

August 11, 2025



Veru Announces Selection of Novel Modified Release Oral Enobosarm Formulation for Chronic Weight Loss Management Following Pharmacokinetic Clinical Study

MIAMI, Aug. 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 selection of a novel modified release oral formulation for enobosarm, a selective androgen receptor modulator, for chronic weight loss management, following confirmation of pharmacokinetic endpoints in a clinical study.

The single dose, open label pilot study evaluated the plasma concentration versus time profile of a proprietary, patentable modified release formulation of enobosarm 3mg. The new formulation demonstrated the intended distinct target product release profile, which includes a reduction in maximum plasma concentration (C_{max}), a delayed time to maximum plasma concentration (T_{max}), a distinct secondary peak plasma concentration, and similar extent of absorption (AUC) compared to historical values for enobosarm immediate release capsules.

“The novel enobosarm oral formulation’s unique manufacturing process is protected by a robust patent estate of already issued global patents with protection through 2037 and beyond. Patent applications on enobosarm’s new oral formulation have been filed and if issued, expiry is expected to be 2046,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “This novel modified release oral enobosarm formulation is planned to be available for the Phase 3 clinical studies and for commercialization.”

The novel modified release oral formulation of enobosarm was developed in collaboration with [Laxxon Medical](#) using smart delivery systems, including the Company’s proprietary patented SPID[®]-Technology to create advanced, unique oral delivery release profiles, as well as an innovative additive manufacturing process.

“We are proud to partner with Veru, which leveraged our proprietary SPID[®]-Technology to develop a novel oral formulation while ensuring strong IP protection for future commercialization,” said Helmut Kerschbaumer, Chief Executive Officer of Laxxon Medical. “This innovation has the potential to meaningfully advance Veru’s clinical program and differentiate its enobosarm formulation.”

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 ***Enobosarm Obesity Program***

The Company has previously 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 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. On June 24, 2025, the Company announced positive results from the Phase 2b QUALITY and Maintenance Extension clinical study showing enobosarm significantly reduced body weight regain, prevented fat regain, and preserved lean mass after semaglutide discontinuation.

In conclusion, the Phase 2b QUALITY and Maintenance Extension clinical trial confirms that preserving lean mass with enobosarm plus semaglutide led to greater fat loss during the active weight loss period, and after semaglutide was discontinued, enobosarm monotherapy significantly prevented the regain of both weight and fat mass during the maintenance period such that by end of study there was greater loss of fat mass while preserving lean mass for a higher quality weight reduction compared to the placebo group.

The Company has been granted an FDA meeting to discuss its Phase 3 program.

About Laxxon Medical

Laxxon Medical is a leading pharma-technology company and global leader of smart drug delivery systems in the pharmaceutical industry, pioneering a new generation of advanced pharmaceuticals designed to optimize drug delivery and maximize patient success through SPID[®]-Technology, Laxxon's proprietary 3D screen printing (3DSP) technology platform.

SPID[®]-Technology unlocks innovative drug delivery advancements paired with fast-tracked market access and extensive IP protection to yield disruptive opportunities in drug development and commercialization.

With SPID[®]-Technology, Laxxon can develop and manufacture advanced versions of new and existing pharmaceutical drugs while extending and adding new patent protection

through the technology transfer process. Laxxon can fully utilize the FDA's 505b(2) regulatory pathway in the US and Hybrid applications under article 10(3) of Directive 2001/83/EC in the EU, which fast tracks product routes to market.

Laxxon's pipeline includes ongoing working-projects with notable pharma players, biotech companies and research universities, in addition to 13 in-house Advanced Patented Generics products. Laxxon's IP is continuously growing, and together with the licensed IP from Exentis Group, consists of more than 230 patents and patent applications with more than 5,000 patent claims.

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, including the expected phase 3 studies of enobosarm in the Company's obesity program and whether the FDA will accept the use of this formulation without further 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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Investor and Media Contact:

Samuel Fisch

Executive Director, Investor Relations and Corporate Communications

Email: veruinvestor@verupharma.com



Source: Veru Inc.