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Veru Announces Meta-analysis of Body Composition Data from Older Patients with Obesity which Supports Potential for Enobosarm to Optimize Weight Loss at ObesityWeek

MIAMI, FL, Nov. 05, 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 data from a meta-analysis presentation at ObesityWeek, which took place November 5, 2024, in San Antonio, Texas.

Highlights from the presentation:

The objective of the meta-analysis was to determine the effects of enobosarm on body composition in older patients that had obesity who were enrolled in 4 previously conducted randomized clinical trials of enobosarm that measured body composition including Phase 2 older males and postmenopausal women, Phase 2 advanced cancer patients with muscle wasting, and two Phase 3 advanced lung cancer patients with cancer wasting.

Meta-analysis was conducted in older (≥ 60 years old) subjects with obesity ($\text{BMI} \geq 30$), treated with enobosarm 3mg per day versus placebo, and who had a Day 84 ($n=60$) and Day 147 ($n=45$) DEXA scans to assess body composition.

Results of DEXA scan assessments of body composition in older subjects with obesity:

At Day 84, enobosarm 3mg treatment compared to placebo resulted in an absolute increase in lean mass (0.05 kg enobosarm vs -1.54 kg placebo) and absolute decrease in fat mass (-1.48 kg enobosarm vs placebo -0.35 kg).

At Day 147, enobosarm 3mg treatment compared to placebo resulted an absolute increase in lean mass (-0.79 kg enobosarm vs -1.77 kg placebo) and absolute decrease in fat mass (-2.05 kg enobosarm vs -0.05 kg placebo).

At Day 147, enobosarm 3mg treated subjects compared to placebo had greater total weight loss by DEXA scan (-2.93 kg for enobosarm and -2.11 kg for placebo).

Enobosarm was generally well-tolerated with no increase in gastrointestinal side effects.

Conclusions:

Meta-analysis shows in older subjects with obesity that enobosarm 3mg daily treatment resulted in DEXA body composition changes of greater total weight loss by day 147 with preservation of lean mass and greater loss of fat. These data support the potential for enobosarm when combined with a GLP-1 RA to also preserve muscle, while preferentially reducing fat resulting in a higher quality weight loss in patients with obesity.

“This meta-analysis data provide support for the Company’s ongoing Phase 2b QUALITY clinical study evaluating enobosarm treatment to preserve lean mass and augment fat loss in obese patients receiving GLP-1 drugs for weight management,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc.

Additional information on the meeting can be found on the following website:

<https://obesityweek.org>

About the Enobosarm Phase 2b QUALITY clinical trial

The fully enrolled Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding QUALITY clinical trial is evaluating the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve muscle and augment fat loss in 168 patients with sarcopenic obesity or overweight elderly (>60 years of age) patients receiving semaglutide (Wegovy®). The primary endpoint is total lean body mass, and the key secondary endpoints are total body fat mass and physical function as measured by stair climb test at 16 weeks. Topline clinical results from the trial are expected in January of 2025.

After completing the efficacy dose-finding portion of the Phase 2b QUALITY clinical trial, it is expected that participants will then continue in blinded fashion 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 blinded 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 causes the loss of appetite 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. We believe 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 appetite suppression 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.

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 QUALITY 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.

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 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 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 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; the Company's existing product, FC2, and any future products, 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; risks relating to the Company's development of its own dedicated direct to patient telehealth platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, product testing, transportation delays or regulatory actions; 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, 2023, as amended by the Form 10-K/A, 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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