Egrifta Gets FDA Approval for HIV-Associated Lipodystrophy

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Egrifta (tesamorelin) has been approved for the treatment of HIV-associated lipodystrophy, according to a November 10 announcement from the U.S. Food and Drug Administration (FDA). The drug, requiring once-daily injections, was approved to reduce visceral adipose tissue (VAT)—deep belly fat surrounding the liver, stomach and other abdominal organs—in people living with HIV experiencing lipodystrophy, a side effect of antiretroviral (ARV) therapy.

Egrifta was developed by Theratechnologies, a company based in Montreal. It is a synthetic growth hormone release factor that acts on pituitary cells in the brain to stimulate growth hormone production, which has been shown to reduce VAT in people with lipodystrophy.

Injecting Egrifta is a multiple-step process. Vials containing a dry version of the active drug must first be mixed, or reconstituted, with sterile water packed with the product. The mixed liquid is then drawn up into a hypodermic needle and injected directly under the skin of the stomach area. One of the FDA's post-marketing requirements is the development of a single-vial drug that does away with the need for reconstitution.

Theratechnologies tested the drug in two Phase III clinical trials involving 816 HIV-positive adult men and women with lipodystrophy and excess abdominal fat. Of these, 543 patients received Egrifta during a 26-week, placebo-controlled period. In both studies, patients treated with Egrifta experienced greater reductions in VAT—about 15 to 17 percent—as measured by CT scan, compared with patients receiving placebo. Some patients reported improvements in their self-image.

Once Egrifta therapy is discontinued, VAT returns. As a result, Egrifta therapy will need to be continued indefinitely in order to mantain reductions in abdominal fat.

The presence of excess VAT associated with this condition may contribute to other health problems, such as cardiovascular disease, as well as affect a patient's quality of life. Whether Egrifta decreases the risk of cardiovascular disease or improves adherence to ARV therapy has not been studied. In the absence of these data, careful consideration should be given to whether Egrifta treatment should be continued in people living with HIV who do not show a clear efficacy response, notably a reduction in VAT measured by waist circumference or CT scan.

The most commonly reported side effects in the Phase III studies included joint pain (arthralgia), skin redness and rash at the injection site (erythema and pruritus), stomach pain, swelling and muscle pain (myalgia). Worsening blood sugar control occurred more often in patients treated with Egrifta than with placebo.

Egrifta will be marketed in the United States by EMD Serono, a company based in Rockland, Massachusetts. The drug is expected to be available in January 2011; distribution of the drug will be tightly regulated, with all prescriptions being processed through an EMD Serono-designated service and fulfilled by select mail-order pharmacies. To learn more about the prescription process, people living with HIV and their health care providers are encouraged to call the Axis center at: 877-714-2947.

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