

PT-141 — Research Summary

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1. What It Is

PT-141 (bremelanotide) is a synthetic cyclic heptapeptide and melanocortin receptor agonist (primarily MC4R, with MC3R activity), derived from research on Melanotan II with modifications intended to concentrate activity at central melanocortin receptors while reducing the MC1R-mediated tanning effects of its parent compound.

Major regulatory distinction: PT-141/bremelanotide IS an FDA-approved prescription drug — approved June 21, 2019 as Vyleesi (1.75 mg subcutaneous auto-injector) for acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women. It is the first and only FDA-approved treatment for female sexual dysfunction acting through a central nervous system (rather than vascular) pathway.

2. Reported Effects in Research Literature

PT-141 has one of the strongest, most complete human clinical trial and regulatory records in this entire set, given its full FDA approval.

- Pivotal Phase 3 trials (RECONNECT, studies 301 and 302): Two identical randomized, placebo-controlled trials in 1,267 premenopausal women with HSDD found bremelanotide 1.75 mg as-needed significantly improved sexual desire (+0.35 points) and reduced desire-related distress (−0.33 points) versus placebo (both $P < .001$) over 24 weeks.
- Long-term safety/efficacy: A 52-week open-label extension confirmed long-term safety and efficacy findings consistent with the pivotal trials.
- Common adverse effect: Nausea, affecting approximately 40% of women in Phase III trials; transient hypertension is also commonly reported, and the drug is not recommended for use with sexual-stimulation drugs or in patients with cardiovascular disease.
- Independent reanalysis: A published critical reanalysis of the RECONNECT trials found that 72.7% of protocol-registered ClinicalTrials.gov outcomes were absent from the primary publication — a selective-outcome-reporting concern worth noting alongside the approval, though it does not overturn the approval itself.
- Male sexual dysfunction (off-label/investigational): Phase II data support PT-141 use in erectile dysfunction in men, including in men who do not respond to PDE5 inhibitors (Viagra, Cialis), but FDA approval for a male indication has not been pursued by the manufacturer.
- Foundational pharmacology: Molinoff et al. (2003) characterized PT-141 as a melanocortin agonist for sexual dysfunction, building on earlier rodent behavioral pharmacology establishing MC4R-dependent erectogenic and proceptive effects.
- Regulatory history note: The FDA placed a clinical hold on earlier intranasal-delivery trials in 2007 due to blood-pressure concerns; the developer pivoted to subcutaneous injection, which showed fewer cardiovascular side effects and ultimately supported approval.

3. Clinical & Preclinical Study References

Kingsberg SA, et al. RECONNECT Phase 3 trials. *Obstet Gynecol.* 2019;134(5):909-917. PMID: 30882442 (Simon et al., same program) and PMID: 31599840 (Kingsberg et al., primary results).

Molinoff PB, et al. "PT-141: a melanocortin agonist for the treatment of sexual dysfunction." *Ann N Y Acad Sci.* 2003;994:96-102. PMID: 12507838

Spielmans GI, et al. Independent critical reanalysis of RECONNECT selective outcome reporting. *J Sex Res.* PMID: 33678061

Regulatory/Safety Note: PT-141 (bremelanotide) is FDA-approved by prescription as Vyleesi for a single specific indication (HSDD in premenopausal women). It is not FDA-approved for men or for erectile dysfunction. Non-prescription/research-labeled PT-141 is a distinct regulatory category from the approved product and is not covered by that approval.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.
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