

### Drugs recently approved or pending approval

#### GENOTROPIN

The United States Food and Drug Administration approved marketing of a new indication for Genotropin (somatropin [rDNA origin] for injection) by Pharmacia & Upjohn (Kalamazoo, MI). Genotropin is now indicated for the long-term treatment of pediatric patients who have growth failure due to Prader-Willi syndrome (PWS). The efficacy of Genotropin for the treatment of PWS was evaluated in two randomized, open-label, controlled clinical trials. In one study, patients ( $n = 15$ ) received Genotropin 0.24 mg/kg/week during the entire study. During the second year, dosage was doubled. Patients in the Genotropin arm showed significant increases in linear growth during the first year of study compared with untreated patients. Treatment with Genotropin did not accelerate bone age, compared with patients who received no treatment. Genotropin is contraindicated when there is any evidence of neoplastic activity. Intracranial lesions must be inactive and antitumor therapy complete prior to therapy institution. Growth hormone should not be initiated to treat patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or to patients having acute respiratory failure. Potential adverse events associated with Genotropin include swelling, arthralgia, upper respiratory infection, pain, and edema. General recommended dosage of Genotropin for pediatric PWS patients is 0.24 mg/kg/week, and must not be injected intravenously.



#### SARAFEM

Approval was granted to Eli Lilly and Company (Indianapolis, IN) to market Sarafem (fluoxetine hydrochloride) for the treatment of premenstrual dysphoric disorder (PMDD). Efficacy of Sarafem was measured in two placebo-controlled trials that enrolled patients meeting the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria for PMDD, and excluded patients receiving oral contraceptives. In one study ( $n = 320$ ), patients were randomized to fixed doses of Sarafem 20 mg and 60 mg/day or placebo continuously throughout the menstrual cycle. Efficaciousness was measured by a Visual Analogue Scale (VAS) total score (including mood and physical symptoms). Average total VAS score decreased 7% for patients in the placebo arm, 36% for patients in the 20 mg Sarafem arm, and 39% for patients in the 60 mg Sarafem arm. Patients should not be administered Sarafem in combination with a monoamine oxidase inhibitor (MAOI), or within a

14-day minimum after discontinuing therapy with an MAOI. Thioridazine should not be administered with Sarafem or within a 5-week minimum after Sarafem has been discontinued. Potential adverse events associated with Sarafem include rhinitis, headache, nausea, asthenia, and pharyngitis. The recommended dosage is 20 mg/day and should not exceed 80 mg/day.

#### ENBREL

Immunex Corporation (Seattle, WA) and Wyeth-Ayerst (Philadelphia, PA) received approval to co-market Enbrel (etanercept) for reducing signs and symptoms and delaying structural damage in patients with moderately to severely active rheumatoid arthritis (RA). Drug efficacy was measured in three randomized, double-blind, controlled studies. In one study, patients ( $n = 234$ ) meeting the following criteria were evaluated: patients with active RA who were at least 18 years old and had failed therapy with at least 1 but no more than 4 disease-modifying antirheumatic drugs, had at least 12 tender joints, at least 10 swollen joints, and either erythrocyte sedimentation rate of at least 28 mm/hr, C-reactive protein greater than 2.0 mg/dL, or morning stiffness for at least 45 minutes. Patients were randomized to Enbrel 10 mg or 25 mg or placebo twice weekly for 6 months. The results of the trials were expressed in percentage of patients with improvement in RA using American College of Rheumatology response criteria. Patients in the 25 mg Enbrel arm ( $n = 78$ ) experienced 62% response at month 3, compared with 23% for patients in the placebo arm ( $n = 80$ ). At month 6, patients in the 25 mg Enbrel arm experienced 59% response, compared with 11% for patients in the placebo arm. Enbrel is contraindicated for patients with sepsis. Potential adverse events include injection site reaction, respiratory infection, headache, nausea, and rhinitis. The recommended dosage for adult patients with RA is 25 mg administered twice weekly as a subcutaneous injection 72 to 96 hours apart. Dosage for pediatric patients ages 4 to 17 years with active polyarticular-course juvenile rheumatoid arthritis is 0.4 mg/kg (maximum 25 mg per dose) administered twice weekly as a subcutaneous injection 72 to 96 hours apart.

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