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FDA approves first drug for neurotrophic keratitis

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Singapore- The U.S. Food and Drug Administration approved the first drug, Oxervate (cenegermin), for the treatment of neurotrophic keratitis, a rare disease affecting the cornea (the clear layer that covers the colored portion of the front of the eye).

"While the prevalence of neurotrophic keratitis is low, the impact of this serious condition on an individual patient can be devastating," said Wiley Chambers, M.D., an ophthalmologist in the FDA's Center for Drug Evaluation and Research. "In the past, it has often been necessary to turn to surgical interventions; these treatments are usually only palliative in this disease. Today's approval provides a novel topical treatment and a major advance that offers complete corneal healing for many of these patients."

Neurotrophic keratitis is a degenerative disease resulting from a loss of corneal sensation. The loss of corneal sensation impairs corneal health causing progressive damage to the top layer of the cornea, including corneal thinning, ulceration, and perforation in severe cases. The prevalence of neurotrophic keratitis has been estimated to be less than five in 10,000 individuals.

Oxervate was granted Priority Review designation, under which the FDA's goal is to take action on an application within six months of application filing where the agency determines that the drug, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Oxervate also received Orphan Drug designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted approval of Oxervate to Dompé farmaceutici SpA.