May 1, 2025

Veru to Report Fiscal 2025 Second Quarter Financial Results on May 8

MIAMI, May 01, 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 it will host a conference call and audio webcast on Thursday, May 8, 2025, at 8:00 a.m. ET to discuss its fiscal 2025 second quarter financial results and to provide a business update.

The audio webcast will be accessible under the Home page and Investors page of the Company's website at www.verupharma.com. To join the conference call via telephone, please dial 1-800-341-1602 (domestic) or 1-412-902-6706 (international) and ask to join the Veru Inc. call. An archived version of the audio webcast will be available for replay on the Company's website for approximately three months. A telephonic replay will be available at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 7682749, for one week.

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.
On January 27, 2025, the Company announced positive topline results from its Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding QUALITY clinical trial to evaluate enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve lean body mass and augment loss of fat in 168 obese or overweight older (>60 years of age) patients receiving semaglutide (Wegovy®).

The trial met its prespecified primary endpoint with a statistically significant and a clinically meaningful benefit in the preservation of total lean body mass in all patients receiving enobosarm + semaglutide versus placebo + semaglutide at 16 weeks (71% relative reduction in lean mass loss, p=0.002). The enobosarm 3mg + semaglutide was the best dose with a >99% mean relative reduction in loss of lean mass (p <0.001).

As for secondary clinical endpoints, enobosarm + semaglutide treatment resulted in dose dependent greater loss of fat mass compared to placebo + semaglutide, with the enobosarm 6mg dose + semaglutide group having a 46% greater relative loss of fat mass compared to the placebo + semaglutide group at 16 weeks (p=0.014). Although enobosarm + semaglutide significantly preserved lean mass, the additional loss of fat mass caused by enobosarm treatment was able to replace the lean mass preserved to allow a similar net mean weight loss with semaglutide at 16 weeks. Accordingly, the tissue composition of the total weight loss shifted to greater and selective loss of fat with enobosarm treatment. The median percentage of total body weight loss in the placebo + semaglutide group that was due to lean mass was 32% and estimated fat loss was 68%. In contrast, in the all enobosarm + semaglutide group, the median total weight loss due to lean mass was 9.4% vs estimated fat loss of 90.6% meaning the all enobosarm + semaglutide group experienced approximately 33.2% more fat loss relative to the placebo + semaglutide group, and for the enobosarm 3mg + semaglutide group, it was 0.9% lean mass vs 99.1% estimated fat loss, meaning the enobosarm 3mg + semaglutide group experienced approximately 45.7% more fat loss relative to the placebo + semaglutide group. Therefore, enobosarm + semaglutide improved changes in body composition resulting in more selective and greater loss of adiposity than in subjects receiving placebo + semaglutide.

Physical function was measured by the Stair Climb Test. Climbing stairs is an activity of daily living, and the Stair Climb Test measures functional muscle strength, balance and agility. Declines in performance measured by Stair Climb Test predicts higher risk for mobility disabilities, gait difficulties, hospitalizations, falls, and bone fractures in older patients. As a point of reference, stair climb power declines by -1.38% annually with aging.

- A responder analysis was conducted using a ≥10% decline in stair climb power as the cut off at 16 weeks which represents 7 to 8 year loss of stair climb power function due to aging. In our study, the loss of lean mass mattered as 42.6% of patients on placebo + semaglutide group had at least a 10% decline in stair climb power physical function at 16 weeks. **This is the first human study to demonstrate that older patients who are overweight or have obesity receiving semaglutide GLP-1 RA are at higher risk for accelerated loss of lean mass with physical function decline.**

- The all enobosarm + semaglutide group had a statistically significant and clinically meaningfully 54.4% mean relative reduction in the proportion of subjects that lost ≥10% stair climb power compared to placebo + semaglutide group (p=0.0049). **Therefore, enobosarm treatment preserved lean mass (muscle) which translated into a reduction in the proportion of patients that had a clinically significant stair climb physical function decline versus subjects receiving semaglutide alone.**

Enobosarm represents a next generation drug that improves GLP-1 RA therapy to result in tissue SELECTIVE quality weight reduction, that is, enobosarm + semaglutide improved changes in body composition which resulted in preservation of lean mass and physical function and more selective and greater loss of adiposity (fat mass) than in subjects receiving placebo + semaglutide alone.

Safety data for the Phase 2b QUALITY study remains blinded as the Phase 2b extension clinical study portion is ongoing. The unblinded complete safety set will be available after the

Phase 2b extension study is completed in second quarter of calendar 2025. However, the aggregate, blinded safety data have not shown any significant differences compared to previous studies of enobosarm and what is expected with GLP-1 RAs. The Independent Data Monitoring Committee met on February 10, 2025 to evaluate the unblinded safety data, and they made the recommendation to continue the study as designed.

After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, the participants continued into a Phase 2b extension trial where all patients have stopped treatment with semaglutide, but continue taking placebo, enobosarm 3mg, or enobosarm 6mg in a blinded fashion for 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat regain that generally occurs after discontinuing a GLP-1 RA. The topline results of the separate blinded Phase 2b extension clinical study are expected in the second quarter of calendar 2025.

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 patients will progress into the extension study; the planned design, number of sites, timing, endpoints, patient population and patient size of such extension 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-released formation 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 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; whether and when enobosarm will be approved by the FDA as a body composition drug; whether and when sabizabulin will be developed for an atherosclerotic coronary artery disease indication (“CAD”), and whether sabizabulin would provide a safer, effective alternative to colchicine; whether prior data regarding sabizabulin’s anti-inflammatory effects would be repeated in any such future CAD indication; the timing of the completion of tox studies and the submission of an IND for sabizabulin in a CAD indication; 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; the ability to enroll sufficient numbers of subjects in clinical studies and the ability 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; 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; the Company's failure to timely file certain reports in February 2024 may impair its ability to raise capital under the Company's current effective shelf registration statement on Form S-3 or under a new registration statement; 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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