Cresemba® (isavuconazonium) – Expanded indication

- On December 8, 2023, Astellas announced the FDA approval of Cresemba (isavuconazonium), for the treatment of invasive aspergillosis (IA) and invasive mucormycosis (IM) in pediatric patients.
    - Cresemba injection is approved for treatment of IA and IM in adults and pediatric patients 1 year of age and older.
    - Cresemba capsules are approved for treatment of IA and IM in adults and pediatric patients 6 years of age and older who weigh 16 kg and greater.
- Cresemba was previously approved for these indications in adults only.
- The approval of Cresemba for the expanded indication for IA was supported by evidence from one adequate and well-controlled trial in adult patients and additional pharmacokinetic and safety data in pediatric patients 1 year of age and older. Adverse reactions in this pediatric population were similar to those reported in the adult population.
- The approval of Cresemba for the expanded indication for IM is supported by one open-label trial in adult patients with IM, a retrospective review of survival data for adult patients with untreated IM, and additional pharmacokinetic and safety data in pediatric patients 1 year of age and older. Adverse reactions in this pediatric population were similar to those reported in the adult population.
- The most common adverse reactions with Cresemba use in pediatric patients were diarrhea, abdominal pain, vomiting, elevated liver chemistry tests, rash, nausea, pruritus, and headache.
- Refer to the Cresemba drug label for pediatric and adult dosing for IA and IM.