Encouraging Data From Second Tesamorelin Study for Lipo

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Treatment with a tesamorelin, a synthetic compound being developed by Theratechnologies in Montreal that sparks the production of natural human growth hormone, resulted in a significant loss of visceral adipose tissue (VAT)—deep belly fat—compared with a placebo in people with lipodystrophy, according to new results reported August 5 at the XVII International AIDS Conference in Mexico City. These data come from the first half of a second confirmatory Phase III clinical trial of the drug and are similar to results seen in the first trial reported in December 2007.

The reported tesamorelin study is a 52-week trial. During the first 26 weeks, 270 patients—about two-thirds of the enrolled study volunteers—received tesamorelin and one-third (126 patients) received a placebo. During the second 26 weeks of the study, those who originally received the placebo will switch to tesamorelin, while those who originally received tesamorelin will either stay on the drug or be switched to placebo.

After the first six months in the study, researcher Steven Grinspoon, MD, of Harvard Medical School in Boston reported that those who received tesamorelin had a 10.9 percent decrease in VAT compared with a 0.6 percent decrease in those who received a placebo. The primary goal of the study was an 8 percent decrease in VAT, indicating that the results are clinically meaningful.

The volume of subcutaneous adipose tissue—fat directly below the skin—increased by an average of 1.1 percent in the tesamorelin group and 0.9 percent in the placebo group.

Patients in the tesamorelin group also had greater improvements in insulin function than those in the placebo group. Most important, there were no significant differences in glucose levels between the two groups after 26 weeks—a noted problem in clinical trials of Serono's Serostim (recombinant human growth hormone) for lipodystrophy and a potential risk for diabetes.

The frequency of side effects was similar between both groups, with injection-site redness, rash, bruises; joint and extremity pain; and diarrhea being the most common side effects reported.