

### Drugs recently approved or pending approval

#### ENBREL

The United States Food and Drug Administration approved Enbrel (etanercept) by Immunex Corporation (Seattle, WA) and Wyeth-Ayerst (Philadelphia, PA) for a new indication. Enbrel is now indicated for reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JRA) in patients who have had an inadequate response to one or more disease-modifying antirheumatic drugs. Safety and efficacy of Enbrel were evaluated in a two-part study. Patients ( $n = 69$ ) ages 4 to 17 years with polyarticular-course JRA unresponsive to or intolerant of methotrexate received Enbrel (0.4 mg/kg/day or 25 mg maximum) twice weekly. Patients who demonstrated a clinical response by day 90 ( $n = 51$ ) entered part two of the study in which they were randomized to remain on Enbrel ( $n = 25$ ) or receive placebo ( $n = 26$ ) for 4 months. Six criteria were evaluated: active joint count, limitation of motion, physician global assessment, patient/parent global assessment, functional assessment, and erythrocyte sedimentation rate. Improvement was defined as a 30% or greater improvement in at least three of the six criteria and a 30% or greater worsening in no more than one of the six criteria. Disease flare was defined as a 30% or greater worsening in three of the six criteria and a 30% or greater improvement in no more than one of the six criteria and a minimum of two active joints. Twenty-four percent of patients in the Enbrel arm experienced disease flare compared with 77% in the placebo arm. All six criteria worsened in the placebo arm and remained stable or improved in the Enbrel arm. Enbrel is contraindicated in patients with sepsis. Potential adverse reactions associated with Enbrel use in pediatric patients include infection, headache, abdominal pain, vomiting, and nausea. Possible severe adverse reactions in pediatric patients include varicella, gastroenteritis, depression/personality disorder, cutaneous ulcer, and esophagitis/gastritis. The recommended dose of Enbrel for pediatric patients ages 4 to 17 years with active polyarticular-course JRA is 0.4 mg/kg (up to a maximum of 25 mg per dose) administered twice weekly as a subcutaneous injection 72 to 96 hours apart.

#### CUTIVATE

Glaxo Wellcome (Research Triangle Park, NC) has received approval to market Cutivate (fluticasone propionate cream) for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in pediatric patients age 3 months or older. Effectiveness of Cutivate in the treatment of

moderate to severe eczema was evaluated in two controlled studies. In the first study, patients were treated with Cutivate cream once daily ( $n = 64$ ) or twice daily ( $n = 65$ ) for 28 days. Based on an investigator's global evaluation, the eczema resolved in 30% of patients in the once-daily treatment arm compared with 48% in the twice-daily treatment arm. The severity of the eczema improved to excellent in 42% of the patients in the once-daily treatment arm and 32% in the twice-daily treatment arm. Adverse reactions associated with the use of Cutivate in pediatric patients include facial telangiectasia, nonfacial telangiectasia, burning, dusky erythema, erythematous rash, and urticaria. Cutivate cream should be administered by gently applying a thin film on the affected skin areas once or twice daily for the treatment of atopic dermatitis and twice daily for treatment of other corticosteroid-responsive dermatoses.



#### DOXIL

The Food and Drug Administration approved Doxil (doxorubicin HCl liposome injection) by Alza Corporation (Mountain View, CA) for a new indication. Doxil is now indicated for the treatment of metastatic carcinoma of the ovary in patients with disease that is refractory to both paclitaxel- and platinum-based chemotherapy regimens. Drug efficacy was

evaluated in three open-label single-arm studies. Patients ( $n = 146$ ) with metastatic ovarian carcinoma refractory to both paclitaxel- and platinum-based chemotherapy received Doxil (50 mg/m<sup>2</sup>) infused over 1 hour every 3 or 4 weeks for three to six treatments or longer if no dose-limiting toxicity or progression of disease occurred. The studies' primary endpoint was response rate based on Southwest Oncology Group criteria. Secondary endpoints were time to response, duration of response, and time to progression. Pooled data from the three studies demonstrated a response rate of 13.8% (95% confidence interval, 8.1% to 19.3%). The median time to response was 17.6 weeks, and the duration of response was 39.4 weeks. Potential adverse events associated with Doxil use in ovarian cancer patients include anemia, neutropenia, leukopenia, nausea, palmar-plantar erythrodysesthesia, stomatitis, and asthenia. The recommended dose of Doxil is 50 mg/m<sup>2</sup> administered intravenously over 1 hour once every 4 weeks for a minimum of four treatments.

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