

Drugs recently approved or pending approval

VANIQA

The United States Food and Drug Administration (FDA) approved marketing of Vaniqa (eflornithine hydrochloride) Cream, 13.9% by Bristol-Myers Squibb Company (Princeton, NJ). Vaniqa is indicated for the reduction of unwanted facial hair in women. Drug efficacy was evaluated in 2 randomized double-blind studies. Patients ($n = 594$) were randomized to Vaniqa or vehicle twice daily for as many as 24 weeks. Women in the trial had a customary frequency of removing hair at least twice a week. Women with facial conditions such as severe inflammatory acne, pregnant women, and nursing mothers were excluded from the studies. Improvement or worsening was assessed from the baseline condition (Physician's Global Assessment [PGA]), 48 hours after shaving, of all treated areas. Approximately 32% of patients showed marked improvement or greater after 24 weeks of treatment with Vaniqa. PGA outcome for patients treated with Vaniqa whose skin was clear/almost clear was 5%, compared with 0% for patients treated with vehicle. Marked improvement was 27% for patients treated with Vaniqa, compared with 8% for patients treated with vehicle. Possible adverse events associated with Vaniqa include acne, pseudofolliculitis barbae, headache, and stinging, itching, or burning skin. Vaniqa should be applied twice daily in conjunction with hair removal techniques as needed.



MALARONE

Glaxo Wellcome (Research Triangle Park, NC) received approval to market Malarone (atovaquone and proguanil hydrochloride) indicated for the prevention and treatment of malaria. Efficacy of Malarone for the treatment of acute malarial infections caused by *Plasmodium falciparum* was measured in 3 phase II clinical trials: atovaquone alone, proguanil hydrochloride alone, and the combination of atovaquone and proguanil hydrochloride. Among evaluable patients ($n = 156$), the parasitological cure rate was 66% with atovaquone alone, 6% with proguanil hydrochloride alone, and 100% with combination of the two. Eight phase III controlled clinical trials evaluated the efficacy of Malarone for treatment of acute malarial infections caused by *P. falciparum*. Among patients ($n = 471$) who were treated with the equivalent of 4 Malarone tablets once daily for 3 days, 464 had a sensitive response (elimination of parasitemia with no recurrent parasitemia during a 28-day follow-up). Overall efficacy in 521 evaluable patients was 98.7%. Malarone was evaluated for

prophylaxis of malaria in 4 clinical trials in malaria-endemic areas. In 3 placebo-controlled studies of 10 to 12 weeks' duration, patients were randomized to Malarone ($n = 326$) or placebo ($n = 341$). Of those patients, 57 patients in the Malarone arm failed to complete the study, and 44 patients in the placebo arm also failed. Of the remaining evaluable patients, 2 patients in the Malarone arm developed parasitemia (*P. falciparum*), compared with 92 patients in the placebo arm. Potential adverse events associated with Malarone include abdominal pain, nausea, vomiting, headache, and diarrhea. One Malarone tablet daily should be administered for the prevention of malaria starting 1 or 2 days before entering a malaria-endemic area and continued daily during the stay and for 7 days after return. Four Malarone tablets should be administered as a single dose daily for the treatment of malaria. Dosages vary for both the prevention and treatment of malaria for pediatric patients, based upon body weight. Daily dose should be taken at the same time each day with food or a milky drink.

INNOHEP

The FDA approved marketing of Innohep (tinzaparin sodium injection) by DuPont Pharma (Wilmington, DE). Innohep is

indicated for the treatment of symptomatic deep vein thrombosis (DVT) with or without pulmonary embolism when administered in conjunction with warfarin sodium. In one randomized, multicenter, double-blind trial, Innohep was compared to unfractionated heparin in patients ($n = 435$) with symptomatic, proximal DVT. Patients were administered Innohep 175 IU/kg body weight once daily ($n = 216$) or heparin 5000 IU as an intravenous (IV) bolus dose and then as a continuous IV infusion with the rate adjusted according to the activated partial thromboplastin time ($n = 219$). Both treatment groups also received oral warfarin sodium commencing on day 2 of treatment. For patients in the Innohep arm, 6 thromboembolic events were reported, compared with 15 in the heparin arm. Innohep is contraindicated in patients with active major bleeding, in patients with (or history of) heparin-induced thrombocytopenia, or in patients with hypersensitivity to tinzaparin sodium. Dosage of Innohep is weight-based, and is administered by subcutaneous injection. It must not be administered by intramuscular or intravenous injection.

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