



17 June 2021

Company Announcements Office
Australian Securities Exchange

VECTUS RECEIVES APPROVAL FOR VB0004 PHASE I HUMAN TRIAL IN AUSTRALIA

HIGHLIGHTS

- Phase I human trial in healthy volunteers to commence in Melbourne in July 2021
- Phase Ib human trial to commence in Melbourne in January 2022
- The trial has been registered by ClinicalTrials.gov – identifier NCT04925050

Vectus Biosystems Limited (Vectus or the Company) is pleased to announce that its Phase I/Ib trial, entitled: “A phase I/Ib, first-time-in-human, single centre, double blind, randomised, 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 received approval from the Human Research Ethics Committee of the Alfred Hospital, Melbourne. The trial has been registered on the Clinical Trials Protocol Registration and Results Systems (ClinicalTrials.gov), and has been provided with the identifier NCT04925050. The trial may be tracked using this number on the ClinicalTrials.gov public website.

The trial site (Nucleus Network, Alfred Campus) will commence the process of recruitment and screening of study subjects in July 2021 for this first-in-human trial. The first component will be what is termed a Single Ascending Dose (SAD) study. In this SAD study a cohort or group of eight subjects (six treated and two placebo) will receive a single nominated dose of VB0004 on one occasion. The dose level is then escalated and the process repeated. This continues until the maximal dose has been reached and this segment of the trial is completed.

The Company’s Chairman, Dr Ron Shnier, said: “This is a significant milestone in the progress of Vectus in bringing forward its orally-active small molecules to first-in-human studies here in Australia. VB0004 is a first-in-class agent for fibrotic disease. It has been shown in animal studies to reverse existing fibrosis in hearts, kidneys and lungs. This addresses a significant unmet need, globally.”

The Company today has a strong portfolio of granted patents with an extensive patent life remaining, a library of over 1,000 compounds and a number of emerging lead compounds that Vectus is targeting to bring to clinical evaluation in the future. The Company believes that the successful translation of peptides into small molecules is an important driver of Vectus’ ability to develop new orally-active agents to treat human disease.

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 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.