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Vivani Medical Provides Update on Clinical Development Plans for NPM-139 Semaglutide Implant for Chronic Weight Management

NPM-139 has potential to provide Wegovy®-level efficacy with once or twice-yearly administration

First-in-human Phase 1 study is expected to initiate in the first half of 2026, pending regulatory clearance

Preparations for dose-ranging Phase 2 study of NPM-139 to occur in parallel with Phase 1 study

ALAMEDA, Calif., Sept. 04, 2025 (GLOBE NEWSWIRE) -- Vivani Medical, Inc. (Nasdaq: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing novel, ultra long-acting drug implants, today announced plans to initiate a Phase 1 clinical study in the NPM-139 semaglutide implant program in the first half of 2026, pending regulatory clearance. The Company is also preparing to initiate a Phase 2 clinical study of NPM-139 pending enabling results from the Phase 1 study and regulatory feedback. The NPM-139 clinical program will evaluate the Company's investigational semaglutide implant for chronic weight management in patients who are either obese or overweight with a related comorbidity.

"Recent promising results from LIBERATE-1™, the first-in-human study of NPM-115, an exenatide implant utilizing NanoPortal™ technology, combined with positive preclinical weight loss data with NPM-139, compel us to move forward aggressively with clinical development of NPM-139. The Phase 1 study, designed to evaluate the safety, tolerability and pharmacokinetic profile of the semaglutide implant and to enable a Phase 2 efficacy study, is expected to initiate in the first half of 2026, pending regulatory clearance," said Vivani President and Chief Executive Officer Adam Mendelsohn, Ph.D. "The overall GLP-1 market in weight management continues to grow at an impressive rate, primarily because of considerable unmet medical needs and the fact that current GLP-1 options have a much better safety and efficacy profile compared to medications previously approved to treat obesity. We believe that NPM-139 could provide clear and compelling differentiation due to its potential to provide Wegovy®-level efficacy with convenient once or twice-yearly administration. Having recently obtained approval for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) and with an expected near-term Phase 3 readout in the treatment of Alzheimer's disease, semaglutide-based products continue to demonstrate tremendous potential to treat chronic diseases, and we believe the therapeutic potential of

semaglutide could be significantly enhanced with an option that enables once or twice-yearly administration."

Dr. Mendelsohn continued, "If clinically validated and approved, we expect our products to stand out in a crowded and competitive field as the only available implant which could potentially enable providers to address new and currently underserved market segments. In addition, we continue to believe that NPM-139 could demonstrate improved tolerability relative to currently available oral or injectable GLP-1 medications, both because of the avoidance of drug fluctuations at each administration of oral or injectable options which provide each dose as a bolus, and by eliminating missed doses that further exacerbate the dosing fluctuations which are largely responsible for the gastrointestinal side effects of GLP-1 treatments."

Clinical Program for Semaglutide Implants for Chronic Weight Management

The first clinical study of NPM-139 is planned as a small Phase 1 randomized, controlled investigation of the safety, tolerability and pharmacokinetic profile of the semaglutide NanoPortal implant in GLP-1 naïve obese or overweight subjects. The planned control arm is low-dose Wegovy injected weekly. The semaglutide implant to be used in this study is expected to produce comparable semaglutide exposure levels to low dose Wegovy injections. This study is expected to be initiated in the first half of 2026, pending regulatory clearance.

The design of the second clinical study will be finalized pending results from the Phase 1 study but is anticipated to be a Phase 2, randomized, placebo-controlled, dose-ranging investigation over 4 to 6 months to evaluate the effects of the semaglutide NanoPortal implant on weight management in obese or overweight subjects. This study will provide safety, efficacy, and dose selection information for Phase 3 and will initiate shortly after Phase 1 completes, if warranted by the Phase 1 results and pending regulatory clearance.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal™ platform, Vivani develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time with the goal of guaranteeing adherence and improving patient tolerance to their medication. Vivani is developing a portfolio of GLP-1 based implants for chronic weight management and other metabolic diseases including type 2 diabetes. These NanoPortal implants are designed to provide patients with the opportunity to realize the full potential benefit of their medication by avoiding the numerous challenges associated with the daily or weekly administration of orals and injectables, including tolerability issues and loss of efficacy. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills.

Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that in this press release, including statements regarding Vivani's business, products in

development, including the therapeutic potential thereof, the planned development therefor, the completion of the LIBERATE-1 Phase 1 study and reporting of study results, Vivani's emerging development plans for NPM-139, NPM-115 or Vivani's plans with respect its technology, strategy, cash position and financial runway. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Vivani's current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Vivani's control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to the development and commercialization of Vivani's products, including NPM-139 and NPM-115; delays and changes in the development of Vivani's products, including as a result of applicable laws, regulations and guidelines, potential delays in submitting and receiving regulatory clearance or approval to conduct Vivani's development activities, including Vivani's ability to commence clinical development of NPM-139; risks related to the initiation, enrollment and conduct of Vivani's planned clinical studies and the results therefrom; or Vivani's history of losses and Vivani's ability to access additional capital or otherwise fund Vivani's business. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 31, 2025, as updated by the Company's subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement made by Vivani in this press release is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of added information, future developments or otherwise, except as required by law.

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