ASX Announcement

25 February 2025

FDA Approves Elate Ocular® Phase 3 Clinical Trial Protocol

Sydney, Australia; 25 February 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 that the U.S. Food and Drug Administration (FDA) has approved the protocol for the registration-enabling Phase 3 clinical trials of Elate Ocular® for the treatment of moderate to severe dry eye disease.

Key Highlights:

- FDA approval of the Phase 3 clinical trial protocol represents a significant milestone in advancing Elate Ocular® towards market registration
- The Phase 3 programme consists of two identical registration-enabling trials (CAMOMILE-2 and CAMOMILE-3) designed to meet FDA requirements for Biologics License Application (BLA)
- The trials will be conducted as a Multi-Regional Clinical Trial (MRCT) across sites in Australia, the United States, and select other countries
- Protocol approval follows the recent grant of FDA Fast Track designation in December 2024, further validating Elate Ocular's potential to address significant unmet needs in dry eye treatment

Phase 3 Programme Design

The Phase 3 programme comprises two identical randomised, double-blinded, vehicle-controlled trials that will evaluate the safety and efficacy of Elate Ocular® compared to placebo:

- Total enrolment of 800 patients (400 per trial) with moderate to severe dry eye disease
- Balanced 1:1 randomisation between Elate Ocular® and placebo arms
- Co-primary endpoints:
    - Signs: Change in Total Corneal Fluorescein Staining score (tCFS)
    - Symptoms: Change in Eye Discomfort Score measured by Visual Analog Scale (VAS)

- Treatment period consists of 2-week run-in followed by 9 weeks of treatment
- A subset of patients will participate in a 43-week long-term safety follow-up.

Cambium Bio CEO, **Karolis Rosickas**, commented: "FDA approval of our Phase 3 protocol marks a pivotal milestone in Elate Ocular's development journey. The trial design reflects extensive consultation with regulatory experts and key opinion leaders to ensure we meet the FDA's requirements for registration. With Fast Track designation now secured and the protocol approved, we are well-positioned to advance Elate Ocular® through its final stages of clinical development."

Development Timeline

The Company is in advanced discussions with several leading Contract Research Organizations (CROs) and expects to finalise the selection shortly. Subject to additional financing, Cambium Bio anticipates:

- First patient enrolment in mid-2025
- Top-line data readout in mid-2026
- BLA submission following successful completion of the 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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