PT-141 (Bremelanotide) — Research Summary

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1. What It Is

PT-141 (generic name bremelanotide) is a synthetic cyclic heptapeptide, structurally derived from Melanotan II, developed by Palatin Technologies (originating from research at the Arizona Cancer Center). It is an analog of alpha-melanocyte-stimulating hormone (α-MSH), engineered to preferentially activate the central melanocortin 3 and 4 receptors (MC3R/MC4R) in the hypothalamus and limbic system, with reduced MC1R (pigmentation-receptor) activity compared to its parent compound, Melanotan II.

Regulatory status: PT-141 (as bremelanotide, brand name Vyleesi) is FDA-approved — the only FDA-approved peptide for sexual health, indicated for hypoactive sexual desire disorder (HSDD) in **premenopausal women**. It was approved in 2019, following Phase 2 and Phase 3 (RECONNECT) trials.

Vyleesi is the FDA-approved pharmaceutical form. This RUO product is not that drug, has not been reviewed by the FDA, and no equivalence is claimed or implied.

Important lab-identity note: Bremelanotide (MW 1025.18, C-terminal -OH) and Melanotan II (MW 1024.20, C-terminal -NH2) differ by only 1 Dalton. Standard unit-resolution mass spectrometry cannot reliably distinguish them — only high-resolution MS (TOF, Orbitrap) can. This is a genuine QC consideration for RUO supply chains and worth flagging in your supplier vetting process.

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2. Reported Effects in Research Literature

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- **FDA-approved indication (women):** The Phase 3 RECONNECT trials demonstrated statistically significant improvement in satisfying sexual events and reduction in distress related to low sexual desire, versus placebo, in premenopausal women with HSDD. 52-week extension data reported sustained benefit without major long-term concerns.
- **Discovery context:** During early clinical investigation of the related compound Melanotan II, researchers observed unexpected spontaneous erections in male subjects — this observation is what redirected development toward a dedicated sexual-dysfunction compound (PT-141/bremelanotide).
- **Male erectile dysfunction (not an approved indication):** PT-141 has progressed through Phase I and Phase IIb trials for male ED, with positive effects reported on erectile function in men, but it has not received FDA approval for this indication.
- **Safety profile:** Nausea is the most common side effect, reported in approximately 40% of women in Phase III trials. Transient blood pressure increases are also noted and incorporated into FDA safety labeling. Hyperpigmentation is a documented adverse event linked to residual MC1R activity — reported at under 1% incidence with as-needed dosing per the approved label, but substantially higher (38.2% in pooled safety data) with daily dosing over 8 days, and may not fully resolve after discontinuation.
- **Mechanism distinction from PDE5 inhibitors:** PT-141 acts through the CNS “desire” pathway (melanocortin receptor activation in the brain) rather than the vascular “performance” pathway targeted by drugs like sildenafil — a mechanistically distinct approach to sexual dysfunction.

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3. Clinical & Preclinical Study References

- Clayton AH, et al. RECONNECT Phase 3 trial program (HSDD in premenopausal women) — pooled safety analysis, 2022.
- Earlier Phase 2 trial (PT-141-54): NCT01382719
- Foundational urology research: PMID: 10869639
- Overview: PT-141 (Bremelanotide) — Grade A, Peptide Intelligence Hub
- Identity/QC note: PT-141 — Evidence-weighted peptide profile, clearbatch.net

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4. Reconstitution Process

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1. **Materials needed:** lyophilized (freeze-dried) PT-141 powder, bacteriostatic water, alcohol swabs, syringe with needle.
2. **Bring the vial to room temperature** before reconstitution.
3. **Sanitize** the rubber stopper of both vials with an alcohol swab.
4. **Add the water slowly** down the *inside wall* of the vial, to reduce shear/foaming.
5. **Do not shake.** Gently swirl or roll between palms until fully dissolved.
6. **Inspect the solution** — should be clear and free of particulates.
7. **Label the vial** with reconstitution date and concentration.
8. **Storage:** refrigerate (2–8°C); avoid freeze-thaw cycles.

Reference: Bacteriostatic Water Volume by Vial Size

Vial Size	BAC Water Added	Resulting Concentration
5 mg	1 mL	5 mg/mL
5 mg	2 mL	2.5 mg/mL
5 mg	5 mL	1 mg/mL
10 mg	1 mL	10 mg/mL
10 mg	2 mL	5 mg/mL
10 mg	4 mL	2.5 mg/mL
10 mg	5 mL	2 mg/mL
10 mg	10 mL	1 mg/mL

Notes: Higher water volume = more dilute solution; lower volume = more concentrated. Always use bacteriostatic water (0.9% benzyl alcohol) for multi-draw vials; sterile water without preservative should be discarded within 24 hours.

Document created: July 16, 2026. **Revision 1:** July 29, 2026. Regulatory status (FDA compounding lists, WADA lists) is actively shifting; re-verify against current sources before any customer-facing use.

This document is intended for research and internal reference use only. It does not constitute medical advice, dosing guidance, or an endorsement of unsupervised human use. PT-141/bremelanotide is FDA-approved (as Vyleesi) only for HSDD in premenopausal women under physician prescription; RUO material is not the approved pharmaceutical product and carries no such approval.