Qlosi™ (pilocarpine) – New drug approval

- On October 18, 2023, Orasis Pharmaceuticals announced the FDA approval of Qlosi (pilocarpine), for the treatment of presbyopia in adults.

- Presbyopia is the loss of ability to focus on near objects as a result of the natural aging process. There are more than 128 million people in the U.S. living with presbyopia. People with presbyopia experience blurred vision when performing daily tasks that require near visual acuity, such as reading a book.

- Qlosi is the second pilocarpine-containing product approved for presbyopia. AbbVie's Vuity™ was approved in October 2021.

- The efficacy of Qlosi was established in two Phase 3, randomized, double-masked, vehicle-controlled studies (NEAR-1 and NEAR-2) in a total of 613 patients with presbyopia. Ophthalmic assessments were conducted on day 1, 8 and 15 of the study at various timepoints. Responders demonstrated improvement by achieving a gain from baseline of 3 lines or more in near BDCVA at 40 centimeters without a loss of 1 line or more (≥ 5 letters) in BDCVA at 4 meters.

    — Overall, the percentages of responders were consistently higher in the Qlosi group than in the vehicle group at each assessment day. The results for day 8 are provided in the table below.

Assessment timing	NEAR-1			NEAR-2		
	Qlosi	Vehicle	p-value	Qlosi	Vehicle	p-value
1 hour post dose 1	39%	17%	< 0.01	42%	21%	< 0.01
2 hours post dose 1	39%	17%	< 0.01	40%	21%	< 0.01
1 hour post dose 2	48%	16%	< 0.01	52%	17%	< 0.01
2 hours post dose 2	39%	15%	< 0.01	46%	19%	< 0.01

- Warnings and precautions for Qlosi include blurred vision, risk of retinal detachment, iritis, and contact lens wear.

- The most common adverse reactions (5% to 8%) with Qlosi use were instillation site pain and headaches.

- The recommended dose of Qlosi one drop instilled in each eye. This can be repeated a second time after 2 to 3 hours for an effect up to 8 hours.

    — Qlosi can be administered on a daily basis, or as needed, up to twice each day.

- Orasis Pharmaceuticals plans to launch Qlosi in first half of 2024. Qlosi will be available as a 0.4% single-patient-use vial.