

Drugs recently approved or pending approval

BRAVELLE

Ferring Pharmaceuticals, Inc, of Tarrytown, NY, received approval from the US Food and Drug Administration (FDA) to market Bravelle (urofollitropin for injection, purified) for ovulation induction following pituitary suppression in women without primary ovarian failure. The efficacy and safety of Bravelle were established in a randomized, active controlled, multicenter study of ovulation induction. Patients underwent pituitary suppression with a gonadotropin-releasing hormone (GnRH) agonist before being randomized to receive either Bravelle subcutaneously (sc), Bravelle intramuscularly (im), or a commercial recombinant follicle-stimulating hormone (FSH) product sc. Of the 111 oligoanovulatory patients randomized, 73 received Bravelle, starting at a dose of 150 IU daily for 5 days. Individual titration of the dose from 75 to 450 IU daily, based on ultrasound and estradiol (E₂) levels, followed. Dosing duration did not exceed 12 days. Results showed no significant differences among the groups. Ovulation occurred in 69.4% of patients taking Bravelle sc (n = 36) and 70.3% of those taking Bravelle im (n = 37). Bravelle is contrain-

dicated in patients who are pregnant or have high FSH levels (ie, primary ovarian failure), uncontrolled thyroid and adrenal dysfunction, an organic intracranial lesion, abnormal bleeding, ovarian cysts, or infertility other than anovulation. The most common adverse effects were ovarian hyperstimulation syndrome, headache, and vaginal hemorrhage. The recommended initial dose of Bravelle for patients who have received either a GnRH agonist or antagonist pituitary suppression is 150 IU daily for the first 5 days of treatment, with subsequent dosing adjusted according to patient response.

REMODULIN

Approval was granted by the FDA (under its accelerated approval regulations) to United Therapeutics Corporation (Silver Spring, MD) to market Remodulin (treprostinil sodium) for the treatment of pulmonary arterial hypertension (PAH) in patients with New York Heart Association (NYHA) Class II-IV symptoms to diminish exercise-induced symptoms. Two 12-week, multicenter, randomized, double-blind studies compared Remodulin to placebo in 470 patients with NYHA Class II-IV PAH. PAH was considered primary in 58% of patients, associated with collagen vascular disease in 19%, and the result of congenital left-to-right shunts in 23%; PAH had been diagnosed for a mean of 3.8 years. The primary endpoint was change in 6-minute walking distance. The effect of Remodulin on this endpoint was small; the medi-

an change from baseline in patients taking Remodulin was 10 m and in those taking placebo was 0 m. However, the Borg dyspnea score was significantly improved by Remodulin during the 6-minute walk. Remodulin also had a significant effect (compared with placebo) on an assessment combining walking distance with Borg dyspnea score. Remodulin is contraindicated in patients with known hypersensitivity to the drug or related compounds. The most common adverse reactions to Remodulin were infusion site pain and reaction, diarrhea, and nausea. Remodulin is administered by continuous sc infusion, at an initial rate of 1.25 ng/kg body weight per minute; the infusion rate is then increased in increments of no more than 1.25 ng/kg per minute each week for the first 4 weeks and then no more than 2.5 ng/kg per minute each week for the duration of infusion.

VFEND

The FDA has approved marketing of Vfend (voriconazole) by Pfizer, Inc, of New York, NY, for the treatment of deadly fungal infections. Vfend is indicated for primary treatment of acute invasive aspergillosis and salvage therapy for rare but serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium* species. The safety and efficacy of Vfend were evaluated in a comparative clinical trial that compared Vfend to amphotericin B, the current treatment standard, for primary treatment of invasive aspergillosis. Results showed that 53% of patients receiving Vfend had successful responses at 12 weeks, compared with 32% of those receiving amphotericin B. The survival rate of Vfend-treated patients was 71%, compared with 58% for amphotericin B-treated patients. Vfend is contraindicated in patients with known hypersensitivity to voriconazole or its excipients. The most common adverse effects of Vfend were visual disturbances, elevations of liver function test results, and skin rash. Vfend can be administered by an oral or intravenous (IV) route. Vfend tablets contain 50 mg or 200 mg of voriconazole and should be taken at least 1 hour before or after a meal. Vfend IV contains (nominally) voriconazole 200 mg and sulfobutyl ether beta-cyclodextrin sodium 3200 mg in a 30 mL clear glass vial; reconstitution of Vfend with water is required (to 10 mg/mL), as is subsequent dilution to 5 mg/mL (or less) prior to administration at a maximum rate of 3 mg/kg per hour over 1 to 2 hours.



Compiled from press reports and pharmaceutical company press releases. For more information, contact Nora Landon, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.

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