers a time, cost and accuracy benefit compared to currently-available systems. The Company's current stage of investment in Accugen is a commercialisation programme that may include direct sales, distribution partnerships and licensing opportunities.