Drugs recently approved or pending approval

BIDIL

The US Food and Drug Administration (FDA) has given approval to NitroMed, Inc. (Lexington, MA) to market BiDil (isosorbide dinitrate/hydralazine hydrochloride) for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status. BiDil was originally evaluated in 2 trials of black and white patients (N = 1692) with mild to severe heart failure; these retrospective analyses suggested an effect on survival in black patients and showed little evidence of an effect in the white population. Therefore, a third study in black patients with heart failure was performed. BiDil was compared with placebo in a trial of 1050 self-identified black patients. Patients were maintained on stable background therapy (a loop diuretic, angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, and/or β-blocker) and were randomized to either BiDil (n = 518) or placebo (n = 532). Patients were treated for up to 18 months. The trial was completed early because the BiDil-treated group showed a statistically significant 43% reduction in all-cause mortality. The BiDil-treated group also showed a 39% reduction in the risk of a first hospitalization for heart failure and had a statistically significant improvement in response to the Minnesota Living with Heart Failure Questionnaire. The most common adverse effects experienced by BiDil-treated patients in the third study were headache, dizziness, chest pain, and asthenia.

ROZEREM

Takeda Pharmaceuticals North America, Inc. (Lincolnshire, IL) was given FDA approval to market Rozerem (ramelteon) 8-mg tablets for the treatment of insomnia characterized by difficulty with sleep onset for long-term use in adults. Rozerem is the first and only prescription sleep medication that has shown no evidence of abuse and dependence and has not been designated as a controlled substance by the US Drug Enforcement Administration. The efficacy of Rozerem has been evaluated in clinical studies involving more than 4200 patients aged 18 to 93 years as well as in a study with 472 patients who received single daily doses of Rozerem for up to 1 year. In a 35-night, double-blind, placebo-controlled, parallel group study, adults with chronic insomnia were randomized to either 8-mg Rozerem or placebo to measure residual effects at 3 time points (weeks 1, 3, and 5). At week 5, next-morning residual effects did not differ between Rozerem- or placebo-treated patients, as measured by the Visual Analog Mood and Feeling Scale. The most common adverse events associated with Rozerem were headache, somnolence, dizziness, and fatigue. The recommended dose of Rozerem is 8 mg taken within 30 minutes before going to bed. Rozerem should not be taken with or immediately following a high-fat meal.

SYNERA

The FDA has given approval to ZARS, Inc. (Salt Lake City, UT) to market Synera (lidocaine 70 mg/tetracaine 70 mg) topical patch for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatologic procedures (eg, excision, electrodessication, shave biopsy of skin lesions). Synera was evaluated in 4 randomized, double-blind, placebo-controlled studies (3 studies of adult and geriatric patients and 1 study of pediatric patients) for use in superficial venous access. In adult patients (N = 101), Synera and placebo patches were placed on opposite arms. In all 3 studies, patients reported less pain, as measured by a Visual Analog Scale, following Synera treatment as compared with placebo. In the pediatric study, patients (N = 61) were stratified by age-group (3–6 years and 7–17 years) and received either Synera or placebo for 20 minutes prior to venipuncture or intravenous cannulation in the antecubital fossa or dorsum of the hand. Children in the younger group reported less pain with Synera than with placebo, whereas pain scores in older children treated with Synera were not statistically significantly different from those of placebo. Synera was also evaluated in 2 randomized, placebo-controlled trials (1 study of adults and 1 study of children) for use in superficial dermatologic procedures. In adult patients (N = 168), Synera or placebo was given 30 minutes prior to a superficial dermatologic procedure. Less pain was reported following Synera treatment as compared with placebo. In the pediatric population (N = 88; stratified by age 3–6 and 7–17 years), a 30-minute Synera or placebo application was given prior to lidocaine injection. Younger children who received Synera reported less pain that those receiving placebo. No difference between treatments was seen in the older children. The most common local adverse effects were erythema, blanching, and edema.

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