Drugs recently approved or pending approval

SEROQUEL XR

The US Food and Drug Administration (FDA) has given approval to AstraZeneca (Wilmington, DE) to market Seroquel XR (quetiapine fumarate) extended-release tablets for the treatment of schizophrenia. Seroquel XR once daily was evaluated in a 6-week, fixed-dose, placebo-controlled trial in inpatients and outpatients (n = 573) who met DSM-IV criteria for schizophrenia. Seroquel XR was administered at 300 mg on day 1, and the dose was increased to either 400 mg or 600 mg by day 2 or 800 mg by day 3. The primary endpoint was the change in Positive and Negative Syndrome Scale (PANSS) total score from baseline to the end of treatment (day 42). Seroquel XR 400, 600, and 800 mg/day were superior to placebo in the PANSS total score at day 42. The most common adverse effects associated with Seroquel XR were dry mouth, somnolence, sedation, and dizziness. The recommended initial dose of Seroquel XR is 300 mg/day (range, 400–800 mg/day), which should be taken in the evening without food or with a light meal (approximately 300 calories). Seroquel XR should not be used for treatment of patients with dementia-related psychosis.

TINDAMAX

Mission Pharmacal Company (San Antonio, TX) has been given FDA approval to market Tindamax (tinidazole) for the treatment of bacterial vaginosis in nonpregnant women. The efficacy of Tindamax was evaluated in a randomized, double-blind, placebo-controlled trial involving 235 women diagnosed with bacterial vaginosis using Amsel's criteria, which requires the presence of 3 of the 4 following features: (1) abnormal homogeneous vaginal discharge, (2) discharge that has a pH greater than 4.5, (3) discharge that emits a "fishy" amine odor when mixed with 10% potassium hydroxide solution, and (4) discharge that contains 20% or more clue cells on microscopic evaluation. Patients were randomized to Tindamax 1 g once daily for 5 days (n = 76), Tindamax 2 g once daily for 2 days (n = 73), or placebo (n = 78). The primary outcome measure was therapeutic cure, defined as clinical cure (return to normal vaginal discharge and resolution of Amsel's criteria) and microbiologic cure (Nugent score, ≤ 3). In both treatment arms, Tindamax demonstrated superior efficacy over placebo, with a therapeutic cure rate of 36.8% in the group that received Tindamax 1 g once daily for 5 days and 27.4% in the group that received Tindamax 2 g once daily for 2 days as compared with 5.1% in the placebo group. The most common adverse effects in Tindamax-treated patients were decreased appetite, flatulence, urinary tract infection, painful urination, urine abnormality, pelvic pain, vulvovaginal discomfort, vaginal odor, menorrhagia, and upper respiratory tract infection. Tindamax is also indicated for the treatment of trichomoniasis, giardiasis, and amebiasis.

TORISEL

The FDA has given approval to Wyeth Pharmaceuticals, Inc. (Philadelphia, PA) to market Torisel (temsirolimus) for the treatment of advanced renal cell carcinoma. Torisel was evaluated in a phase 3, multicenter, 3-arm, randomized, open-label study involving 626 previously untreated patients (mean age, 59 yr) with advanced renal cell carcinoma. Patients were randomized to receive IFN-α alone (n = 207), Torisel alone (25 mg/wk; n = 209), or Torisel plus IFN-α (n = 210). Overall survival (OS; time from randomization to death), progression-free survival (PFS; time from randomization to disease progression or death), objective response rate (ORR), and safety were compared in patients receiving Torisel alone, IFN-α alone, or Torisel plus IFN-α. The median duration of treatment in the Torisel arm and Torisel plus IFN arm was 17 weeks and 8 weeks, respectively. Patients receiving Torisel (25 mg) alone had significant improvements in OS as compared with patients receiving IFN-α alone (10.9 mo versus 7.3 mo; $P = 0.0078$). Torisel (15 mg) plus IFN-α did not result in a significant increase in OS when compared with IFN-α alone. Torisel also was associated with a statistically significant improvement over INF-α in both PFS (5.5 mo versus 3.1 mo; $P = 0.0001$) and ORR (8.6 mo versus 4.8 mo; $P = 0.1232$). The most common adverse effects associated with Torisel were rash, asthenia, mucositis, nausea, edema, and anorexia. The recommended dose of Torisel is 25 mg weekly infused over a 30- to 60-minute period.

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