

### Drugs recently approved or pending approval

#### TRILEPTAL

The United States Food and Drug Administration approved marketing of Trileptal (oxcarbazepine) by Novartis (East Hanover, NJ). Trileptal is indicated for use as monotherapy or as an adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children ages 4 to 16 years with epilepsy. Drug efficacy as monotherapy was evaluated in four randomized, double-blind, multicenter studies. In one study, untreated patients ( $n = 67$ ) with newly diagnosed and recent-onset partial seizures were randomized to placebo or Trileptal (300 mg twice daily titrated over 6 days to 600 mg twice daily, followed by maintenance therapy for 84 days). The study's primary endpoint was comparison of time to onset of first seizure. According to Kaplan-Meier estimates, the rates for first seizure event were statistically significant in favor of Trileptal compared with the placebo arm. Drug efficacy as adjunctive therapy was evaluated in two randomized, double-blind, multicenter studies. In one study, patients ( $n = 692$ ) who were taking one to three concomitant antiepileptic drugs (AEDs) were stabilized on the optimum dosages of AEDs in an 8-week baseline phase. Patients who experienced at least eight partial seizures during the baseline phase were randomized to placebo or Trileptal; treatment duration was 14 weeks for pediatric patients and 24 weeks for adult patients. The study's primary endpoint was a comparison of the percentage change from baseline in frequency of partial seizures. The results were statistically significant in favor of the Trileptal arm compared with the placebo arm. Potential adverse events associated with Trileptal include dizziness, somnolence, diplopia, fatigue, nausea, and vomiting. The recommended daily dose of Trileptal depends on type of therapy (monotherapy or adjunctive therapy) and patient age and weight.



#### TARGRETIN

Ligand Pharmaceuticals (San Diego, CA) received approval to market Targretin (bexarotene). Targretin is indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma (CTCL) in patients who are refractory to at least one prior systemic therapy. Drug effectiveness was evaluated in two multicenter, open-label, historically controlled clinical studies. Patients ( $n = 152$ ) with advanced CTCL who were refractory to at least one prior systemic therapy or with early-stage CTCL who were intolerant to or refractory to at least two prior systemic therapies were treated with Targretin at an initial dose of

300 mg/m<sup>2</sup>/day. The study's primary endpoint was tumor response, which was assessed by observation of baseline-defined index lesions using the Composite Assessment of Index Lesion Disease Severity. A partial response was defined as an improvement of at least 50% in the index lesions without worsening or development of new cutaneous tumors or noncutaneous manifestations. A complete response was defined as complete disappearance of all manifestations of the disease. At the initial dose of 300 mg/m<sup>2</sup>/day, one of 62 (1.6%) patients experienced a complete clinical response and 19 of 62 (30%) patients experienced a partial response. Adverse reactions associated with Targretin may include hyperlipemia, hypercholesteremia, hyperthyroidism, headache, asthenia, and leukopenia. The recommended initial dose of Targretin is 300 mg/m<sup>2</sup>/day taken with food.

#### TEQUIN

The Food and Drug Administration approved marketing of Tequin (gatifloxacin) by Bristol-Myers Squibb (Princeton, NJ). Tequin is indicated for treatment of the following infections caused by susceptible strains of the designated organisms: acute bacterial exacerbations of chronic bronchitis caused by

*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, or *Staphylococcus aureus*; acute sinusitis caused by *S. pneumoniae*, or *H. influenzae*; community-acquired pneumonia caused by *S. pneumoniae*, *H. influenzae*, *H. parainfluenzae*, *M. catarrhalis*, *S. aureus*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, or *Legionella pneumophila*; uncomplicated and complicated urinary tract infections (UTIs) caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*; pyelonephritis caused by *E. coli*; uncomplicated urethral and cervical gonorrhea caused by *Neisseria gonorrhoeae*; and acute uncomplicated rectal infections in women caused by *N. gonorrhoeae*. Tequin has demonstrated activity against most strains of the organisms listed previously in vitro and in clinical infections. Potential adverse reactions associated with Tequin include nausea, vaginitis, diarrhea, headache, and dizziness. The recommended dosage of Tequin is 400 mg/day for all indicated infections (uncomplicated UTI may be treated with 200 mg); treatment duration depends on the type of infection.

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.