Xdemvy™ (lotilaner) – New drug approval

- On July 25, 2023, Tarsus announced the FDA approval of Xdemvy (lotilaner), for the treatment of *Demodex* blepharitis.

- *Demodex* blepharitis is caused by an infestation of *Demodex* mites, the most common ectoparasite found on humans and accounts for over two-thirds of all blepharitis cases. Patients may experience redness, inflammation, missing or misdirected eyelashes, horizontal itching along the eyelid base and the presence of collarettes.

    - *Demodex* blepharitis may affect as many as 25 million Americans.

- Xdemvy is a gamma-aminobutyric acid (GABA)-gated chloride channel inhibitor selective for mites.

- The efficacy of Xdemvy was established in two 6-week, randomized, double-masked, vehicle-controlled studies (Saturn-1 and Saturn-2) in 833 patients with *Demodex* blepharitis. Patients received Xdemvy or vehicle twice daily in each eye. The primary endpoint was demonstrated by improvement in lids (reduction of collarettes to no more than 2 collarettes per upper lid) at day 43 in each study.

    - In Saturn-1, 44% of Xdemvy-treated patients vs. 7% of vehicle treated patients achieved the primary endpoint ($p < 0.01$).
    - In Saturn-2, 55% of Xdemvy-treated patients vs. 12% of vehicle treated patients achieved the primary endpoint ($p < 0.01$).

- The most common adverse reaction (10%) with Xdemvy use was instillation site stinging and burning.

- The recommended dose of Xdemvy is instill one drop of Xdemvy in each eye twice daily (approximately 12 hours apart) for 6 weeks.

- Tarsus plans to launch Xdemvy by the end of August 2023. Xdemvy will be available as a 0.25% ophthalmic solution.