September 23, 2025

Veru Announces Successful FDA Meeting Providing Regulatory Clarity for Enobosarm for Muscle Preservation in Combination with GLP-1 RA for Greater Weight Loss in the Treatment of Obesity

MIAMI, FL, Sept. 23, 2025 (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 a successful meeting with FDA providing regulatory clarity for enobosarm, a selective androgen receptor modulator, as a muscle preservation drug product candidate in combination with GLP-1 RA for greater weight loss for the treatment of obesity.

Highlights from FDA meeting

The regulatory landscape continues to evolve for muscle preservation drugs in the treatment of obesity. Based on FDA feedback on Veru's clinical development program for enobosarm, FDA now guides that incremental weight loss with enobosarm added to GLP-1 RA treatment over the GLP-1 RA treatment alone is an acceptable primary endpoint to support approval. FDA confirmed that enobosarm 3mg is an acceptable dosage for future Veru clinical development. Further, FDA has encouraged Veru to expand the enobosarm development program to include a younger population with obesity as younger patients could also benefit from a muscle preservation drug like enobosarm.

"Although FDA's position has evolved based on previous communications with Veru, this change is a big step forward as FDA's current regulatory position that incremental weight loss is an acceptable approvable primary endpoint provides what we believe is a more certain regulatory pathway for the development of enobosarm for the treatment of obesity," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "Our positive Phase 2 QUALITY clinical study provided proof of concept that 16 weeks of enobosarm treatment was able to preserve lean mass, burn additional fat mass, and improve physical function in older patients who have obesity and were receiving semaglutide for weight reduction. Although weight loss was similar across treatment groups at the end of this short active weight loss period of 16 weeks, it is expected that incremental weight loss will be observed in a longer clinical study in patients with obesity as preservation of lean mass and physical function will continue to increase energy expenditure coupled with enobosarm's ability to directly cause greater fat loss. In fact, 12 weeks after discontinuation

of semaglutide in the maintenance period of the Phase 2 QUALITY study, enobosarm monotherapy continued to burn fat and was able to prevent weight regain by 46% resulting in greater additional fat loss compared to placebo group by end of study. Accordingly, we will now take advantage of this current FDA guidance, allowing incremental weight loss as the primary endpoint and accepting enobosarm 3mg as the optimal dose, to advance enobosarm into a planned Phase 2b trial. Receiving this regulatory clarity is especially important as we seek to advance our partnering efforts."

Advancing enobosarm clinical development program to benefit from recent FDA regulatory input: Preserve muscle and physical function and burn additional fat to reset the GLP-1 RA weight loss plateau resulting in clinically meaningful incremental weight reduction

The weight loss plateau occurs when the patient with obesity stops losing weight while on a GLP-1 RA. In the SURMOUNT-1 clinical study conducted by Eli Lilly and Company, about 88% of patients with obesity receiving tirzepatide reached the weight loss plateau by 72 weeks. Unfortunately, 62.6% of these patients are still clinically overweight or have obesity at 72 weeks. We believe treatment with tirzepatide when combined with enobosarm, will lead to additional fat loss by preserving muscle and physical function, especially in older patients. Enobosarm's ability to directly and indirectly cause additional fat loss is expected to reset the weight loss plateau leading to incremental weight reduction, thereby increasing the number of patients who achieve and maintain a normal weight.

The evolving FDA thinking for the development of muscle preservation drugs for obesity and the critical changes in the current FDA guidance related to the acceptable primary endpoint of incremental weight loss, have necessitated the change in Veru's clinical development plan. The clinical development program of enobosarm will take advantage of both the FDA regulatory clarity on the acceptable primary endpoint and of enobosarm's key attributes, preservation of muscle and physical function, and greater selective fat loss (100% fat loss and 0% lean mass weight loss), that were demonstrated in Veru's Phase 2 QUALITY study at 16 weeks.

