Norvir® (ritonavir) – New formulation approval

- On June 7, 2017, the FDA approved AbbVie's Norvir (ritonavir) oral powder in combination with other antiretroviral agents for the treatment of pediatric patients with human immunodeficiency virus type 1 (HIV-1) infection.

- Norvir is also available as a tablet and oral solution.

- After administration of a single 100 mg dose under fed conditions, Norvir oral powder demonstrated comparable bioavailability to the oral solution.

- Norvir carries a boxed warning regarding drug-drug interactions leading to potentially serious and/or life-threatening infections.

- Contraindications with Norvir include: when co-administering Norvir with other protease inhibitors, see the full prescribing information for that protease inhibitor, including contraindication information; use with drugs that are highly dependent on cytochrome 3A (CYP3A) for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions; use with drugs that are potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance; and patients with known hypersensitivity (e.g. toxic epidermal necrolysis or Stevens-Johnson syndrome) to ritonavir or any of its ingredients.

- Warnings and precautions of Norvir include: risk of serious adverse reactions due to drug interactions, toxicity in preterm neonates, hepatotoxicity, pancreatitis, allergic reactions/hypersensitivity, PR interval prolongation, lipid disorders, diabetes mellitus/hyperglycemia, immune reconstitution syndrome, fat redistribution, patients with hemophilia, resistance/cross-resistance, and laboratory tests.

- The most common adverse reactions with Norvir alone or in combination with other antiretroviral drugs were gastrointestinal (including diarrhea, nausea, vomiting, abdominal pain [upper and lower]), neurological disturbances (including paresthesia and oral paresthesia), rash, and fatigue/asthenia.

- The recommended dose of Norvir oral powder is twice daily based on body surface area in children greater than one month of age. The dose should not exceed 600 mg twice daily with meals.

    - Norvir oral powder should be used only for dosing increments of 100 mg. Norvir powder should not be used for doses less than 100 mg or for incremental doses between 100 mg intervals. Norvir oral solution is the preferred formulation for patients requiring doses less than 100 mg or incremental doses between 100 mg intervals.
    - Norvir oral powder should be mixed with soft food such as apple sauce or vanilla pudding, or mixed with liquid such as water, chocolate milk, or infant formula. The bitter aftertaste of Norvir oral powder may be lessened if administered with food.
    - Consult the drug label for additional dosing information.

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- AbbVie's launch plans for Norvir oral powder are pending. Norvir oral powder will be available in packets containing 100 mg of ritonavir.