

Drugs recently approved or pending approval

LEXIVA

The US Food and Drug Administration (FDA) gave approval to GlaxoSmithKline (Triangle Park, NC) and Vertex Pharmaceuticals Incorporated (Cambridge, MA) to market Lexiva (fosamprenavir calcium), a new protease inhibitor (PI), for the treatment of HIV infection in adults in combination with other antiretroviral medications. Lexiva was evaluated in 3 trials including more than 1200 antiretroviral therapy (ART)-naïve and PI-experienced patients. In all 3 trials, Lexiva was given in combination with nucleoside reverse transcriptase inhibitors (ie, abacavir, lamivudine). In study 1, Lexiva was compared with nelfinavir in 249 ART-naïve patients. 57 percent of Lexiva-treated patients achieved and maintained confirmed HIV-1 RNA levels of < 400 copies/mL compared with 42% for nelfinavir. In study 2, Lexiva plus ritonavir was compared with nelfinavir in 649 ART-naïve patients. 58 percent of Lexiva-treated patients achieved and maintained HIV-1 RNA levels of < 400 copies/mL compared with 55% for nelfinavir. In study 3, Lexiva plus ritonavir was compared with lopinavir/ritonavir in 315 PI-experienced patients.

58 percent of patients in the Lexiva treatment group achieved and maintained HIV-1 RNA < 400 copies/mL versus 61% for lopinavir/ritonavir. Study 3 was not large enough to reach a definitive conclusion that Lexiva/ritonavir and lopinavir/ritonavir are clinically equivalent. Lexiva can be dosed 3 different ways: twice daily; once daily in combination with ritonavir (not recommended for PI-experienced patients); and twice daily in combination with ritonavir. The most common adverse effects seen with Lexiva in all 3 trials were diarrhea, nausea, vomiting, headache, and rash. Lexiva is contraindicated with ergot derivatives, cisapride, pimozone, midazolam, and triazolam. Lexiva can be taken without food or water restrictions.

NAMENDA

The FDA has granted approval to Forest Laboratories, Inc. (New York, NY) to market Namenda (memantine hydrochloride) for the treatment of moderate-to-severe Alzheimer's disease. Namenda is the first N-methyl-D-aspartate antagonist to be approved for Alzheimer's disease and is the only therapy approved for treatment of moderate-to-severe disease. The effectiveness of Namenda was evaluated in 3 randomized, double-blind, placebo-controlled trials; 2 studies took place in the US. The mean age of US participants (N = 656) was 76 years (range, 50–93 years). In each US study, Namenda was evaluat-

ed using the modified Alzheimer's disease Cooperative Study-Activities of Daily Living Inventory and the Severe Impairment Battery. Both studies showed that patients who received Namenda experienced significant improvement in overall function and cognition. In the third study, which took place in Latvia, participants (N = 166) with dementia were evaluated using the Behavioral Rating Scale for Geriatric Patients and the Clinical Global Impression of Change. Patients experienced a statistically significant treatment difference using Namenda versus placebo; however, no valid measure of cognition was used in this study. The most common adverse effects observed in Namenda-treated patients were dizziness, headache, confusion, and constipation.



RAPTIVA

Genentech, Inc. (San Francisco, CA) and XOMA (Berkeley, CA) were granted approval by the FDA to market Raptiva (efalizumab) for the treatment of adult patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Raptiva was evaluated in 4 randomized, double-blind, placebo-

controlled trials in adults with chronic (> 6 months), stable, plaque psoriasis who had a minimum body surface area involvement of 10% and were candidates for or previously received systemic therapy or phototherapy. Patients with clinically significant flares and patients with guttate, erythrodermic, or pustular psoriasis as the sole form of psoriasis were excluded. Median patient age was 44 years (range, 18–75). Patients (N = 2762) were evaluated using the Psoriasis Area and Severity Index (PASI). Baseline median PASI score in all treatment groups was 17. Baseline median body surface area involvement ranged from 22% to 28%. Compared with placebo, Raptiva-treated patients had at least a 75% reduction from PASI score 1 week after the 12-week treatment period. The most common adverse effects associated with Raptiva were headache, chills, fever, nausea, and myalgia. Recommended dosage of Raptiva is a single 0.7 mg/kg subcutaneous conditioning dose followed by weekly subcutaneous doses of 1 mg/kg.

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

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