# Tesamorelin Diminished Gut Fat in Phase 3 Study

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The Canadian company Theratechnologies announced Monday that its experimental drug tesamorelin reduced belly fat accumulation by 18 percent over 52 weeks in the second of two Phase 3 clinical trials. And in a second announcement on Tuesday, the company confirmed a proposed deal with EMD Serono to sell the drug in the United States once it is approved.

Tesamorelin prompts the pituitary gland to release more growth hormone into the body and promotes fat loss.

The most recent Phase 3 clinical trial was similar in design to a previous study reported by the company. HIV-positive participants with gut-fat accumulation received either a placebo or tesamorelin for 26 weeks. At that point, people who had taken the placebo switched to tesamorelin and those who had taken the drug either stayed on it or switched to a placebo for an additional 26 weeks. After the first 26 week portion of the trial, people on tesamorelin lost 11 percent of their gut fat; those who remained on the drug for a full 52 weeks ultimately lost 18 percent. The drug appears not to interfere with the body's development of insulin and control of blood sugar, a problem with EMD Serono's Serostim (recombinant human growth hormone), another product studied to treat gut-fat accumulation in people with HIV.

In its deal with EMD Serono, Theratechnologies received a $30 million up-front payment. In return, EMD Serono will assist Theratechnologies with its application to the U.S. Food and Drug Administration for tesamorelin's approval. Serono EMD will also sell the drug in the United States. Theratechnologies stands to gain as much as $215 million from the deal in addition to further royalties from future U.S. sales of the drug.

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