Omidria® (phenylephrine/ketorolac) – Expanded indication

- On December 12, 2017, Omeros announced the FDA approval of Omidria (phenylephrine/ketorolac), to include use in pediatric patients (ages birth through 17 years old) when added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.
    - Previously, Omidria was only approved for use on adults.
    - Omidria was also granted an additional 6 months of market exclusivity.
- The safety and effectiveness of Omidria have been established in the pediatric population from neonates to adolescents (birth to younger than 17 years). In addition, use of Omidria in this population is supported by evidence from adequate and well-controlled studies of Omidria in adults with additional data from a single active-controlled safety study in pediatric patients up to 3 years old.
    - As in the adult studies, mydriasis was maintained in the Omidria-treated group in the pediatric safety study.
    - No overall differences in safety were observed between pediatric and adult patients.
- Omidria must be diluted prior to use for administration to a single patient undergoing cataract surgery or intraocular lens replacement. Omidria 4 mL should be diluted in 500 mL of ocular irrigating solution and used as needed for the surgical procedure.
    - The storage period for the diluted product is not more than 4 hours at room temperature or 24 hours under refrigerated conditions.
    - Omidria should not be used if the solution is cloudy or if it contains particulate matter.