

March 9, 2026



Veru Enrolls First Patient in Phase 2b PLATEAU Clinical Trial of Enobosarm and Semaglutide Combination for High Quality Weight Loss

-- The Phase 2b study to assess enobosarm's ability to preserve lean mass, physical function, and bone as well as burn more fat to produce greater quality and quantity of weight loss in older patients with obesity receiving semaglutide --

-- Interim analysis expected in the first quarter calendar year 2027--

-- Final topline clinical data expected in the fourth quarter calendar year 2027--

MIAMI, FL, March 09, 2026 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases, today announced that it has enrolled the first patient in its Phase 2b PLATEAU clinical trial of enobosarm, an oral selective androgen receptor modulator (SARM), to preserve muscle and physical function and to augment fat and weight loss when combined with semaglutide (Wegovy[®]), a Glucagon-like peptide-1 receptor agonist (GLP-1 RA) drug, for potentially higher quality and quantity of weight loss in older patients with obesity.

"We are thrilled to enroll the first patient in the Phase 2b PLATEAU clinical trial, marking an important milestone in the development of enobosarm for high quality weight loss," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. "There is a significant unmet medical need for a combination therapy to enable the vast majority of patients to break through the weight loss plateau observed with current weight reduction therapies, particularly for those patients who sadly still have clinical obesity at the time they reach this weight loss plateau where they are no longer able to lose any more weight. Veru is convinced that the strategy for the next generation of obesity drugs should be a combination therapy with GLP-1 receptor agonists for patients to maximize fat loss, while preserving lean mass and physical function and increasing bone mineral density for the highest quality weight reduction."

"While there is a clear medical benefit from weight loss with semaglutide, the next generation of weight loss drugs will likely include the combination of a GLP-1 RA in conjunction with a compound which preserves lean mass like enobosarm to improve both the amount and the quality of weight loss. The Phase 2b PLATEAU clinical trial of enobosarm will provide

important clinical information that will help in the design of the Phase 3 clinical development program for a next generation combination therapy with GLP-1 receptor agonists,” said Louis Aronne, M.D., an obesity expert, past president of the Obesity Society and a scientific advisor and consultant to Veru.*

Phase 2b PLATEAU Clinical Study

Veru’s Phase 2b PLATEAU clinical trial is a double-blind, placebo-controlled study to evaluate the effect of enobosarm 3mg on total body weight, fat mass, lean mass, physical function, bone mineral density and safety in approximately 200 older patients (age \geq 65 years) who have obesity (BMI \geq 35) and are initiating semaglutide treatment for weight reduction. The Phase 2b PLATEAU study is designed to assess the ability of enobosarm treatment to break through the weight loss plateau observed in patients with obesity receiving semaglutide treatment by preserving muscle mass and physical function to achieve clinically meaningful incremental weight reduction. The primary efficacy endpoint of the study is the percent change from baseline in total body weight at 68 weeks. An interim analysis will be conducted at 34 weeks to assess the percent change from baseline in lean body mass and fat mass, as measured by DXA scan. The key secondary endpoints are total fat mass, total lean mass, physical function (stair climb test), bone mineral density, and patient reported outcome questionnaires for physical function, HbA1c, and insulin resistance.

Semaglutide was selected as the GLP-1 RA for the Phase 2b PLATEAU study to build on Veru’s previous clinical experience using enobosarm in combination with semaglutide in the positive Phase 2 QUALITY clinical study. Further, the clinical data from the Phase 2b PLATEAU clinical trial using injectable semaglutide should support the use of oral semaglutide in combination with oral enobosarm in future Phase 3 clinical studies. In contrast, tirzepatide injectable does not have an oral formulation.

The Principal Investigator for the Phase 2b PLATEAU clinical trial is Steven Heymsfield, MD, a Professor and the Director of the Body Composition-Metabolism Laboratory at the Pennington Biomedical Research Center in Baton Rouge, Louisiana. Dr. Heymsfield was also the Principal Investigator of Veru’s Phase 2 QUALITY clinical study.

An interim analysis to assess change in lean body mass and fat mass as measured by DXA will be conducted at 34 weeks with data expected in the first quarter of calendar year 2027. Final topline clinical data is expected in the fourth quarter of calendar year 2027.

