Drugs recently approved or pending approval

EXTINA

The US Food and Drug Administration (FDA) has given approval to Stiefel Laboratories, Inc. (Coral Gables, FL) to market Extina (ketoconazole) foam 2% for the topical treatment of seborrheic dermatitis in immunocompetent patients aged 12 years and older. The safety and efficacy of Extina foam were evaluated in a randomized, double-blind, vehicle-controlled study in 847 immunocompetent patients aged 12 years and older with mild to severe seborrheic dermatitis. Patients were given either Extina foam (n = 427) or placebo vehicle foam (n = 420) applied to affected areas (face, scalp, and/or chest) twice daily for 4 weeks. The overall disease severity in terms of erythema, scaling, and induration was assessed at baseline and week 4 as measured by a 5-point Investigator's Static Global Assessment (ISGA) scale. Treatment success was defined as achieving an ISGA score of 0 (clear) or 1 (minimal or faint) at week 4 (end of treatment) and at least 2 grades of improvement from baseline. Based on the ISGA scale, 56% of Extina-treated patients achieved treatment success compared with 42% of vehicle-treated patients. The most common adverse effects were dryness, erythema, irritation, paresthesia, pruritus, rash, and warmth.

SANCTURA XR

Indevus Pharmaceuticals, Inc. (Lexington, MA) has been given FDA approval to market Sanctura XR (trospium chloride) extended-release capsules for the treatment of overactive bladder (OAB). Once-daily Sanctura XR was evaluated in two 12-week, randomized, double-blind, placebo-controlled studies in patients with OAB who had symptoms of urinary frequency, urgency, and urge urinary incontinence. For both studies, patients (mean age, 60 yr; N = 1135) met the following criteria: (1) the presence of urge incontinence (predominance of urge); (2) at least 1 incontinence episode per day; and (3) 10 or more micturitions (voids) per day (assessed by 3-day urinary diary). Patients were administered either Sanctura XR 60 mg or placebo. The co-primary endpoints were the mean change from baseline to week 12 in the number of voids/24 hours (reductions in urinary frequency) and number of incontinence episodes/24 hours. In both studies, Sanctura XR demonstrated statistically significantly greater reductions in urinary frequency (study 1, $P < 0.0001$; study 2, $P = 0.0009$) and incontinence episodes (study 1, $P = 0.0024$; study 2, $P < 0.0001$) as well as increases in void volume (study 1, $P = 0.0039$; study 2, $P = 0.0014$) when compared with placebo at week 12. The most common adverse effects in patients treated with Sanctura XR were dry mouth and constipation. The recommended dose of Sanctura XR is one 60 mg capsule daily in the morning. Sanctura XR should not be used in patients who have urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma.

SELZENTRY

The FDA has given approval to Pfizer Inc. (New York, NY) to market Selzentry (maraviroc) tablets to be used in combination with other antiretroviral agents for the treatment of adult patients infected with only CCR5-tropic HIV-1 who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. The efficacy and safety of Selzentry were established in two 24-week ongoing, double-blind, randomized, placebo-controlled, multicenter studies (A4001027 [MOTIVATE-1] and A4001028 [MOTIVATE-2]) involving 635 treatment-experienced patients with CCR5-tropic HIV-1 infection. Patients were required to have an HIV-1 RNA of greater than 5000 copies/mL despite at least 6 months of prior therapy with at least 1 agent from 3 of the 4 antiretroviral drug classes (≥ 1 nucleoside reverse transcriptase inhibitor, ≥ 1 non-nucleoside reverse transcriptase inhibitor, ≥ 2 protease inhibitors, and/or enfuvirtide) or documented resistance or intolerance to at least 1 member of each class. Patients received an optimized background regimen of 3 to 6 antiretroviral agents (excluding low-dose ritonavir) based on prior treatment history and baseline genotypic and phenotypic viral resistance measurements. Patients were then randomized in a 2:2:1 ratio to Selzentry 300 mg once daily, Selzentry 300 mg twice daily, or placebo. After 24 weeks, 60.8% of Selzentry-treated patients had an HIV-1 RNA of less than 400 copies/mL compared with 27.8% of placebo-treated patients. The most common adverse effects associated with Selzentry were cough, pyrexia, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness.

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.