ASX Announcement

11 July 2025

Cambium Bio Clears FDA Regulatory Hurdles to Commence Phase 3 Dosing for Elate Ocular®

Sydney, Australia; 11 July 2025: Cambium Bio Limited (ASX:CMB) (**Cambium Bio, Cambium** or **Company**), a clinical-stage regenerative medicine company focused on ophthalmology and tissue repair, is pleased to announce that it has now cleared U.S. Food and Drug Administration (FDA) regulatory requirements to initiate patient dosing in its registration-enabling Phase 3 clinical trials of Elate Ocular® for the treatment of moderate to severe dry eye disease (DED).

This milestone follows a Type C FDA meeting held on 16 January 2024, during which the FDA requested comparability data to address manufacturing changes implemented following the Company's Phase 2 study. These changes included the addition of a pathogen inactivation step, in line with FDA guidance for blood-derived therapeutics such as Elate Ocular®.

Over the past 18 months, Cambium Bio has conducted an extensive Chemistry, Manufacturing and Controls (CMC) comparability programme, including validation of a potency bioassay and production of cGMP drug product for use in the Phase 3 studies. The Company has also secured ethics approvals in both Australia and the United States and finalised its trial protocol with the FDA.

Dr Neera Jagirdar, VP of Clinical Development at Cambium Bio, commented:

> *"We are very pleased to have satisfied all FDA requirements to start dosing patients in our Phase 3 trials for dry eye disease. This marks an important milestone in our mission to bring Elate Ocular® to patients suffering from this debilitating condition. We are excited to be entering the final stages of what has been a long and rigorous development process for a therapy that has the potential to significantly improve quality of life for millions of patients who currently lack access to safe and effective treatments."*

With regulatory clearance secured, initiation of the Phase 3 trials—CAMOMILE-2 and CAMOMILE-3—is now subject only to additional financing. Cambium Bio is actively

engaged in discussions with strategic investors and capital markets participants to fund this next critical stage of development.

- ENDS -

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.

For further information, please contact:
Acclime Australia – Company Secretary
Email: info@cambium.bio

Cambium Bio Limited
Unit 2.06/31 Lexington Drive, Bella Vista, NSW 2153 Australia
ABN 13 127 035 358
Phone: 1300 995 098
www.cambium.bio