

June 11, 2025



Veru to Participate in the Virtual BTIG Obesity Health Forum

MIAMI, FL, June 11, 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 company will be participating in one-on-one meetings and a fire side chat presentation with investors at the virtual BTIG Obesity Health Forum on June 18, 2025.

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. Sabizabulin, a microtubule disruptor, is being developed for the treatment of inflammation in atherosclerotic cardiovascular disease.

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 Company has announced positive topline and safety results from the Phase 2b QUALITY clinical study, which is a 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 chronic weight management. After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, participants continued into a Phase 2b extension study where all patients discontinued semaglutide treatment, but continued receiving placebo, enobosarm 3mg, or enobosarm 6mg as monotherapy in a blinded fashion for 12 weeks. The Phase 2b extension clinical trial is evaluating whether enobosarm, by preserving muscle mass, also prevents the fat regain that generally occurs after stopping a GLP-1 RA. The topline efficacy and safety results for the Phase 2b extension clinical study are expected in the second calendar quarter of 2025. As the Phase 2b QUALITY clinical trial is a positive study, we have requested an End of Phase 2 meeting with the FDA.

Atherosclerosis Inflammation Program

Veru has evolved its drug development strategy for sabizabulin and is exploring the possibility of the clinical development of sabizabulin, a novel oral broad anti-inflammatory agent, for the treatment of inflammation in atherosclerotic cardiovascular disease. The

Company believes there are compelling scientific evidence and rationale to evaluate sabizabulin as a treatment for the inflammation associated with atherosclerotic cardiovascular disease. Atherosclerotic coronary artery disease (CAD) remains the leading cause of mortality worldwide. Inflammation and high cholesterol jointly contribute to atherosclerotic cardiovascular disease. It appears that the pathogenesis and progression of coronary artery disease, however, is largely driven by inflammation in response to atheromatous plaques containing cholesterol in the arterial wall. Even with maximum cholesterol reduction therapies, there remains a major and largely untreated residual inflammatory risk. The realization that the combined use of aggressive lipid-lowering and inflammation-inhibiting therapies might be needed to further reduce atherosclerotic risk has sparked the search for anti-inflammatory medications that could lower the risk of atherosclerotic events in patients with CAD. Sabizabulin has stable pharmacokinetics and low potential for drug-drug interactions; thus, sabizabulin may be administered potentially more safely as a secondary therapy in combination with statin therapy for the reduction of inflammation to slow the progression or promote regression of atherosclerotic cardiovascular disease. Overall preclinical data from *in vitro* and *in vivo* inflammation studies show that sabizabulin treatment suppressed all cytokines and chemokines tested. In Phase 2 and 3 pulmonary inflammation COVID-19 clinical studies, sabizabulin has demonstrated broad anti-inflammatory activity. The safety database consists of 266 dosed patients from the previous sabizabulin clinical development programs.

The Company's decision to explore this major cardiometabolic indication was based on the significant unmet medical need to treat inflammation in atherosclerotic cardiovascular disease, the large global market opportunity, current clinical and safety sabizabulin database of 266 patients, high probability of success given that sabizabulin drug's mechanism of action is similar to colchicine, strong intellectual property position, and is consistent with Company's focus on cardiometabolic diseases. Furthermore, the Company believes sabizabulin may be evaluated in a small Phase 2 dose finding proof of concept study to assess high sensitivity CRP and the progression of coronary atherosclerosis in patients using as the primary endpoint coronary plaque volume and composition measured by coronary CT angiography imaging. The chronic nonclinical toxicology studies are expected to be completed and a new IND for the proposed indication is planned to be submitted by the first half calendar 2026. Veru currently has sufficient drug substance to supply the proposed Phase 2 clinical study.

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 whether and when the full data set, including safety data, from the Phase 2b QUALITY study of enobosarm discussed above will be made available and whether that data will align with disclosed topline results or change any of the conclusions drawn from the topline data; whether and when the Company will present the full data from the Phase 2b QUALITY study and in what forum; whether and when the Company will present data from the extension maintenance study and whether such extension study will successfully meet any of its endpoints; whether and when the Company will have an end-of-Phase-2 meeting with FDA and the results of any such meeting; whether the results of the Phase 2b QUALITY study of enobosarm will be replicated to the same or any degree in any future Phase 3 studies; the expected costs, timing, patient population, design, endpoints and results of the planned Phase 3 studies of enobosarm as a body composition drug or any

other Phase 3 studies; whether the Company and FDA will align on the Phase 3 program for enobosarm as a body composition drug and whether any such program will be able to be funded by the Company; whether the modified-release formulation of enobosarm will be developed successfully and whether such formulation will have the same effectiveness 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 Phase 3 study or other Phase 3 studies; whether FDA will require more than one Phase 3 study for enobosarm as a body composition drug; whether enobosarm will enhance weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will enhance weight loss in any planned or other Phase 3 studies or if approved, in clinical practice; whether patients treated with enobosarm for a longer period of time than in the Phase 2b QUALITY study will have a greater loss of adiposity or greater weight loss than with semaglutide alone; and whether and when enobosarm will be approved by the FDA as a body composition drug. 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 3 program for enobosarm as a body composition drug and the number of 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 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 product liability claims 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.

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