is to “significantly advance the health and well being of patients by developing and disseminating a futuristic practice model that supports the most effective use of pharmacists as direct patient care providers.”

To date, the initiative, including the summit, has 14 corporate supporters: McKesson Corporation, Amgen, Omnicell Inc., CareFusion, Apexus, Baxa, Baxter International Inc., Cardinal Health Foundation, Medco Health Solutions Inc., Cerner, Epic, Grifolis, Pharmacy OneSource Inc., and Siemens.

The proceedings of the summit and the full set of recommendations will be published next year in AJHP.

—Cheryl A. Thompson
DOI 10.2146/news100081

FDA approves tesamorelin for HIV-related lipodystrophy

FDA on November 10 announced the approval of tesamorelin, a once-daily injectable treatment to reduce excess abdominal fat in HIV-infected patients with lipodystrophy.

Tesamorelin was developed by Theratechnologies of Montréal, Canada, and will be marketed in the United States by Massachusetts-based EMD Serono.

Tesamorelin is a synthetic analogue of growth hormone-releasing factor, according to the drug’s FDA-approved labeling.

Theratechnologies President Yves Rosconi said during a November 11 investors’ briefing that the drug will be available to U.S. patients in “a matter of weeks” under the brand name Egrifta.

Rosconi said tesamorelin is the first drug to be approved in the United States for the reduction of abdominal fat in HIV-infected patients with lipodystrophy.

The labeling states that tesamorelin is not indicated for weight loss and had no effect on overall weight in patients who received the drug in clinical trials.

Tesamorelin is contraindicated in patients with conditions that disrupt the hypothalamic-pituitary axis, including hypophysectomy, hypopituitarism, pituitary tumor or surgery, and head irradiation or trauma. The drug is also contraindicated during pregnancy and in patients who have a hypersensitivity to tesamorelin or mannitol, an excipient in the formulated product.

Patients with an active cancer should not receive tesamorelin, although treatment can begin after the cancer therapy has ended, according to the labeling for tesamorelin.

The recommended dosage of tesamorelin is 2 mg injected subcutaneously into the abdomen once daily. The injection site should be rotated among various areas of the abdomen to reduce the occurrence of injection-site reactions.

In clinical trials, the most frequently reported adverse events in patients treated with tesamorelin were hypersensitivity reactions and injection-site reactions. Adverse events attributed to the effects of growth hormone, such as arthralgia, pain in the extremities, peripheral edema, carpal tunnel syndrome, and hyperglycemia, also occurred during clinical trials and were cited as reasons for discontinuation of therapy.

Monitoring of blood glucose and serum levels of insulin-like growth factor 1 (IGF-1) are recommended during treatment with tesamorelin. The labeling recommends that discontinuation of treatment be considered for patients with persistent elevations of IGF-1 greater than three standard deviation scores.

Discontinuation should also be considered if glucose intolerance or diabetes develops during tesamorelin treatment and the drug has not reduced the amount of visceral adipose tissue.

Each vial of Egrifta will contain 1 mg of tesamorelin and 50 mg of mannitol that have been lyophilized for later reconstitution to a tesamorelin concentration of 1 mg/mL.

The labeling states that Egrifta will be available packaged as two boxes, one containing 60 vials of tesamorelin and the other containing 30 10-mL vials of diluent and a 30-day supply of needles and syringes. The tesamorelin vials must be stored at 2–8 °C, and the other supplies should be stored at controlled room temperature, 20–25 °C.

Once reconstituted, the drug should be injected immediately.

—Kate Traynor
DOI 10.2146/news100082

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