ASX Announcement

18 March 2025

FDA Approves Cambium Bio's Potency Assay Strategy for Elate Ocular® Phase 3 Clinical Trials

Sydney, Australia; 18 March 2025: Cambium Bio Limited (ASX:CMB) (**Cambium Bio, Cambium** or **Company**), a clinical-stage regenerative medicine company focusing on the development of innovative biologics for ophthalmology and tissue repair applications, is pleased to announce successful outcomes from its Type D meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's potency assay strategy for Elate Ocular®.

Key Highlights:

- The FDA has agreed that Cambium Bio's proposed cell-based assay for assessing biological activity, complemented by EGF and PDGF-BB ELISA assays, is suitable as a lot release potency assay to support Phase 3 clinical trials through to BLA approval
- The FDA also agreed with the Company's approach to determine acceptance criteria for the cell-based EGF activity bioassay for lot release of clinical trial material and a commercial product
- The FDA confirmed that the proposed cell-based EGF-activity bioassay is suitable for incorporation into a comparability protocol designed to demonstrate equivalence between Phase 1/2 and pathogen-inactivated Phase 3 investigational products
- This regulatory milestone represents one of the final Chemistry, Manufacturing, and Controls (CMC) topics to be addressed before initiating registration-enabling Phase 3 clinical trials

These positive outcomes from the FDA meeting enable Cambium Bio to finalize the validation of this potency assay with its Contract Development and Manufacturing Organization (CDMO) ahead of Phase 3 clinical trials for Elate Ocular®, which are planned to commence in mid-2025.

Karolis Rosickas, CEO of Cambium Bio, commented: "The FDA's agreement on our potency assay strategy represents a significant regulatory milestone for Cambium Bio as we prepare to advance Elate Ocular® into pivotal Phase 3 clinical trials for moderate to severe dry eye disease. This positive outcome underscores the robustness of our CMC and analytical development approach and keeps us on track to initiate our registration-enabling Phase 3 programme mid-year."

About Elate Ocular®

Elate Ocular® is Cambium Bio's lead product candidate, based on the Company's proprietary fibrinogen-depleted human platelet lysate (FD hPL) technology. Elate Ocular® is being developed to address significant unmet medical needs in the treatment of moderate to severe dry eye disease. The product has demonstrated promising efficacy and safety in Phase 1/2 clinical trials.

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About Cambium Bio Limited

Cambium Bio Limited (ASX:CMB) is a Sydney-based clinical-stage regenerative medicine company focusing on the development of innovative biologics for ophthalmology and tissue repair applications. The Company's proprietary technology, based on human platelet lysate, is being leveraged to create a pipeline of novel therapeutics, with a primary focus on ophthalmology. Cambium Bio's lead product candidate, Elate Ocular®, is being developed to address significant unmet medical needs in the treatment of dry eye disease. In addition, the Company's stem cell platform, Progenza™, is being applied to the development of therapies for knee osteoarthritis and other tissue repair indications. Cambium Bio is committed to advancing its pipeline through clinical development and commercialization, with the goal of providing transformative treatments to improve patient outcomes. For more information about the Company and its programs, please visit www.cambium.bio

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of Cambium Bio Limited.

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