**Robust Clinical Trial Data**

**LARGEST, MOST COMPREHENSIVE TRIAL PROGRAM IN DRY EYE DISEASE IN SUPPORT OF AN INVESTIGATIONAL PRODUCT**

- 5 clinical trials; more than 2,500 patients

**PHASE 2** - Efficacy/safety of three concentrations (0.1%, 1.0%, 5.0%)**1,2**
- 230 patients
- 5 sites
- 12 week trial
- Primary endpoint: Effect on ocular signs

**OPUS-1** - Phase 1 efficacy/safety trial**2**
- 588 patients
- 13 sites
- 12 week trial
- Primary endpoints: Effect on ocular signs and symptoms

**OPUS-2** - Phase 3 efficacy/safety trial**2**
- 718 patients
- 30 sites
- 12 week trial
- Primary endpoints: Effect on ocular signs and symptoms

**OPUS-3** - Phase 3 efficacy/safety trial**2**
- 711 patients
- 41 sites
- 12 week trial
- Primary endpoints: Effect on ocular signs and symptoms

**SONATA** - Phase 3 safety trial**2**
- 331 patients
- 22 sites
- 1 year trial
- Primary endpoint: Adverse events

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**COMMITTED TO DRY EYE INNOVATION**

- ~10 years from compound to U.S. FDA approval

**INDICATION**

*Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).*

**IMPORTANT SAFETY INFORMATION**

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increase lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, click here for Full Prescribing Information.

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**References:**


2. Xiidra [Prescribing Information]. Lexington, MA: Shire US.


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