Tesamorelin for Lipodystrophy Approval Application Filed

June 3, 2009

Montreal-based Theratechnologies announced on Monday, June 1, that it has filed a New Drug Application (NDA) with the U.S. Food and Drug Administration for tesamorelin, its experimental product for the treatment of excess abdominal fat in HIV-positive people with lipodystrophy. If approved, tesamorelin will be sold in the United States by EMD Serono.

Tesamorelin 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 15 percent. Unlike Serostim (recombinant human growth hormone), an earlier contender for treating excess VAT, tesamorelin has fewer side effects when used for at least a year, including a minimal effect on blood sugar (glucose) levels.

“We plan to work closely with the FDA in order to facilitate the completion of their review,” said Martine Ortega, the vice president of compliance and regulatory affairs at Theratechnologies, in a press release issued by the company. “Treatment for excess abdominal fat in HIV patients with lipodystrophy represents an unmet medical need. If approved, tesamorelin could be the first product available to treat this condition,” she noted.

The FDA may take up to 12 months from the date of the NDA submission to decide whether to approve the drug.