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China completes largest ever dry eye disease clinical trial

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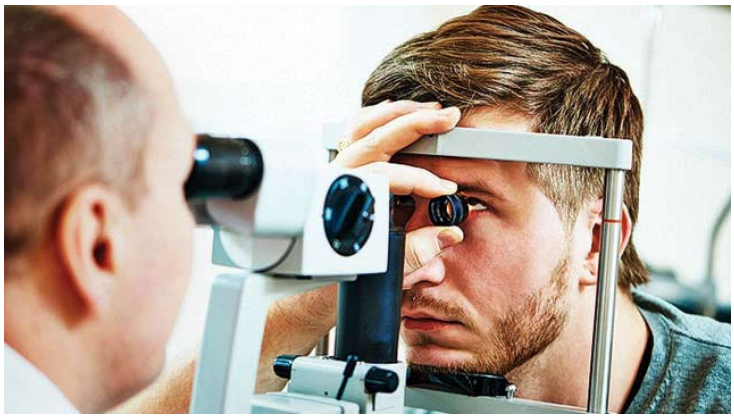
Potential to become new standard of care for moderate-to-severe DED and a new blockbuster drug for China



Zhaoke Ophthalmology has announced that the Phase III clinical trial of one of the company's core drug candidates, Cyclosporine A (CsA) Ophthalmic Gel for the treatment of Dry Eye Disease (DED) has met its primary endpoint in inferior fluorescein corneal staining score (ICSS).

Analysis of the results shows that the patient group who received CsA Ophthalmic Gel demonstrated statistically significant ($P<0.0001$) and clinically meaningful improvements, when compared to the patient group receiving the comparator treatment.

Detailed results are expected to be announced at an upcoming medical meeting after the comprehensive statistical analysis is completed. Zhaoke Ophthalmology plans to submit a new drug application (NDA) to the National Medical Products Administration (NMPA) by the end of 2021, with the aim of commercializing the new treatment as early as 2023.

CsA Ophthalmic Gel is an innovative cyclosporine gel being developed by Zhaoke Ophthalmology in China for the treatment of DED. It is a proprietary hydrogel with patent approval in China and internationally.

According to China Insights Consultancy, the market size of DED drugs in China is forecast to increase from $430.1 million in 2019 to $6.7 billion in 2030, at a compound annual growth rate of 28.4%.