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Vivani Medical Achieves First Implant and Full Enrollment in the First-in-Human Clinical Trial of GLP-1 Implant NPM-115 in Obese or Overweight Adults

Miniature, twice-yearly GLP-1 (exenatide) implant under development for chronic weight management

NPM-115 has demonstrated comparable preclinical weight loss to injections of semaglutide, the active ingredient in Ozempic®/Wegovy®

Rapid full study enrollment with all 24 subjects initiating the 8-week run-in period within four weeks; top-line study results expected in mid-2025

ALAMEDA, Calif.--(BUSINESS WIRE)-- Vivani Medical, Inc. (NASDAQ: VANI) ("Vivani" or the "Company"), a clinical-stage biopharmaceutical company developing miniature, ultra long-acting drug implants, today announced the successful administration of its first GLP-1 (exenatide) implant in the LIBERATE-1™ clinical trial. This milestone marks a critical step toward addressing one of healthcare's most pressing challenges: medication adherence in metabolic diseases including chronic weight management and type 2 diabetes. The Company also announced full enrollment in the LIBERATE-1 study, which was achieved in just four weeks after enrollment of the first subject, signaling early potential interest for this six-month, subdermal GLP-1 implant and reaffirming previous estimates that top-line results should be available in mid-2025.

"We are excited to report that the first dose of the NPM-115 implant was successful. The insertion was well tolerated by the subject. Combined with the achievement of full enrollment in the study, this represents important progress in advancing our GLP-1 implant through clinical development," said Vivani Chief Executive Officer Adam Mendelsohn, Ph.D. "With obesity affecting more than one billion people globally, our implants could redefine treatment paradigms by providing a convenient therapeutic alternative with significantly reduced dosing frequency compared to daily orals and weekly injectables.

"We also believe our innovative NanoPortal™ platform technology could improve medication adherence and thereby significantly improve patient outcomes," explained Dr. Mendelsohn. "About half of people regularly miss doses as indicated by real-world medication adherence data. Missed doses not only lead to suboptimal efficacy but can also exacerbate tolerability issues. In fact, manufacturers of marketed, weekly injectable GLP-1 products recommend that a patient consider reinitiating GLP-1 therapy at the initial starting dose if two doses or more are missed, to avoid tolerability issues associated with rapid increases in GLP-1

exposure levels. We believe our miniature, ultra long-acting implants, designed to improve medication adherence, have the potential to improve efficacy and minimize tolerability issues."

The LIBERATE-1 study is exploring the full pharmacokinetic profile of NPM-115, which has demonstrated consistently smooth and minimally fluctuating drug release both *in vitro* and in animal models. Successful translation to humans is expected to ultimately demonstrate greater effectiveness and tolerability in otherwise poorly adherent patients, potentially providing a transformative option for chronic weight management patients. Vivani expects these results to support the potential application of this GLP-1 (exenatide) implant in the treatment of type 2 diabetes and other diseases for which GLP-1 treatment has demonstrated, or will demonstrate, clinical benefit.

Bydureon BCise® is a registered trademark under license by AstraZeneca.
Ozempic® and Wegovy® are registered trademarks of Novo Nordisk A/S.

About LIBERATE-1

LIBERATE-1 is a Phase 1, first-in-human study of a miniature, ultra long-acting GLP-1 (exenatide) implant to investigate the safety, tolerability, and full pharmacokinetic profile in obese or overweight subjects. The trial will enroll participants who will be titrated on weekly semaglutide injections for 8 weeks (0.25 mg/week for 4 weeks followed by 0.5 mg/week for 4 weeks) before being randomized to receive a single administration of Vivani's exenatide implant (NPM-115, n=8), weekly exenatide injections (Bydureon BCise®, n=8), or weekly 1 mg semaglutide injections (Wegovy®, n=8) for a 9-week treatment duration. Changes in weight will be measured. The study is currently on-going at two study centers in Australia and is fully enrolled. Top-line data from the study is anticipated to be available in mid-2025.

If available, Vivani intends to utilize research and development incentives and rebates from the Australian government to defray a portion of the costs from this clinical trial. Since clinical studies conducted in Australia comply with the International Conference on Harmonization guidelines, data generated in Australia generally are acceptable to the U.S. Food and Drug Administration and other regulatory authorities. Vivani anticipates use of relevant clinical data generated in Australia to support regulatory submissions in other geographies including the United States. Additional guidance regarding future regulatory submissions will be provided as new information becomes available.

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 potentially to improve patient tolerance to their medication. Vivani's lead program, NPM-115, is a six-month, subdermal, GLP-1 (exenatide) implant under development for chronic weight management in obese or overweight individuals. Vivani's emerging pipeline includes NPM-139 (semaglutide implant) which is also under development for chronic weight management in obese and overweight individuals. The semaglutide implant has the added potential benefit of once-yearly administration. NPM-119 refers to the Company's six-month, subdermal, GLP-1 (exenatide) implant under development for the treatment of 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 challenges associated with the daily or weekly administration of orals and injectables. 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. Medication non-adherence, which contributes to more than $500 billion in annual avoidable healthcare costs and 125,000 potentially preventable deaths annually in the U.S. alone, is a primary and daunting reason why obese or overweight patients, and patients taking type 2 diabetes or other chronic disease treatments, face significant challenges in achieving positive real-world effectiveness. While the current GLP-1 landscape includes over 50 new molecular entities under clinical stage development, Vivani remains confident that its highly differentiated portfolio of miniature long-acting GLP-1 implants have the potential to provide an attractive therapeutic option for patients, prescribers and payers. For more information, please visit www.vivani.com.

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 trial and reporting of trial results, Vivani’s emerging development plans for NPM-115, NPM-139, NPM-119, or Vivani’s plans with respect to Cortigent and 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-115, NPM-139, and NPM-119; 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; risks related to the initiation, enrollment and conduct of Vivani’s planned clinical trials and the results therefrom; Vivani’s history of losses and Vivani’s ability to access additional capital or otherwise fund Vivani’s business; market conditions and the ability of Cortigent to complete its intended spin-off from the Company. 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 filed on March 26, 2024, 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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