# CLINICAL PHARMACOLOGY REVIEW

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| **NDA** | 207986/S-002 |
| **Submission Date** | 05/02/2017 |
| **Drug** | OTIPRIO® (Ciprofloxacin otic suspension) |
| **OCP Reviewer** | Dakshina M. Chilukuri, PhD |
| **OCP Team Leader** | Philip M. Colangelo, PharmD, PhD |
| **OCP Division** | DCP4 |
| **OND Division** | DAIP |
| **Sponsor** | Otonomy Inc. |
| **Submission Type** | 505(b)(2) |
| **Formulation** | 6% suspension |
| **Indication** | Treatment of acute otitis externa due to *Pseudomonas aeruginosa* and *Staphylococcus aureus* |
| **Dosage and Administration** | Single external auditory canal administration of 0.2 mL (12 mg) into the affected ear(s). |

## 1. EXECUTIVE SUMMARY

OTIPRIO® is a sterile, fluoroquinolone antibacterial suspension of 6% ciprofloxacin in a buffered solution containing a poloxamer 407. The poloxamer 407 vehicle in the formulation exhibits thermosensitive properties allowing the product to exist as a liquid at room temperature and transition to a gel after exposure to body temperature.

OTIPRIO® was approved in the US in 2015 for treatment of pediatric patients ≥6 months of age with bilateral otitis media with effusion (OME) undergoing tympanostomy tube placement. The approved dose for bilateral OME is single intratympanic administration of 0.1 mL (6 mg) into each affected ear during the myringotomy procedure. This supplemental NDA was submitted by the applicant to support a new indication for OTIPRIO®to treat AOE in pediatric (age 6 months and older), adult, and elderly patients due to *Pseudomonas aeruginosa* and *Staphylococcus aureus.* The dosage regimen for all patients is a single otic administration of 0.2 mL (12 mg) OTIPRIO®to the external ear auditory canal of the affected ear(s).

Data from a Phase 3 study (201-201609) supported the efficacy of OTIPRIO®for the treatment of AOE in pediatric (age 6 months and older), adult, and elderly patients due to *P. aeruginosa* and *S. aureus*. The primary efficacy endpoint, the proportion of clinical cures at the Day 8 Visit, favored OTIPRIO® treatment over sham and was statistically significant in both the ITT population (randomized patients who did not have Group A streptococci cultured on Day 1) and the Mic-ITT population (ITT patients who had a positive baseline culture for *P. aeruginosa* or S. *aureus*). Statistical significance was maintained when the assessment of otorrhea was incorporated into the primary efficacy endpoint.

No clinical pharmacology studies have been conducted and the applicant did not submit any new clinical pharmacology information with this sNDA. The labeling submitted by the applicant contained no new changes to the clinical pharmacology section.

## 2. RECOMMENDATIONS

No new clinical pharmacology was submitted by the applicant in this sNDA and thus, the clinical pharmacology team has no additional comments on this submission or the proposed labeling.

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02/27/2018

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