

Orasis submits Australia application for presbyopia eye drop

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The submission marks the first ex-US regulatory filing for BESKA, known as QLOSI in the United States.



Orasis Pharmaceuticals and Aspen Australia have announced submission of a New Drug Application in Australia for BESKA, pilocarpine hydrochloride ophthalmic solution 0.4 per cent, for the treatment of presbyopia in adults.

The filing was submitted to Australia's Therapeutic Goods Administration by Aspen Australia, which will be responsible for distribution and marketing of BESKA in the country. The product is known as QLOSI in the United States.

Presbyopia affects near vision as people age, typically becoming noticeable after the age of 40. The condition affects almost two billion people globally and more than 128 million people in the United States, creating a large population seeking alternatives or complements to reading glasses.

BESKA is a low-dose pilocarpine ophthalmic solution intended to improve near vision in adults with presbyopia. The Australia submission is the product's first regulatory filing outside the United States, making it an important step in Orasis' international expansion strategy.

The submission is supported by positive data from two pivotal Phase 3 clinical trials, NEAR-1 and NEAR-2, which evaluated efficacy, safety and tolerability in more than 600 adult patients with presbyopia.

Both trials met their primary and key secondary endpoints on Day 8. Patients achieved statistically significant three-line or greater gain in distance-corrected near visual acuity, without losing one line or more in distance visual acuity.

The safety profile reported in the trials included adverse events in the single digits, with headache at 6.8 per cent and instillation site pain at 5.8 per cent as the most common treatment-related adverse events.

The commercial angle is important because presbyopia is a high-volume ophthalmic condition where convenience, tolerability and patient preference can shape adoption. Eye drops may appeal to patients seeking a flexible option beyond reading glasses, contact lenses or surgical correction.

Aspen's role gives the product a regional commercial pathway in Australia. The company will work with local regulators and prepare for potential launch if the application is approved.