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing innovative medicines for the treatment of cardiometabolic and inflammatory diseases. The Company’s drug development program includes two late-stage novel small molecules, enobosarm and sabizabulin. Enobosarm, an oral selective androgen receptor modulator (SARM), is being developed as a next generation drug that makes weight reduction by GLP-1 RA drugs more tissue selective for loss of fat and preservation of lean mass to improve body composition and physical function which is expected to result in clinically meaningful incremental weight reduction versus GLP-1 RA therapy alone. Sabizabulin, a microtubule disruptor, is being developed for the treatment of chronic inflammation related to atherosclerotic cardiovascular disease

Enobosarm Obesity Program - Enobosarm is a next generation drug that in combination with GLP-1 RA results in higher quality weight reduction

The Phase 2b QUALITY clinical study was a positive multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial designed to evaluate the safety and efficacy of enobosarm 3 mg, enobosarm 6 mg, or placebo as a treatment to augment fat loss and to prevent muscle loss in 168 older patients (≥ 60 years of age) receiving semaglutide (Wegovy[®]) for weight reduction. After the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial was completed at 16 weeks, participants continued into a Phase 2b maintenance extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3 mg, or enobosarm 6 mg as monotherapy in a double-blind fashion for 12 weeks. The Phase 2b QUALITY and Maintenance Extension clinical trial was a positive study that demonstrated that preserving lean mass and physical function with enobosarm plus semaglutide led to greater fat loss during the 16 week active weight loss period. While weight loss was similar across treatment groups in this short 16 week study, we anticipate that preservation of lean mass and function will lead to increased energy expenditure, and this effect coupled with the direct effects of enobosarm on the additional selective reduction in fat mass will result in incremental weight reduction in a longer clinical study in patients who have obesity.

Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, express or implied statements related to the planned design, enrollment, timing, commencement, interim, topline and full data readout timing, scope and regulatory pathways for the continued development of enobosarm in patients with obesity, including the PLATEAU Phase 2b study; the planned design, number of sites, timing, endpoints, patient population and patient size of such trial and whether the PLATEAU trial will successfully meet any of its primary or secondary endpoints; whether the results of the Phase 2b QUALITY study and the extension maintenance study of enobosarm, including weight loss, preservation of lean mass and physical function and loss of fat mass, will be replicated to the same or any degree in the PLATEAU Phase 2b study or in any future Phase 3 studies; whether and when the PLATEAU Phase 2b study of enobosarm will produce an interim analysis and/or topline data; whether enobosarm in combination with a GLP-1 RA drug will provide a higher quality and/or greater quantity weight loss in patients and whether this combination therapy will be the next generation drug that makes weight reduction more tissue selective for loss of fat, preservation of lean mass, and physical function, improved body composition and maintaining or increasing bone mineral density; whether patients treated with enobosarm in the PLATEAU Phase 2B study will preserve lean mass and function leading to an increased use of energy and whether such effects will result in incremental weight reduction; whether patients treated with enobosarm in the PLATEAU Phase 2B study will break through the weight loss plateau and achieve clinically meaningful incremental weight reduction by preserving muscle mass and physical function; and whether enobosarm will enhance or achieve a higher quality weight loss or the preservation of muscle in, or meet any unmet need for, obesity patients, including whether it will enable patients to break through the weight loss plateau or provide important insights into quality weight loss therapy and the design of a Phase 3 clinical development program; whether the oral form of semaglutide may be used in combination with enobosarm in future Phase 3 clinical studies and whether the injectable semaglutide used in the PLATEAU Phase 2B study data of enobosarm will support the use of oral semaglutide formulation in combination with oral enobosarm in future Phase 3 clinical studies; and whether the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and oncology; the

anticipated timing for the interim analysis for such study. The words "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based upon current plans and strategies of the Company and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this press release. The Company assumes no obligation to update any forward-looking statements contained in this press release because of new information or future events, developments, or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: the development of the Company's product portfolio and the results of clinical studies, including any interim or topline analysis, possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; although the Company has sought and received feedback from the FDA on the designs of its clinical trials and intends to continue to do so, the FDA may ultimately disagree that the Company's clinical trials support approval; the Company's ability to reach agreement with FDA on study design requirements for the Company's planned clinical studies, including for the Phase 2b program for enobosarm as a weight loss or body composition drug and the number of future Phase 3 studies to be required and the cost thereof; potential delays in the timing of and results from clinical trials and studies, including as a result of an inability to enroll sufficient numbers of subjects in clinical studies or an inability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development as well as other operations of the Company; whether the Company will be able to partner with another company in the development of enobosarm or sabizabulin; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the potential for disruptions at the FDA or other government agencies to negatively affect our business, including as a result of a future shutdown of the U.S. government; any products of the Company, if approved, possibly not being commercially successful; the ability of the Company to obtain sufficient financing, including any partnership or collaboration agreements, on acceptable terms when needed to fund development and operations and to enable us to continue as a going concern; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to protect and enforce its intellectual property; costs and other effects of litigation, including regulatory challenges, product liability claims, intellectual property, securities litigation and litigation with the purchaser of the Company's FC2 business; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2025, and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website

at www.verupharma.com/investors.

*Dr. Aronne, like certain other members of the Company's Scientific Advisory Board, receives compensation from the Company for his services.

Wegovy[®] is a registered trademark of Novo Nordisk A/S.

Investor and Media Contact:

Samuel Fisch

Executive Director, Investor Relations and Corporate Communications

Email: veruinvestor@verupharma.com



Source: Veru Inc.