RXADVANCE
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CLINICAL UPDATE

Brand Name	Tivicay® and Tivicay® PD
Generic Name	dolutegravir
Drug Manufacturer	ViiV Healthcare

Clinical Update

FDA Approves Tivicay PD (dolutegravir) Once-Daily Dispersible Tablet Formulation for Children with HIV.

FDA Approval Date: June 12, 2020

Overview

Tivicay and Tivicay PD contain dolutegravir, an integrase strand transfer inhibitor for use in combination with other antiretroviral agents for the treatment of HIV. Integrase inhibitors inhibit HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration which is essential for the HIV replication cycle.

Dolutegravir is the first integrase inhibitor available as a dispersible tablet for oral suspension for children as young as four weeks of age and weighing at least 3kg. Prior to this, dolutegravir was indicated in the US for children from six years of age and weighing more than 30kg. This step will expand the use of dolutegravir by providing an age-appropriate formulation to a younger population and will help to close the gap between HIV treatment options available for adults and children.

US Food and Drug Administration (FDA) has approved Tivicay PD (dolutegravir) tablets for oral suspension, which are used in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in paediatric patients (treatment-naïve or -experienced but INSTI- naïve) aged at least four weeks and weighing at least 3kg, as well as an extended indication to expand the use of the already approved Tivicay (dolutegravir) 50mg film-coated tablet in paediatric HIV patients weighing 20kg and above.

Tivicay PD and the extended indication of the existing Tivicay 50mg film-coated tablet are both currently under review by the European Medicines Agency (EMA).

P1093 (NCT03016533): a safety, tolerability and dose finding registrational study in paediatric patients aged four weeks to 18 years being conducted by the IMPAACT network in the USA, Brazil, Thailand, South Africa, Zimbabwe, Kenya and Tanzania.

ODYSSEY (Penta20) (NCT02259127): a randomised control efficacy trial in first and second- line treatment, in paediatric patients aged four weeks to 18 years being conducted by the PENTA network in Europe, South America, Thailand, Uganda, Zimbabwe, and South Africa.

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