

### Drugs recently approved or pending approval

#### FLUMIST

The US Food and Drug Administration (FDA) approved marketing of FluMist (Influenza Virus Vaccine Live, Intranasal) by MedImmune, Inc (Gaithersburg, MD) and Wyeth Pharmaceuticals (Madison, NJ) for active immunization for the prevention of disease caused by influenza A and B in healthy persons aged 5 to 49 years. FluMist is the first influenza vaccine delivered as a nasal mist and will be available for the upcoming influenza season. FluMist was evaluated in a multicenter, randomized, double-blind, placebo-controlled study of healthy children that included 238 subjects aged 60 to 71 months. Those who received FluMist experienced a significant reduction in the incidence of culture-confirmed influenza (efficacy, 87.4%;  $P \leq .05$ ). FluMist also was evaluated in a multicenter, randomized, double-blind, placebo-controlled trial of healthy adults that included 3920 participants aged 18 to 49 years. The primary endpoint was the reduction in episodes of any febrile illness (AFI) (ie, 2 or more consecutive days of symptoms, with fever on at least 1 day and 2 or more symptoms on at least 1 day). Severe febrile illness (SFI) and febrile upper respiratory illness (FURI) also were assessed. FluMist recipients experienced significant reductions in SFI (19.5% reduction;  $P \leq .05$ ) and FURI (23.7% reduction;  $P \leq .05$ ), but not in AFI. The most common adverse effects reported with healthy children using FluMist were runny nose/nasal congestion, cough, and headache. FluMist should not be administered to pregnant women or to patients with chronic underlying medical conditions, including asthma and reactive airway disease.



#### PREMPRO

Wyeth Pharmaceuticals (Madison, NJ) received approval from the FDA to market low-dose 0.3 mg/1.5 mg Prempro (conjugated estrogens/medroxyprogesterone acetate tablets) for the treatment of moderate to severe symptoms associated with menopause, such as hot flashes, night sweats, and vaginal dryness; and for the prevention of postmenopausal osteoporosis. Data supporting the efficacy and tolerability of Prempro 0.3 mg/1.5 mg are based on the Women's Health, Osteoporosis, Progestin, and Estrogen Study, a prospective, randomized, double-blind, placebo-controlled, multicenter trial of 2673 healthy postmenopausal women aged 40 to 65 years. Efficacy for vasomotor symptoms was assessed during the first 12 weeks of treatment using Prempro doses (ie, 0.625 mg/2.5 mg, 0.45 mg/1.5 mg, and 0.3 mg/1.5 mg) or placebo in a subset of symptomatic women ( $n = 124$ ) who had at least

7 moderate to severe hot flushes daily or at least 50 moderate to severe hot flushes during the week before randomization. All Prempro dosages were shown to be statistically better than placebo at weeks 4 and 12 for relief of both frequency and severity of moderate to severe vasomotor symptoms (Prempro 0.3 mg/1.5 mg,  $P < .001$ ). There was no difference in commonly reported side effects for women taking Prempro 0.3 mg/1.5 mg compared to those taking placebo. Prempro 0.3 mg/1.5 mg should not be used if a woman has unusual vaginal bleeding, has or had cancer of the breast or uterus, had a stroke or heart attack in the past year, has or had blood clots, has liver problems, or thinks she may be pregnant. Patients should be treated with the lowest effective dose of Prempro; dosage adjustment may be made based on individual patient response.

#### REYATAZ

Bristol-Myers Squibb Company (Princeton, NJ) received approval from the FDA to market Reyataz (atazanavir sulfate), a once-daily azapeptide protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Reyataz was evaluated in 15 clinical trials enrolling more than 2400 people living with HIV. A phase III randomized, double-blind, multicenter trial involving treatment-naïve subjects compared Reyataz with efavirenz, each in combination with lamivudine and zidovudine.

Results showed that the Reyataz combination had comparable antiviral efficacy to the efavirenz combination (67% versus 62%) after 48 weeks of treatment (405 patients in each treatment group). An ongoing phase III, randomized, open-label, multicenter trial involving treatment-experienced subjects evaluated the efficacy of Reyataz plus 2 nucleoside reverse transcriptase inhibitors (NRTIs) versus a combination regimen of lopinavir, ritonavir, and 2 NRTIs. The treatment containing Reyataz demonstrated antiviral efficacy and also resulted in decreased low-density lipoprotein cholesterol, total cholesterol, and triglyceride levels (-6%, -2%, -2%, respectively). Reyataz is contraindicated for patients who are taking benzodiazepines, ergot derivatives, gastrointestinal motility agents, or neuroleptics. Side effects associated with Reyataz include heart rhythm changes, lactic acidosis syndrome, and body fat changes.

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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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