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Veru Enrolls First Patients in Phase 2b Clinical Trial of Enobosarm and Semaglutide Combination for High Quality Weight Loss

-- The Phase 2b study planned to be conducted in 15 clinical sites in the United States --

-- Topline clinical data expected in the fourth quarter calendar year 2024 --

MIAMI, FL, April 30, 2024 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for preserving muscle for high quality weight loss, oncology, and viral induced acute respiratory distress syndrome, today announced that it has enrolled the first patients in its Phase 2b clinical trial of enobosarm, an oral selective androgen receptor modulator (SARM), to avoid muscle loss and to augment fat loss when combined with semaglutide (Wegovy®), a Glucagon-like peptide-1 receptor agonist (GLP-1 RA) drug, for potentially higher quality weight loss. Topline clinical data is expected in the fourth quarter of the calendar year 2024.

"We are excited to enroll the first patients in the Phase 2b clinical trial, marking an important milestone in the development of enobosarm for high quality weight loss," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. "There is a significant unmet medical need to have a drug that may effectively preserve muscle in patients undergoing weight loss therapy with GLP-1 drugs. Patients receiving GLP-1 drugs lose significant muscle as part of the weight loss which can lead to muscle weakness in older patients with both obesity and low muscle reserves. Muscle weakness is associated with mobility disability and loss of balance resulting in a higher risk for falls and hip and pelvic fractures. In fact, the package insert for Wegovy® has been updated based on the recently reported SELECT (Semaglutide Effects on Heart Disease and Stroke in Patients with Overweight or Obesity) cardiovascular outcomes clinical trial to highlight the four-fold increase in pelvic and hip fractures that was observed in patients greater than 75 years of age receiving Wegovy® compared to placebo."

"While there is clear medical benefit from weight loss with semaglutide, improving weight loss quality by minimizing the loss of lean mass is the next step forward in improving metabolic complications of obesity. This Phase 2b clinical trial of enobosarm will provide important insights into how this goal can be achieved," said Louis Aronne, MD, obesity medicine specialist at Weill Cornell Medicine in New York, Chief Medical Advisor to Veru*.

About the Enobosarm Phase 2b clinical trial
The Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial was designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve muscle and augment fat loss in approximately 90 patients with sarcopenic obesity or overweight elderly (>60 years of age) patients receiving semaglutide (Wegovy®).The primary endpoint is difference in total lean body mass measured by DEXA, and the key secondary endpoints are differences in total body fat mass measured by DEXA and physical function as measured by stair climb test at 16 weeks. Topline clinical results from the trial are expected by the end of 2024.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, participants will then continue into a Phase 2b extension clinical trial where all patients will stop receiving a GLP-1 RA, but will continue taking placebo, enobosarm 3mg, or enobosarm 6mg for an additional 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat and weight gain that occurs after discontinuing a GLP-1 RA. The topline results of the separate Phase 2b extension clinical study are expected in calendar Q2 2025.

About Sarcopenic Obesity
According to the CDC, 41.5% of older adults have obesity in the United States and could benefit from a weight loss medication. Up to 34.4% of these obese patients over the age of 60 have sarcopenic obesity. This large subpopulation of sarcopenic obese patients is especially at risk for taking GLP-1 drugs for weight loss as they already have critically low amount of muscle due to age-related muscle loss. Further loss of muscle mass when taking a GLP-1 RA medication may lead to muscle weakness leading to poor balance, decreased gait speed, mobility disability, loss of independence, falls, bone fractures and increased mortality which is a condition like age-related frailty. Because of the magnitude and speed of muscle loss while on GLP-1 RA therapy for weight loss, GLP-1 RA drugs may accelerate the development of frailty in older obese or overweight elderly patients.

About Enobosarm
Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), a novel oral daily selective androgen receptor modulator (SARM), has been previously studied in 5 clinical studies involving 968 older normal men and postmenopausal women as well as older patients who have muscle wasting because of advanced cancer. Advanced cancer simulates a “starvation state” where there is significant unintentional loss or wasting of both muscle and fat mass which is similar to what is observed with in patients taking GLP-1 RA drugs. The totality of the clinical data from these previous five clinical trials demonstrates that enobosarm treatment leads to dose-dependent increases in muscle mass with improvements in physical function as well as significant dose-dependent reductions in fat mass. The patient data that were generated from these five enobosarm clinical trials in both elderly patients and in patients with a cancer induced starvation-like state provide strong clinical rationale for enobosarm. The expectation is that enobosarm in combination with a GLP-1 RA would potentially augment the fat reduction and total weight loss while preserving muscle mass.

Importantly, enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women, some of which included patients dosed for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increases in gastrointestinal side effects. This is important as there are already significant and frequent

gastrointestinal side effects with a GLP-1 RA treatment alone.

About Veru Inc.
Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases, oncology, and ARDS. 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 for two indications: (i) Phase 2b clinical study of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, Phase 3 ENABLAR-2 clinical trial of enobosarm and abemaciclib for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting.

Sabizabulin, a microtubule disruptor, is being developed as a Phase 3 clinical trial for the treatment of hospitalized patients with viral-induced ARDS. The Company does not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources.

The Company also has an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

*Dr. Aronne, like certain other members of the Company's Scientific Advisory Board, receives compensation from the Company for his services.

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 phase 2b trial of enobosarm discussed above will produce topline data or patients will progress into the extension study, the planned design, number of sites, timing, endpoints, patient population and patient size of such trial and whether such trial will successfully meet any of its endpoints, 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 or provide important insights into quality weight loss therapy, and whether the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and oncology. 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 risks that are detailed in the Company's periodic reports filed with the SEC, including the Company's Form 10-K for the year ended September 30, 2023, as amended by the Form 10-K/A.

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Source: Veru Inc.