FDA approves Xdemvy for Demodex blepharitis

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The U.S. Food and Drug Administration has approved Xdemvy (lotilaner

ophthalmic solution) 0.25 percent for the treatment of *Demodex* blepharitis, caused by *Demodex* mites.

The approval was based on results from two randomized, vehicle-controlled studies (Saturn-1 and Saturn-2) in which 833 patients were randomly assigned (1:1) to either Xdemvy or vehicle twice daily in each eye for six weeks.

The results of the trials showed significant improvement in eyelids (reduction of collarettes, the pathognomonic sign of the disease, to no more than two collarettes per upper lid) in each study by day 43. Some patients saw improvement as early as two weeks. The end points of mite eradication (mite density of zero mites per lash) and erythema cure (grade 0) were significantly improved at day 43 in both studies.

Xdemvy was generally safe and well tolerated. The most common ocular adverse reactions included instillation site stinging and burning (reported in 10 percent of patients), as well as chalazion/hordeolum (stye) and punctate keratitis (less than 2 percent of patients).

"After years of seeing *Demodex* blepharitis in my practice without an effective way to target the root cause of the disease, I'm so pleased to have a new treatment to offer my patients," ophthalmologist Christopher Starr, M.D., from Weill Cornell Medicine and New York Presbyterian Hospital in New York City, said in a statement. "This new medicine is a positive step forward for the treatment of this disease in many patients who have been struggling for years."

Approval of Xdemvy was granted to Tarsus Pharmaceuticals.

More information: More Information