

ASX ANNOUNCEMENT

30 September 2026

Vectus Granted FDA Pre-IND Meeting Request for VB0004 in IPF

Vectus Biosystems Limited (ASX:VBS) (Vectus or the Company) is pleased to announce that the US Food and Drug Administration (FDA) has granted the Company's request for a pre-Investigational New Drug (pre-IND) Type B meeting, in which written responses regarding Vectus' proposed development program for VB0004 in Idiopathic Pulmonary Fibrosis (IPF) will be tabled.

The FDA's detailed responses are expected to be received by mid-November 2026.

In conjunction with its US Regulatory Agent, Cardinal Health Regulatory Services, the Company will now finalise and submit its meeting package to the FDA.

Vectus' Chief Executive Officer and Chief Technology Officer (CEO & CTO), Dr Tara Speranza, said: "FDA granting of our pre-IND meeting request represents an important step in progressing the US regulatory pathway for VB0004 and provides us with the opportunity to obtain formal guidance on our proposed development program in IPF.

"We are now focused on finalising our meeting package, with the FDA's written responses expected in November 2026. This feedback will help inform the next stages of VB0004's clinical and regulatory development as we work towards advancing the program."

VB0004 is the Company's first-in-class oral vasoactive intestinal peptide (VIP)-mimetic and natriuretic peptide receptor C (NPR-C)-agonist in development for the treatment of IPF. Vectus has completed a Phase Ia clinical study in healthy volunteers establishing a favourable safety and pharmacokinetic profile. US regulatory activities are now underway to establish the foundation for future clinical development in the US.

Dr Ronald Shnier
Chairman

Dr Tara Speranza
CEO & CTO
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This announcement was authorised by the Board of Directors.

About Vectus Biosystems Limited

Vectus Biosystems Limited (ASX:VBS) (Vectus or the Company) is an Australian clinical-stage biotechnology company developing novel therapies for fibrotic diseases, with an initial focus on advancing its lead compound, VB0004, for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive, and often fatal, lung disease with significant unmet medical need. VB0004 is a first-in-class antifibrotic candidate that has demonstrated the ability to reverse established fibrosis in pre-clinical models, and has successfully completed Phase Ia clinical studies, establishing a favourable safety and pharmacokinetic profile.

Beyond IPF, the Company is advancing a broader pipeline of antifibrotic assets targeting cardiovascular, renal and liver fibrosis, leveraging a platform approach to address diseases driven by pathological tissue scarring. The commercial potential of the platform has been externally validated through a licensing agreement with an international biotechnology company for one of Vectus' renal fibrosis assets, showing a pathway for potential future milestone and royalty revenues.

The Company will continue its clinical development with an ambition to create shareholder value through the advancement, partnering and commercialisation of innovative therapies that address significant unmet needs in fibrotic disease.