Drugs recently approved or pending approval

DORIBAX

The US Food and Drug Administration (FDA) has given approval to Ortho-McNeil Pharmaceutical, Inc. (Raritan, NJ) to market Doribax (doripenem for injection) for the treatment of complicated intra-abdominal infections and complicated urinary tract infections (UTIs), including pyelonephritis. Doribax was evaluated in 2 multinational, randomized, double-blind studies of adult patients with complicated intra-abdominal infections and 1 single-arm, multicenter study of patients with complicated UTIs including pyelonephritis. In studies 1 and 2, patients (N = 946) were randomized to Doribax 500 mg/hr every 8 hours or meropenem 1 g over 3 to 5 minutes every 8 hours. In microbiologically evaluable (ME) patients and in microbiological modified intent-to-treat (mMITT) patients, clinical cure rates were similar between Doribax- and meropenem-treated patients (study 1, 82.8% versus 85.9% in ME patients and 73.7% versus 78.0% in mMITT patients, respectively; study 2, 81.0% versus 82.1% in ME patients and 71.9% versus 74.2% in mMITT patients, respectively). Patients (N = 1171) in study 3 were allocated to Doribax 500 mg/hr every 8 hours or intravenous levofloxacin 250 mg/24 hr. Microbiological eradication rates were comparable between the Doribax- and levofloxacin-treated patients (82.1% versus 83.4% in ME patients and 79.2% versus 78.2% in mMITT patients, respectively). The most common adverse effects were headache, nausea, and diarrhea.

ISENTRESS

Merck & Co., Inc. (Whitehouse Station, NJ) has received FDA approval to market Isentress (raltegravir) tablets to be used in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients (aged ≥ 16 yr) who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. The efficacy and safety of Isentress were established in 2 ongoing, 24-week, phase 3, randomized, double-blind, placebo-controlled trials involving 699 patients with documented resistance to at least 1 drug in each of 3 classes (nucleoside reverse transcriptase inhibitors [NRTIs], non-NRTIs, and protease inhibitors) of antiretroviral therapies. Patients were randomized to Isentress 400 mg twice daily plus an optimized background therapy (OBT) or placebo plus OBT. Based on pooled results for patients who completed 24 weeks of treatment or discontinued earlier, 75.5% of Isentress-treated patients had less than 400 copies/mL of HIV RNA and 62.6% had less than 50 copies/mL, as compared with 39.3% and 33.3% of placebo-treated patients. The mean changes in plasma HIV-1 RNA from baseline were –1.85 $\log_{10}$ copies/mL and –0.84 $\log_{10}$ copies/mL in Isentress-treated patients and placebo-treated patients, respectively. The mean increase from baseline in CD4+ cell counts was higher with Isentress as compared with placebo (89 cells/mm^3 versus 35 cells/mm^3). The most common adverse effects were diarrhea, nausea, and headache.

IXEMPRA

Bristol-Myers Squibb Co. (Princeton, NJ) has received FDA approval to market Ixempra (ixabepilone) to be used in combination with capecitabine or as monotherapy for the treatment of patients with metastatic or locally advanced breast cancer. The safety and efficacy of Ixempra in combination with capecitabine were evaluated in an open-label, multinational, randomized trial involving 752 patients whose cancer was resistant to treatment with an anthracycline/taxane regimen or was taxane-resistant and for whom further anthracycline therapy was contraindicated. Patients were randomized to Ixempra (40 mg/m^2 every 3 wk) plus capecitabine (1000 mg/m^2 twice daily for 2 wk followed by 1 wk rest) or capecitabine alone (1250 mg/m^2 twice daily for 2 wk followed by 1 wk rest). Patients in the Ixempra/capecitabine and capecitabine monotherapy arms received a median of 5 and 4 cycles of treatment, respectively. The primary endpoint was progression-free survival (PFS). The Ixempra/capecitabine arm demonstrated a statistically significant improvement in PFS as compared with capecitabine alone (hazard ratio, 0.69 [95% confidence interval, 0.58–0.83]). Ixempra as monotherapy was evaluated in a multicenter single-arm study of 126 women whose tumors were resistant or refractory to anthracyclines, taxanes, and capecitabine. Patients received Ixempra 40 mg/m^2 intravenously over 3 hours every 3 weeks (median, 4 cycles). The tumor response rate was 12.4%. The most common adverse effects were peripheral sensory neuropathy, fatigue/asthenia, and myalgia/arthralgia.

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