Drugs recently approved or pending approval

ERAXIS

The US Food and Drug Administration (FDA) has given approval to Pfizer Inc. (New York, NY) to market Eraxis (anidulafungin) for the treatment of candidemia and other forms of *Candida* infections. The safety and efficacy of Eraxis were evaluated in a randomized, double-blind, phase III study. Patients were randomized to intravenous (IV) Eraxis once daily (200 mg loading dose followed by 100 mg maintenance dose; n = 127) or IV fluconazole (800 mg loading dose followed by 400 mg maintenance dose; n = 118). Treatment was administered for at least 14 days and no more than 42 days. The most frequent species isolated at baseline was *C. albicans* (61.6%) followed by *C. glabrata* (20.4%), *C. parapsilosis* (11.8%), and *C. tropicalis* (10.6%). At the end of all therapy, 94 Eraxis-treated patients achieved global response (ie, clinical cure/improvement and documented or presumed microbiologic eradication) compared with 67 fluconazole-treated patients (treatment difference, 17.24% [98.3% confidence interval {CI}, 2.9%–31.6%]). The most common adverse effects associated with Eraxis were diarrhea, hypokalemia, and increased alanine transferase level.

ERBITUX

ImClone Systems Incorporated (New York, NY) and Bristol-Myers Squibb Company (Princeton, NJ) have been given FDA approval to market Erbitux (cetuximab) for use in combination with radiation therapy for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck or as monotherapy for the treatment of recurrent metastatic squamous cell carcinoma of the head and neck in patients who have failed platinum-based therapy. Erbitux was evaluated in 2 trials. In study 1, patients were randomized to either Erbitux plus radiation (n = 211) or radiation therapy alone (n = 213). Radiation therapy was administered for 6 to 7 weeks as once daily, twice daily, or concomitant boost (chosen by investigator prior to enrollment). One week before radiation, a 400-mg/m^2 initial dose of Erbitux was given followed by 250 mg/m^2 weekly for the duration of radiation therapy (6–7 wk). Mean duration of locoregional control was 24.4 months in the Erbitux/radiation group compared with 14.9 months in the radiation only group (hazard ratio, 0.68 [95% CI, 0.52–0.89]; P = 0.005). Median duration of overall survival was 49.0 months in the Erbitux/radiation group compared with 29.3 months in the radiation only group (hazard ratio, 0.74 [95% CI, 0.57–0.97]; P = 0.03). In study 2, 103 patients received a 20-mg test dose of Erbitux on day 1 followed by a 400-mg/m^2 initial dose and 250-mg/m^2 weekly dose until disease progression or unacceptable toxicity. Patients whose disease progressed were given the option to receive Erbitux plus the platinum regimen they had failed prior to enrollment. The objective response rate was 13% (95% CI, 7%–21%). The most common adverse effects were acneform rash, mucositis, radiation dermatitis, and weight loss in the combination study and acneform rash, asthenia, pain, fever, and weight loss in the monotherapy study.

RITUXAN

Biogen Idec Inc. (Cambridge, MA) and Genentech, Inc. (South San Francisco, CA) have been given FDA approval to market Rituxan (rituximab) for use in combination with methotrexate (MTX) to reduce signs and symptoms in adult patients with moderate to severe rheumatoid arthritis (RA) who have had an inadequate response to 1 or more tumor necrosis factor (TNF) antagonists. The efficacy and safety of Rituxan were evaluated in a multicenter, randomized, double-blind, placebo-controlled, phase III study. Patients (N = 517) were aged 18 years or older, were diagnosed with RA according to American College of Rheumatology (ACR) criteria and had at least 8 swollen and 8 tender joints, were receiving MTX, and had a prior inadequate response to at least 1 TNF inhibitor. Patients received 2 doses of either Rituxan 1000 mg or placebo as an IV infusion on days 1 and 15 in combination with continued MTX 10 to 25 mg weekly. Efficacy was assessed at 24 weeks. At week 24, a statistically significant improvement for all components of ACR response was observed in patients treated with Rituxan plus MTX as compared with placebo plus MTX (51% versus 18%, 27% versus 5%, and 12% versus 1% for ACR response of 20, 50, and 70, respectively; all $P < 0.001$). The most common adverse effects were hypertension, nausea, upper respiratory tract infection, and arthralgia. Rituxan is also approved for treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell, non-Hodgkin's lymphoma and for first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone or other anthracycline-based chemotherapy regimens.

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