ASX Announcement

30 June 2025

Cambium Bio Receives Ethics Approvals in Australia and the United States for Phase 3 Clinical Trials of Elate Ocular®

Sydney, Australia; 30 June 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 obtained ethics approval to commence its registration-enabling Phase 3 clinical trials of Elate Ocular® for the treatment of moderate to severe dry eye disease in both Australia and the United States.

Key Highlights:

- Ethics approval granted by Bellberry Human Research Ethics Committee (HREC) in Australia on 26 June 2025
- Ethics approval granted by Advarra Institutional Review Board (IRB) in the United States on 9 May 2025
- First patient dosing anticipated in October 2025
- Top-line data expected in calendar Q3 2026
- Trials form part of a global Multi-Regional Clinical Trial (MRCT) programme

The Australian ethics approval (HREC2025-03-448) was granted by Bellberry Limited for the Phase III CAM-101-003 study, which will assess the safety and efficacy of Elate Ocular®, Cambium's novel biologic eye drop derived from fibrinogen-depleted human platelet lysate (FD hPL). In parallel, Advarra IRB has approved the same protocol (Pro00086421) for US-based sites, with site-specific submissions to follow.

These approvals mark another important milestone in Cambium Bio's development pathway for Elate Ocular®, following FDA clearance of the clinical protocol in February 2025 and confirmation of the potency assurance strategy in March 2025.

Karolis Rosickas, CEO of Cambium Bio, commented:

"Obtaining ethics approvals in both Australia and the United States is a critical step forward in our mission to bring Elate Ocular® to patients suffering from moderate to severe dry eye disease. We will now focus on site activation and operational readiness for first patient dosing in October 2025. This is a pivotal moment for Cambium Bio as we prepare to initiate the final stage of clinical development for our lead product."

The Phase 3 trials, CAMOMILE-2 and CAMOMILE-3, will randomise approximately 800 patients globally in a double-masked, placebo-controlled design. Co-primary endpoints include improvement in both signs (Total Corneal Fluorescein Staining) and symptoms (Eye Discomfort VAS Score) of dry eye disease.

These trials are designed to support registration of Elate Ocular® in major markets, with a Biologics License Application (BLA) submission targeted following completion of the Phase 3 programme.

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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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