Vuity™ (pilocarpine) – New drug approval

- On October 29, 2021, Allergan, an AbbVie company, announced the FDA approval of Vuity (pilocarpine), for the treatment of presbyopia in adults.

- Presbyopia, known as age-related blurry near vision, is a common and progressive eye condition that reduces the eye's ability to focus on near objects and usually impacts people after age 40.

- The efficacy of Vuity was established in two randomized, double-masked, vehicle-controlled studies (GEMINI 1 and GEMINI 2) in a total of 750 patients aged 40 to 55 years old with presbyopia. Patients were randomized to Vuity or vehicle. The primary endpoint in both studies was the proportion of participants gaining 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA), at day 30 (hour 3).

    - In GEMINI 1, the primary endpoint was met in 31% of patients treated with Vuity vs. 8% with vehicle ($p < 0.01$).
    - In GEMINI 2, the primary endpoint was met in 26% of patients treated with Vuity vs. 11% with vehicle ($p < 0.01$).

- Warnings and precautions for Vuity include poor illumination, risk of retinal detachment, iritis, use with contact lenses, and potential for eye injury or contamination.

- The most common adverse reactions (> 5%) with Vuity use were headache and conjunctival hyperemia.

- The recommended dose of Vuity is one drop in each eye once daily.

    - If more than one topical ophthalmic product is being used, the products should be administered at least 5 minutes apart.

- AbbVie launch plans for Vuity are pending. Vuity will be available as a 1.25% ophthalmic solution.