

### Drugs recently approved or pending approval

#### CLARINEX

Schering-Plough Corporation (Kenilworth, NJ) received approval from the US Food and Drug Administration (FDA) to market Clarinex (desloratadine) for the treatment of seasonal allergic rhinitis (SAR) in adults and children age 12 years and older. The clinical efficacy and safety of Clarinex tablets were evaluated in over 2300 patients age 12 to 75 years who had SAR. A total of 1838 patients received 2.5 to 20 mg of Clarinex daily in 4 double-blind, randomized, placebo-controlled clinical trials of 2- to 4-weeks' duration conducted in the United States. The results of these studies showed the efficacy and safety of Clarinex 5 mg in the treatment of adult and adolescent patients with SAR. In a dose-ranging trial, daily doses of 5, 7.5, 10, and 20 mg of Clarinex were superior to placebo; no additional benefit was seen at doses above 5.0 mg. In two 4-week studies of 924 patients (age 15 to 75 years) with SAR and concomitant asthma, Clarinex improved rhinitis symptoms with no decrease in pulmonary function. Clarinex is contraindicated in patients who are hypersensitive to desloratadine or loratadine. The most common adverse effects of Clarinex are pharyngitis, dry mouth, myalgia, fatigue, somnolence, and dysmenorrhea. In adults and children age 12 years and older, the recommended dose of Clarinex is 5 mg once daily.



#### PAXIL CR

Approval was granted by the FDA to GlaxoSmithKline (Philadelphia, PA) to market Paxil CR (paroxetine hydrochloride) to treat panic disorder. Paxil CR was previously approved to treat major depressive disorder. The efficacy of Paxil CR was established in 3 10-week, multicenter, placebo-controlled, flexible-dose trials in patients with panic disorder. These trials were assessed based on 3 variables: (1) the proportions of patients free of full panic attacks at endpoint; (2) change from baseline to endpoint in the median number of full panic attacks; and (3) change from baseline to endpoint in median Clinical Global Impression Severity scores. Concomitant use of Paxil CR with either monoamine oxidase inhibitors or thioridazine is contraindicated. Adverse reactions associated with the use of Paxil CR for panic disorder were abnormal ejaculation, somnolence, impotence, decreased libido, tremor, sweating, and female genital disorders. Paxil CR should be administered as a single daily dose. The recommended initial dose is 12.5 mg daily. Dose changes should occur in 12.5 mg daily increments at intervals of at least 1 week. The maximum dosage should not exceed 75 mg daily.

#### REBIF

The FDA has approved marketing of Rebif (interferon beta-1a) by Serono, Inc, of Rockland, MA, for the treatment of relapsing-remitting multiple sclerosis (RRMS). Two multicenter studies evaluated the safety and efficacy of Rebif in patients with RRMS. Study 1 was a randomized, double-blind, placebo-controlled study in patients with MS for at least 1 year, Kurtzke Expanded Disability Status Scale (EDSS) scores ranging from 0 to 5, and at least 2 acute exacerbations in the previous 2 years. Patients received subcutaneous (sc) injections of either placebo (n = 187), Rebif 22 µg (n = 189), or Rebif 44 µg (n = 184) administered 3 times a week for 2 years. Doses of study agents were progressively increased to their target doses during the first 4 to 8 weeks for each patient. The primary endpoint was the number of clinical exacerbations. Progression of disability was defined as an increase in the EDSS score of at least 1 point lasting for at least 3 months. Rebif at doses of 22 µg and 44 µg administered subcutaneously 3 times weekly significantly reduced the number of exacerbations per patient, compared with placebo. The time to onset of progression in

disability sustained for 3 months was significantly longer in patients treated with Rebif than in placebo-treated patients. Study 2 was a randomized, open-label, evaluator-blinded, active comparator study in patients with RRMS who had EDSS scores ranging from 0 to 5.5 and at least 2 exacerbations in the previous 2 years. Patients were randomized to 48 weeks of treatment with Rebif 44 µg 3 times weekly by sc injection (n = 339) or Avonex (interferon beta-1a) 30 µg once a week by intramuscular injection (n = 338). The primary efficacy endpoint was the proportion of patients who remained exacerbation-free at 24 weeks. Patients taking Rebif were more likely to remain relapse-free during the treatment period than were those taking Avonex. Rebif is contraindicated in patients with a hypersensitivity to interferon, human albumin, or any component of the formulation. Adverse effects of Rebif are psychiatric disorders, injection site disorders, influenza-like symptoms, and abdominal pain. The recommended dosage of Rebif is 44 µg injected subcutaneously 3 times weekly, administered, if possible, at the same time (preferably late afternoon or evening) and on the same 3 days at least 48 hours apart each week.

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