Planned Phase 2b PLATEAU clinical study

Veru's planned Phase 2b PLATEAU clinical study will evaluate the effect of enobosarm 3mg on total body weight, physical function, and safety in approximately 180 older (≥65 yo) and younger (<65 yo) patients who have obesity and are initiating tirzepatide treatment for weight reduction. The primary efficacy endpoint of the study is the percent change from baseline in total body weight at 72 weeks. 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 (SF-36 PF-10, and IWQOL-lite CT physical function).

The Phase 2b PLATEAU clinical study is designed to assess the ability of enobosarm treatment to break through the weight loss plateau observed in patients with obesity receiving tirzepatide treatment to achieve clinically meaningful incremental weight reduction and preserve muscle mass and physical function by 72 weeks. Subject to sufficient capital, the clinical study is expected to begin in calendar Q1 2026.

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, a 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 thereby improving body composition and physical function with expected clinically meaningful incremental weight reduction versus GLP-1 RA monotherapy. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in atherosclerotic cardiovascular disease.

Enobosarm Obesity Program - Enobosarm is a next generation drug that makes weight reduction by GLP-1 RA more tissue selective for fat loss – Phase 2b QUALITY clinical study

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 3mg, enobosarm 6mg, 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 completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial ended at 16 weeks, participants continued into a Phase 2b maintenance extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg 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, it is expected that preservation of lean mass and function will increase energy expenditure 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 and full data readout timing, scope and regulatory pathways for the continued development of enobosarm in patients with obesity, including the planned PLATEAU Phase 2b study; whether clinically meaningful incremental weight loss in the PLATEAU Phase 2b study will continue to be seen as an acceptable primary endpoint by the FDA to support potential approval; whether the FDA will continue to accept 3mg as an acceptable dosage for enobosarm in the planned PLATEAU Phase 2b study or in any other studies; whether the FDA will further evolve its position on the acceptable patient population for the PLATEAU Phase 2b study or any other future studies; whether the Company will be able to partner with any other company in the development of enobosarm; whether the results of the Phase 2b QUALITY study and the extension maintenance study of enobosarm will be replicated to the same or any degree in the planned PLATEAU Phase 2b study or in any future Phase 3 studies; the expected costs, timing, patient population, design, endpoints and results of the planned PLATEAU Phase 2b study or any future Phase 3 studies of enobosarm in patients with obesity; whether the Company will be able to raise sufficient capital, dilutive or

otherwise, to fund the PLATEAU Phase 2b study of enobosarm in patients with obesity or any other studies; whether the Company will be able to recruit a sufficient number of patients in a timely manner for the PLATEAU Phase 2b study; whether the modified-released formulation of enobosarm will be developed successfully and whether such formulation will have the same effectiveness or bioequivalence as the current formulation, and whether and when such modified-release formulation will be available for any planned or future clinical studies; whether and when any patents will actually issue regarding such modified-release formulation and what any expiration dates of any such patents might be; whether the Company will be able to obtain sufficient tirzepatide or any other GLP-1 RA drugs in a timely or cost-effective manner in the planned PLATEAU Phase 2b study or any future Phase 3 studies; whether the Company will be able to engage clinical research organizations and recruit patients for the PLATEAU Phase 2b program and in a timely or cost-effective manner; whether enobosarm will cause weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will cause weight loss in the planned PLATEAU Phase 2b study or any future Phase 3 studies or, if approved and commercialized, in clinical practice; whether patients treated with enobosarm for a longer period of time than in the Phase 2b QUALITY study will experience weight loss or have a greater loss of adiposity or greater weight loss than with tirzepatide, semaglutide or other GLP-1 drug alone; whether and when enobosarm will be approved by the FDA as a weight loss drug or a body composition drug or any other type of drug; and whether and when the Company will be able to further advance the development of sabizabulin in atherosclerotic disease. 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 possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; 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; 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; 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; 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 and securities litigation; 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, 2024, 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. Wegovy® is a registered trademark of Novo Nordisk A/S.

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