CLOSER LOOK

MEMORANDUM

Vivani Medical enters agreement with Novo Nordisk to evaluate NPM-139 implantable semaglutide – July 7, 2026

Phase 1 trial follows strong preclinical and early human data for NPM-139 and NanoPortal technology

Alameda, California-based Vivani Medical announced today an agreement with Novo Nordisk to evaluate NPM-139, a semaglutide drug implant designed for chronic weight management. NPM-139 uses Vivani's NanoPortal technology, which enables extended delivery of large hydrophilic molecules, such as peptides and proteins. Implantable GLP-1 RAs have shown promise in reducing burdens associated with daily or weekly medication administration. There are no exclusivity provisions associated with this agreement, and no financial details have been disclosed.

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Growing market for long-acting GLP-1 RA implants

Dr. Adam Mendelsohn, Vivani's President and CEO, said the new agreement strengthens the company's confidence in the market opportunity for its GLP-1 RA implant portfolio and reflects Novo Nordisk's interest in the technology. Dr. Mendelsohn highlighted that long-acting implants like NPM-139 could appeal to patients seeking the convenience of a once- or twice-yearly treatment option with the reassurance that treatment can still be discontinued at any time despite the implant.

Several companies are exploring the opportunity for extended release or implantable incretin therapies. For example, Israel-based PolyPid is developing a system for prolonged delivery. PolyPid uses a polymer-lipid based matrix that provides subcutaneous delivery of GLP-1 RAs for up to 60 days.

Intarcia's implantable GLP-1 RA, ITCA 650, was unable to prove the benefits of the implant outweighed the risks of acute kidney injury, as well as concerns about consistency of drug release over time. ITCA 650 did not make it to market following a 19-0 vote against its approval in September 2023. In July 2024, Dr. Mendelsohn and CMO Dr. Lisa Porter discussed this specific risk with our team, suggesting that the NPM-115 and NPM-139 implants had a different risk profile because of NanoPortal's fundamentally different delivery technology, in which the drug is passively and smoothly delivered compared to the osmotic pump technology incorporated in ITCA 650. Vivani expects to be able to generate a scientific bridge to reference the safety database of the marketed injectable versions of the drugs delivered using NanoPortal technology in future approval applications by demonstrating adequate pharmacokinetic comparability during the clinical program. By contrast, the FDA provided analysis indicating that the pharmacokinetic variability of ITCA 650 was wider than the marketed version of the drug being delivered. The smooth and steady delivery mechanisms built into the NanoPortal's design stand to set this technology apart from any predecessors.

NPM-139 moves into human testing following strong preclinical and LIBERATE-1 data

Vivani announced the initiation of a randomized, first-in-human study, comparing NPM-139 semaglutide implant with Novo Nordisk's Wegovy (semaglutide). The study aims to assess safety, tolerability, and pharmacokinetics of NPM-139 and is expected to launch in mid-2026.

Additionally, phase 1 results from the first-in-human LIBERATE-1 trial (n=24) supported the use of Vivani's NanoPortal implant technology in people with obesity and overweight.

--by Allison Platt, Kayla Mathieu, Monica Oxenreiter, and Kelly Close