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Company Announcements Office  
Australian Securities Exchange

## **Vectus Announces a Significant Milestone for VB0004**

Vectus Biosystems Limited (Vectus or the Company) is pleased to announce that the fourth of the five planned cohorts in the Single Ascending Dose (S.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”, has been reviewed by the Trial Safety Review Committee (Committee).

To-date, the results of the 2mg, 10mg, 30mg and 100mg doses of VB0004 have been reviewed by the Committee. Most significantly, no adverse events have been observed at any of the four doses of VB0004 studied to-date and the latest dose of 100mg has added materially to the therapeutic safety margin for VB0004. The lack of adverse events has allowed the Committee to give permission to proceed with three further studies, being:

- the last S.A.D. Cohort, which has a planned dose of 300mg of VB0004;
- the Food Effect study, in which Cohort 3 subjects will return and have pharmacokinetic (PK) measurements undertaken when VB0004 is taken following food ingestion; and
- the first Multiple Ascending Dose (M.A.D.) Cohort, which will receive a dose of 10mg of VB0004 per day for 14 days.

Thus, this approval represents a significant milestone in VB0004’s trajectory.

The interim PK analysis showed that the maximum plasma concentration of VB0004 increased with the increased dose. The time to achieve its maximal concentration ( $T_{max}$ ) after dosing did not change, but the plasma half-life (the time taken for the plasma concentration of VB0004 to decrease by 50%) increased to 17-17.5 hours. This preliminary data provides further 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.

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 Biosystems Limited**

#### **Karen Duggan**

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 several 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.