

Veru to Present Two Abstracts at ObesityWeek 2025

MIAMI, FL, Oct. 31, 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 the presentation of two abstracts at ObesityWeek 2025 taking place November 4-7, 2025, in Atlanta, Georgia.

Poster presentation name: Enobosarm Reduced Body Weight and Fat Regain and Preserved Lean Mass After Discontinuing Semaglutide

Presenter: Steven B. Heymsfield, M.D., a Professor and the Director of the Body Composition-Metabolism Laboratory at the Pennington Biomedical Research Center in

Baton Rouge, Louisiana

Session Date: Tuesday, November 4, 2025 Session Time: 7:30 pm - 8:30 pm Eastern Time

Session Room: Exhibit Hall A1

Oral presentation name: Enobosarm in Combination With GLP-1RA is Selective for Fat Loss While Preserving Lean and Function

Presenter: Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru

Session Date: Friday, November 7, 2025

Session Time: 8:00 am - 8:15 am Eastern Time Session Room: GWCC Building A: A411-A412

Additional information on the meeting can be found on the following website: https://obesityweek.org/.

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, placebocontrolled, 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.

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 older (≥65 yo) and younger (<65 yo) patients who have obesity 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. 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 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 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 forwardlooking 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 governmentdriven 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.

Investor and Media Contact:

Samuel Fisch

Executive Director, Investor Relations and Corporate Communications

Email: veruinvestor@verupharma.com



Source: Veru Inc.