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Eyestem announces completion of Ph 1 study of its RPE Cell Therapy

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Phase 2 of the trial will begin as soon as Eyestem receives approval from the CDSCO

Bengaluru-based startup Eyestem Research has announced the completion of its phase one study for its investigational retinal pigment epithelium (RPE) cell therapy, Eyecyte-RPE.

The clinical study report of the study has been submitted to the Central Drugs Standard Control Organisation (CDSCO) for permission to start the phase 2 study.

The trial, designed to evaluate the safety and efficacy of Eyecyte-RPE in patients with geographic atrophy (GA) secondary to dry age-related macular degeneration (dry AMD), has shown promising outcomes in the initial phase.

“Our phase 1/2a trial demonstrated an excellent safety profile with no serious adverse events, while delivering clinically meaningful vision improvement—an average of 15.8 letters in the first six patients over six months,” said Dr Rajani Battu, Chief Medical Officer, Eyestem. “These encouraging results position us to advance this important therapy, and we are ready to initiate phase 2 immediately upon receiving CDSCO approval,” she added.

Leading ophthalmologists across India involved in the trial have collectively recognised the transformative potential of the therapy.

Commenting on the development, Dr Jogin Desai, Founder and CEO, Eyestem, said, “The data from phase 1 supports our direction, and we’re preparing to begin phase 2 in India, subject to CDSCO approval. Planning is also underway for the US leg of the trial, targeted for the first half of next year. Our focus remains on generating strong clinical evidence and advancing a scalable cell therapy platform for retinal diseases.”