FDA Review of HIV Lipodystrophy Drug Is Delayed

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Montreal-based Theratechnologies announced yesterday that the U.S. Food and Drug Administration (FDA) will reschedule its meeting with independent experts to help decide whether to approve Egrifta (tesamorelin) for the treatment of HIV-associated lipodystrophy. Originally scheduled for Wednesday, February 24, the meeting of the Endocrinologic and Metabolic Drugs Advisory Committee is being delayed for procedural reasons, Theratechnologies reports, not because of concerns surrounding tesamorelin's safety or efficacy.

Theratechnologies submitted its request for approval—known as a new drug application (NDA)—to the FDA on May 29, 2009, for Egrifta. The drug works by prompting the body to release growth hormone, which has been shown to diminish abnormal fat accumulation—a hallmark symptom of HIV-associated lipodystrophy.

Once approved, Egrifta will be marketed and sold in the U.S. by Rockland, Massachusetts-based EMD Serono.

Though the FDA has not yet scheduled an alternative date for the advisory committee, March 29 is the target date for the FDA to complete its review of Egrifta's NDA and either approve or deny the drug's use for HIV-positive people with lipodystrophy.

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