December 4, 2025

Veru to Present at The Society on Sarcopenia, Cachexia, and Wasting Disorders 18th International Conference and Regulatory and Clinical Trials Update Regulatory Workshop

MIAMI, FL, Dec. 04, 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 multiple presentations at The Society on Sarcopenia, Cachexia, and Wasting Disorders (SCWD) 18th International Conference, and the SCWD's Regulatory and Clinical Trials Update Regulatory Workshop, both in Rome, Italy.

18th International Conference of the Society on Sarcopenia, Cachexia, and Wasting Disorders

Program Session P: Weight loss drugs and cardiovascular health
Presenter: Mitchell Steiner, Veru Inc.'s Chairman, President & CEO
Session Date: December 12, 2025
Presentation Number: P3
Presentation Name: The Veru Experience
Presentation Time: 4:30 pm – 4:45 pm Central European Time
Presentation Location: Hall A, A. Roma Lifestyle Hotel, Rome, Italy

Program Session U: THERAPEUTICS, Novel strategies to address sarcopenia while treating obesity - round table discussion
Presenter: Mitchell Steiner, Veru Inc.'s Chairman, President & CEO
Session Date: December 13, 2025
Presentation Number: U3
Presentation Name: Enobosarm
Presentation Time: 10:00 am - 10:15 am Central European Time
Presentation Location: Hall A, A. Roma Lifestyle Hotel, Rome, Italy

Additional information on the meeting can be found on the following website:https://society-scwd.org/annual-conference/

SCWD Regulatory and Clinical Trials Update - Regulatory Workshop

Presentation Name: Treatment Approaches to Address Muscle Wasting in the Context of Obesity Therapy & Regulatory Issues
Therapeutic approaches to prevent/counteract skeletal muscle loss during incretin therapy – drugs, trial designs, and endpoints. Comments from industry representatives:

- Lilly approach
- Veru approach: Mitchell Steiner, Veru Inc.'s Chairman, President & CEO
- Actimed approach
- Regeneron approach

Academic discussants
Regulatory considerations: EMA+FDA representatives
General discussion
Session Date: December 11, 2025
Session Number: C2
Session Time: 10:15 am - 11:15 am Central European Time
Session Location: A.Roma Lifestyle Hotel, Rome, Italy

Presentation Name: Possible Endpoints for Regulatory Approval of Treatments Addressing Muscle Wasting in the Context of Obesity Therapy

- Reviewing possible endpoints
- Industry viewpoint: Mitchell Steiner, Veru Inc.'s Chairman, President & CEO
- Regulatory considerations
- General discussion

Session Date: December 11, 2025
Session Number: C3
Session Time: 11:15 am - 11:55 am Central European Time
Session Location: A.Roma Lifestyle Hotel, Rome, Italy

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 leading to improved 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, 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.

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 200 patients who have obesity (BMI ≥ 35) and are initiating GLP-1 RA treatment for weight reduction. The primary efficacy endpoint of the study is the percent change from baseline in total body weight at 72 weeks. An interim analysis will be conducted at 36 weeks to assess the percent change from baseline in lean body mass and fat mass, as measured by DEXA scans. 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 GLP-1 RA treatment to achieve clinically meaningful incremental weight reduction and preserve muscle mass and physical function by 72 weeks. The clinical study is expected to begin in calendar Q1 2026.

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, including weight loss, preservation of lean mass and function, will be replicated to the same or any degree in the planned PLATEAU Phase 2b study or in any future Phase 3 studies; whether patients treated with enobosarm in the planned PLATEAU Phase 2B study will exhibit increased energy and whether such effects will result in incremental weight reduction; 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 Company will be able to obtain sufficient 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 GLP-1 RA 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, 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, 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.

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Investor and Media Contact:
Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Source: Veru Inc.