



## Tyrvaya™ (varenicline) – New drug approval

- On October 18, 2021, [Oyster Point Pharma announced](#) the FDA approval of [Tyrvaya \(varenicline\)](#), for the treatment of the signs and symptoms of dry eye disease.
- Tyrvaya is the first nasal spray approved for dry eye disease.
  - Tyrvaya is a highly selective cholinergic agonist. The parasympathetic nervous system controls tear film homeostasis partially via the trigeminal nerve, which is accessible within the nose.
- Varenicline ([Chantix®](#)) was previously available in an oral tablet formulation for smoking cessation treatment.
- The efficacy of Tyrvaya was established in two randomized, double-masked, vehicle-controlled studies (ONSET-1 and ONSET-2). In the ONSET-1 study, 182 patients were randomized to receive one spray in each nostril twice daily of varenicline solution 0.006 mg, Tyrvaya 0.03 mg, varenicline solution 0.06 mg, or vehicle. In the ONSET-2 study, 758 patients were randomized to receive one spray in each nostril twice daily of Tyrvaya 0.03 mg, varenicline solution 0.06 mg, or vehicle. Tear film production was measured by anesthetized Schirmer's score assessed using a Schirmer's strip (0 to 35 mm).
  - Of the patients treated with Tyrvaya, 52% achieved  $\geq 10$  mm increase in Schirmer's score from baseline vs. 14% of vehicle-treated patients in the ONSET-1 study at day 28 (proportion difference 38%, 95% CI: 21, 56;  $p < 0.01$ ).
  - In ONSET-2, 47% of patients treated with Tyrvaya achieved  $\geq 10$  mm increase in Schirmer's score from baseline vs. 28% with vehicle (proportion difference 20%, 95% CI: 11, 28;  $p < 0.01$ ).
- The most common adverse reaction with Tyrvaya use was sneezing (82% of patients). Additional common adverse reactions (5% to 16%) were cough, throat irritation, and instillation-site (nose) irritation.
- The recommended dose of Tyrvaya is one spray in each nostril twice daily (approximately 12 hours apart).
- Oyster Point Pharma plans to launch Tyrvaya in November 2021. Tyrvaya will be available in a carton containing two nasal spray bottles (each bottle delivering 0.03 mg varenicline per spray [0.05 mL]).



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