

Drugs recently approved or pending approval

ALLI

The US Food and Drug Administration (FDA) has given approval to GlaxoSmithKline Consumer Healthcare (Pittsburgh, PA) to market alli (orlistat 60 mg capsules) for weight loss in overweight adults aged 18 years and older when used with a reduced-calorie, low-fat diet. Alli is the first FDA-approved over-the-counter weight loss product and is the first nonprescription product to include a comprehensive support program. According to labeling, most patients who took alli in conjunction with a reduced-calorie, low-fat diet (containing about 15 g of fat/meal) and an exercise program, lost 5 to 10 lb over 6 months. A higher dose of alli has been marketed as the prescription drug Xenical (orlistat 120 mg capsules), which is supported by findings from the 4-year XENDOS (XENical in the prevention of diabetes in obese subjects) study that included 3304 patients with obesity-related risk factors and comorbidities. The most common adverse effects associated with alli were bowel changes, including gas with oily spotting and loose stools. Alli should be taken at mealtime because it prevents the absorption of dietary fat (about 25%). Users should also take a multivitamin once daily at bedtime, as alli can reduce the absorption of some vitamins. The recommended dose of alli is one 60 mg capsule 3 times daily with meals containing fat.



LIALDA

Shire (Philadelphia, PA) has been given FDA approval to market Lialda (mesalamine), the first once-daily oral formulation of mesalamine, for the induction of remission in patients with active, mild to moderate ulcerative colitis. Lialda was evaluated in 2 randomized, double-blind, placebo-controlled trials involving 517 adults. In both studies, patients were randomized to Lialda 2.4 g/day and 4.8 g/day once daily for 8 weeks except for the 2.4 g/day group in study 1, in which Lialda was administered in divided doses twice daily (1.2 g). The primary efficacy endpoint in both clinical trials was to compare the percentage of patients in remission after 8 weeks of treatment for the Lialda treatment groups versus placebo. Remission was defined as an Ulcerative Colitis Disease Activity Index score of 1 or less, with scores of zero for rectal bleeding and stool frequency, and a sigmoidos-

copy score reduction of 1 point or more from baseline. Both doses demonstrated superiority over placebo in the primary endpoint (study 1, 34.1% with 2.4 g/day, 29.2% with 4.8 g/day, 12.9% with placebo; study 2, 40.5% with 2.4 g/day, 41.2% with 4.8 g/day, 22.1% with placebo) and provided consistent benefit in secondary efficacy parameters (eg, clinical improvement, treatment failure, clinical remission, sigmoidoscopic improvement). The most common adverse effects associated with Lialda were headache and flatulence. The recommended dose of Lialda is two to four 1.2 g tablets once daily with food for a total daily dose of 2.4 g or 4.8 g for up to 8 weeks.

YAZ

The FDA has given approval to Berlex, Inc. (Wayne, NJ) to market Yaz (3 mg drospirenone/0.02 mg ethinyl estradiol) for the treatment of moderate acne vulgaris in women (age, ≥ 14 yr) who desire an oral contraceptive for birth control. The efficacy of Yaz was evaluated in 2 multicenter, double-blind, randomized, placebo-controlled studies involving 889 patients (ages, 14–45 yr) with moderate acne. Patients received Yaz or placebo for six 28-day cycles. The primary endpoints were the percent change in inflammatory lesion count, noninflammatory lesion count, and total lesion count and the percentage of patients with a “clear” or “almost clear” rating on the Investigator’s Static Global Assessment scale on day 16 of cycle 6. In both studies, Yaz significantly reduced total inflammatory and noninflammatory lesion counts. Also, ratings of clear and almost clear skin, as measured by the Investigator’s Static Global Assessment scale, were almost 4 times greater in the Yaz treatment group compared with the placebo group. The most common adverse effects were upper respiratory infection, metrorrhagia, headache, suspicious Papanicolaou smear, nausea, and sinusitis. Yaz is also indicated for treatment of symptoms of premenstrual dysphoric disorder and treatment of premenstrual syndrome.

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

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