Tesamorelin Research Summary

Research Library Summary — PHX Performance Research

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What the Research Suggests, in Plain Language

Tesamorelin is a lab-made compound that prompts the body to release more of its own growth hormone. It is a prescription medicine (Egrifta) approved by the U.S. Food and Drug Administration for one narrow use: reducing excess belly fat in adults with HIV who have a fat-distribution condition called lipodystrophy.

• In people, large trials with a placebo comparison found that adults in that HIV group lost more deep belly fat (fat around the organs) than people given placebo.

• Later, smaller trials in people with HIV also looked at fat in the liver.

• Very little research has looked at people outside that HIV group, and there are very few animal studies.

In short: these results apply to the specific patient group that was studied. They do not show that tesamorelin is safe or effective for any other use.

Overview

Tesamorelin is a synthetic analog of growth hormone-releasing hormone (GHRH). It is FDA-approved (as Egrifta) for reduction of excess abdominal fat in adults with HIV-associated lipodystrophy.

What the Research Actually Presents

Phase 3 randomized controlled trials that supported FDA approval (NEJM 2007, 412 patients, PMID 18057338, and subsequent trials): Participants with HIV-associated lipodystrophy showed greater reductions in visceral adipose tissue (deep abdominal fat) compared with placebo.

JCEM 2010 pooled analysis of two phase 3 trials (n=543; PMID 20554713) confirmed the visceral fat reduction finding in the indicated population.

Later trials in HIV populations (Massachusetts General Hospital and others), including a randomized trial in non-alcoholic fatty liver disease in HIV (61 patients; PMID 31611038), reported effects on visceral and liver fat in those populations.

Data outside the HIV-associated lipodystrophy population are limited.

What the Research Suggests

The phase 3 trials that led to FDA approval report that tesamorelin reduced excess abdominal (visceral) fat more than placebo in adults with HIV-associated lipodystrophy under the conditions studied.

These findings are specific to the approved indication and population. Evidence outside that population is limited.

Mechanism and Signaling Pathways (as described in the literature)

As a GHRH analog, tesamorelin is described as stimulating growth hormone (GH) release from the pituitary via the GHRH receptor. The approved-use trials report downstream effects on visceral adipose tissue in the HIV population studied.

Research Landscape

Catalog: 114 records — 38 human randomized controlled trials (RCTs, including registry entries), 23 other human, 5 animal, 1 in-vitro, 25 reviews, 3 systematic reviews/meta-analyses, 19 other. 21 ClinicalTrials.gov entries.

Key Studies

• Falutz J et al. 2007 (NEJM): phase 3 randomized, placebo-controlled trial in HIV-associated abdominal fat accumulation; 412 patients (PMID 18057338).

• Falutz J et al. 2010 (JCEM): pooled analysis of two phase 3 trials; 543 patients (PMID 20554713).

• Falutz J et al. 2008: long-term safety extension (PMID 18690162).

• Stanley TL et al. 2019 (Lancet HIV): randomized, double-blind trial in HIV-associated non-alcoholic fatty liver disease; 61 patients (PMID 31611038).

Safety Findings Reported in the Studies

In the 2007 phase 3 trial, adverse events did not differ significantly between groups, but more participants in the tesamorelin group withdrew because of an adverse event (PMID 18057338). Data outside the approved population are limited.

Limitations and Evidence Gaps

Little published data outside the HIV-associated lipodystrophy indication. Animal studies are minimal.

Regulatory Status

FDA-approved (Egrifta, November 2010) for reduction of excess abdominal fat in adults with HIV-associated lipodystrophy. Not approved for other uses. Prohibited by the World Anti-Doping Agency (WADA) as a growth hormone-releasing factor.

References

Falutz J et al. NEJM 2007 (PMID 18057338). Falutz J et al. AIDS 2008 (PMID 18690162). Falutz J et al. JCEM 2010 (PMID 20554713). Stanley TL et al. Lancet HIV 2019 (PMID 31611038). Additional phase 3 and meta-analysis publications listed in the research catalog.

Evidence reviewed through November 2026 (PHX research catalog snapshot of PubMed, ClinicalTrials.gov and Europe PMC).

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