## Otiprio® (ciprofloxacin otic suspension) – New Indication

- On March 2, 2018, Otonomy announced the FDA approval of Otiprio® (ciprofloxacin otic suspension) 6% for the treatment of acute otitis externa (AOE) in patients 6 months of age and older due to *Pseudomonas aeruginosa* and *Staphylococcus aureus*.
    - Otiprio is also approved for the treatment of pediatric patients (age 6 months of age and older) with bilateral otitis media with effusion undergoing tympanostomy tube placement.
- The safety and efficacy of Otiprio for AOE was based on a randomized multicenter, sham-controlled clinical trial in 262 pediatric and adult patients with unilateral or bilateral AOE. Otiprio was administered by a healthcare professional as a single dose to the external ear canal.
    - The primary efficacy endpoint was the proportion of patients with clinical response at day 8, which was defined as the complete absence of signs and symptoms of AOE and no concomitant systemic or topical antibacterial drug was taken for any reason at or prior to the study visit.
    - The intention to treat (ITT) group was all patients who were randomized and did not have group A streptococci cultured on day 1. The difference between the Otiprio and sham groups for the primary endpoint was 23.1% (95% CI: 10.66, 34.62 $p < 0.001$).
    - The microbiological ITT group was all ITT patients who had a positive culture for *S.aureus* or *P.aeruginosa* on day 1. The difference between the Otiprio and sham groups for the primary endpoint was 25.7% (95% CI: 6.57, 43.32$p < 0.012$).
- The most common adverse reactions for (> 2%) with Otiprio use in AOE were ear pruritus, headache, otitis media and ear discomfort.
- Otiprio is for intratympanic or otic administration by a healthcare professional only. The recommended dose of Otiprio for AOE is a single 0.2 ml (12 mg) administration to the external ear canal of each affect ear.
    - The recommended dose of Otiprio for bilateral otitis media with effusion is a single intratympanic administration of one 0.1 mL (6 mg) dose into each affected ear.