April 25, 2024

Veru to Present at the American Association of Clinical Endocrinology (AACE) 2024 Annual Meeting on May 9-11

MIAMI, FL, April 25, 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 the Company will present two late-breaking abstract presentations at the American Association of Clinical Endocrinology (AACE) 2024 Annual Meeting, taking place May 9-11, 2024 in New Orleans, LA.

The late-breaking presentations are:

Double-Blind, Multiple Ascending Dose, Safety, Pharmacokinetic and Body Composition Study of Enobosarm in Healthy Young and Older Men
Date: Thursday May 9, 2024
Start and end time: 12:25 PM-12:40 PM Central Daylight Time

Potential to Optimize Weight Loss with Enobosarm: Augment Reduction of Fat Mass while Preserving Muscle in Older Patients with Obesity
Date: Thursday May 9, 2024
Start and end time: 2:30 PM-2:45 PM Central Daylight Time

Additional information on the meeting can be found on the AACE website:
https://pro.aace.com/

About the Enobosarm Phase 2b clinical trial
The Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial is 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 sarcopenic obese or overweight elderly (>60 years of age) patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. The primary endpoint is lean body mass (muscle) measured by DEXA, and the key secondary endpoints are total body fat mass and physical function measured by stair climb test at 16 weeks. We expect to enroll our first patient in April 2024 with topline clinical results expected by calendar year-end 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 rebound gain that occurs after stopping a GLP-1 RA drug. 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 similar to what is observed with GLP-1 RA treatment. The totality of the clinical data from these 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 avoiding muscle loss.

In addition, enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women dosed with duration of treatment in some patients for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increase 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.

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 planned phase 2b trial of enobosarm discussed above will commence or produce topline data or patients will progress into the extension study, the planned design, 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 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.