HIV Lipo Treatment Egrifta to Be Reviewed May 27

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A U.S. Food and Drug Administration (FDA) independent advisory committee is set to review Montreal-based Theratechnologies' New Drug Application (NDA) for Egrifta (tesamorelin) for the treatment of HIV-associated fat increases (lipohypertrophy), according to an announcement from the Office of the Federal Register. The meeting of the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) to review the supporting safety and efficacy data is scheduled for May 27 at the University of Maryland University College in Adelphi.

Should EMDAC recommend Egrifta be approved, the FDA has until the end of July to decide whether to grant marketing clearance for the drug. Though the agency is not required to follow the recommendations of its advisory committees, it usually does.

Egrifta prompts the pituitary gland to release more growth hormone, which has been shown to promote fat loss in people with lipohyertrophy. Two completed Phase III clinical trials of Egrifta showed a decrease in visceral adipose tissue (VAT)—fat deep within the belly—of up to 18 percent and a favorable side effect profile.

Should the FDA approve Egrifta, EMD Serono of Rockland, Massachusetts, will assume full responsibility for marketing and selling the drug in the United States. Theratechnologies has retained the rights to sell the drug elsewhere in the world.

Theratechnologies submitted its NDA to the FDA on May 29, 2009. The agency filed it August 12, 2009, which initiated a substantive review of the application. The EMDAC meeting was originally scheduled for February 24, 2010, but was postponed due to administrative delays at the FDA. As a result, the FDA has indicated that the action goal date, which is the target date for the FDA to complete its review of the Egrifta NDA, will be extended to July 27 of this year.

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