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Sirturo (bedaquiline) Tablets
Clinical Update

Clinical Update: FDA Approves New Pediatric Formulation of Sirturo (bedaquiline) as Part of Combination Therapy to Treat Children with Pulmonary Multidrug-Resistant Tuberculosis.

FDA approval date: May 27, 2020

TB is the world's deadliest infectious disease, claiming approximately 1.5 million lives in 2018 alone – more than HIV and malaria combined. While TB most often affects adults in their most productive years, in 2018, an estimated 1.1 million children became ill with TB worldwide and more than 200,000 died. According to the World Health Organization, however, these are likely underestimates of the true burden of the disease in children. These grim statistics underscore the urgent need for effective pediatric TB treatments. Sirturo® (bedaquiline) is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo® should be reserved for use when an effective treatment regimen cannot otherwise be provided. This indication is approved under accelerated approval based on time to sputum culture conversion. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

The U.S. Food and Drug Administration (FDA) has granted approval for a new pediatric formulation of Sirturo (bedaquiline). Sirturo is now indicated for use as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multidrug-resistant tuberculosis (MDR-TB). In the U.S., the medicine should be reserved for use when an effective treatment regimen cannot otherwise be provided. This marks the first regulatory approval for the pediatric formulation of Sirturo® and is a key component of Johnson & Johnson's global pediatric research and development (R&D) program for the medicine. The new 20 mg tablet can be administered with water for patients who are able to swallow the intact tablet and taken with food. For patients who have difficulty swallowing intact tablets, the tablet can be dispersed in water and administered. To aid with administration, the dispersed mixture in water can be further mixed with a beverage or soft food. Alternatively, the tablet can be crushed and mixed with soft food immediately prior to use and administered. This FDA approval is supported by evidence from a single-arm, open-label, Phase 2 study that enrolled pediatric patients aged 5 to less than 12 years of age with confirmed or probable pulmonary MDR-TB infection who were treated at half the adult dose with the Sirturo® 20mg tablet for 24 weeks in combination with a background regimen for the treatment of MDR-TB. The application for the pediatric formulation obtained priority review from the FDA.

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