ASX Announcement

09 December 2024

FDA Grants Fast Track Designation to Elate Ocular® for Treatment of Dry Eye Disease

Sydney, Australia; 9 December 2024: 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 granted Fast Track designation to Elate Ocular® (CAM-101) for the treatment of moderate to severe dry eye disease (DED).

Key Highlights:

- FDA grants Fast Track designation to Elate Ocular® for treatment of dry eye disease
- Designation recognises the serious nature of DED and Elate Ocular's potential to address significant unmet medical needs
- Fast Track status enables more frequent FDA interactions and potential eligibility for accelerated approval and rolling review
- Further validates Cambium Bio's development strategy for Elate Ocular®
- Supports planned initiation of Phase 3 trials in calendar Q2 2025

Fast Track designation is designed to facilitate the development and expedite the review of drugs that treat serious conditions and address unmet medical needs. The designation enables more frequent interactions with the FDA throughout the drug development process and makes Elate Ocular® eligible for potential Accelerated Approval and Priority Review. Additionally, the designation allows for Rolling Review, whereby Cambium Bio can submit completed sections of its Biologics License Application (BLA) for review as they become available, rather than waiting until the complete application is ready.

Dr. Neera Jagirdar, VP of Clinical and Regulatory Development at Cambium Bio, commented: "Receiving Fast Track designation for Elate Ocular® represents a significant milestone in our development program and validates the potential of our innovative therapy to address the substantial unmet needs in dry eye disease treatment. The designation offers several important advantages that could accelerate our development timeline and potentially bring this promising

therapy to patients sooner. We look forward to working closely with the FDA as we advance our Phase 3 clinical programme."

The Fast Track designation was supported by compelling Phase 1/2 clinical data demonstrating Elate Ocular's potential for superior efficacy compared to currently approved therapies, along with a favourable safety profile. The Company remains on track to initiate two registration-enabling Phase 3 clinical trials in calendar Q2 2025.

About Dry Eye Disease

Dry eye disease is a chronic condition affecting millions of people worldwide, with a prevalence of 6.8% in the United States alone and up to 50% in Asian countries. Current treatment options often provide only temporary symptom relief and are associated with significant side effects and low patient compliance. The U.S. market for dry eye treatments exceeds US$2 billion annually and continues to grow as the population ages and screen time increases.

About Fast Track Designation

Fast Track is an FDA designation designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill unmet medical needs. The designation enables:

- More frequent meetings with FDA to discuss development plans
- More frequent written communications about trial design and biomarkers
- Eligibility for Accelerated Approval and Priority Review
- Rolling Review of completed sections of the Biologics License Application.

- 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.

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