

## Tesamorelin in HIV-associated lipodystrophy

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### OVERVIEW

Tesamorelin (TH9507), an investigational new drug, is Theratechnologies' lead compound for the treatment of visceral fat (VAT) accumulation associated with HIV-associated lipodystrophy and more specifically with lipohypertrophy, which is a risk factor for cardiovascular disease and type 2 diabetes. There are currently no approved treatments for this condition, which affects an estimated 285,000 HIV patients in North America and Europe.

### PRODUCT DESCRIPTION

Tesamorelin is a synthetic analogue of growth hormone-releasing factor (GRF). GRF acts on pituitary cells in the brain, triggering the formation and secretion of growth hormone (GH). GH has been shown to play an important role in regulating lipid metabolism, body composition (e.g., muscle mass), and glucose.

Clinical research has demonstrated that tesamorelin:

- Reduces excess abdominal fat (in particular VAT associated with lipohypertrophy), without reducing subcutaneous fat tissue (SAT) and without compromising glycemic control (blood glucose) levels.
- Increases muscle mass.
- Is associated with fewer side effects than GH therapy.

### CLINICAL TRIAL PROGRAM

The results of a Phase 2 placebo-controlled study in HIV-infected men and women with evidence of abdominal fat accumulation showed that 2mg of tesamorelin injected once daily for 12 weeks decreased VAT. Based on these results, Theratechnologies initiated a Phase 3 development program evaluating tesamorelin in patients with HIV-associated lipodystrophy.

The program included two multicenter, randomized, double-blind, placebo-controlled Phase 3 studies that had:

- Primary endpoint: the reduction of VAT after 26 weeks of treatment;
- Secondary endpoints: changes in total cholesterol/HDL-cholesterol ratio, triglyceride levels and insulin-like growth factor (IGF-I); patient-reported outcomes related to body image; and safety of tesamorelin relative to placebo;
- Tesamorelin was generally well tolerated in most patients.

Positive 26-week and 52-week data for the first of the two Phase 3 trials were announced in December 2006 and October 2007.

Theratechnologies recently announced that the last patient has completed 26 weeks of treatment in its confirmatory Phase 3 trial and that top-line results are anticipated in the first half of 2008.