FDA Committee Unanimously Recommends Egrifta for Lipodystrophy

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A U.S. Food and Drug Administration (FDA) advisory committee has unanimously recommended that Egrifta (tesamorelin), Montreal-based Theratechnologies' experimental product for the treatment of excess abdominal fat in HIV-positive people with lipodystrophy, be approved by the agency. Though the FDA is not required to follow the recommendations of its advisory committees, it usually does so.

Several of the 16 panelists making up the Endocrinologic and Metabolic Drugs Advisory Committee, which met May 27 at the University of Maryland University College (UMUC) Marriott Conference Centers in Adelphi, Maryland, stressed that there is a need for additional follow-up studies to monitor the long-term safety and efficacy of the drug.

Egrifta is a synthetic human growth hormone-releasing factor. Phase III clinical trials of the drug indicate that it decreases visceral adipose tissue (VAT)—fat deep within the belly—by about 17 percent.

According to Christian Marsolais, MD, vice president of clinical research and medical affairs at Theratechnologies, who reviewed the Phase III efficacy results at today's hearing, 57.4 percent of patients taking Egrifta experienced an 8 percent or greater reduction in VAT—the primary goals of the studies—compared with 29.3 percent of the placebo group.

Unlike Serostim (recombinant human growth hormone), an earlier contender for treating excess VAT, Egrifta has long been suggested to have fewer side effects when used for at least a year, including a minimal effect on blood sugar (glucose) levels.

There were, however, conflicting reports at today's hearing regarding the risk of diabetes in people receiving Egrifta in the Phase III clinical trials.

Graziella Soulban, MD, director of clinical research at Theratechnologies, reported higher rates of pre-diabetes and diabetes among those receiving Egrifta, compared with placebo, during the first 26 weeks of the studies. But between weeks 26 and 52 of the studies, however, the number of people with glucose intolerance and diabetes dropped.

Ali Mohamadi, MD, a clinical reviewer from the FDA, unveiled a slightly more detailed analysis.

According to the FDA safety analysis reported this morning, 49.2 percent of patients receiving Egrifta had no instances of raised blood-glucose levels. However, 17.3 percent of those receiving Egfrifta had three or more increased blood-glucose measurements during the clinical trial, compared with 7.3 percent of those receiving placebo.

Mohamadi also reported that 25 percent of patients in the tesamorelin group who started off as pre-diabetic eventually went on to develop frank diabetes in the studies. Among those who began treatment without a history of diabetes and had normal glucose levels, Mohamadi confirmed, the risk of diabetes during the study remains low.

Increases in insulin-like growth factor 1, or IGF-1, was another safety issue discussed at length during today's meeting. Though increases in IGF-1 are considered to be an indicator of Egrifta's activity, IGF-1 has also been suggested to promote tumor growth, which can be problematic in a population of individuals—including people living with HIV—who already face a higher risk of cancer. According to Mohamadi, a third of patients receiving Egrifta had significantly elevated IGF-1 levels. However, according to Soulban, these increases were not found to be associated with an increased risk of any type of cancer in the 52-week Phase III studies.

Mohamadi reiterated that decreases in decreases in VAT associated with the use of Egrifta have not been shown to decrease the risk of cardiovascular disease—an important potential benefit of any drug that treats abdominal obesity—and several panelists reiterated that future studies should explore this goal. And though the panelists were divided on the data submitted to the FDA regarding improvements in body image and body perception in the studies, many were clearly impressed by the mid-day public testimony offered by three people living with HIV—Jeff Berry of the AIDS Treatment Activists Coalition and two Egrifta clinical trial participants—who emphasized the detrimental effects of lipodystrophy in people living with HIV.

As the clock approached 4 p.m., the final vote was cast by the advisory committee members, in response to a single question put forth by the FDA: Does the risk-benefit assessment support approval of Egrifta? Sixteen voted "yes"—there were zero "no" votes and no abstentions.

Several panelists stressed that follow-up data should be collected to better understand the long-term risks of glucose abnormalities and IGF-1 increases. Theratechnologies noted that it is already planning a safety monitoring program that will go into effect if the FDA agrees with the advisory committee panel and approves the drug for use in the United States.

A final decision from the FDA is expected within the next two months. The agency has until July 27 to notify Theratechnologies of the drug's approval status and of any post-marketing studies that must be conducted.

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