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Veru Announces FDA Clearance of IND Application to Initiate Phase 2b Clinical Trial with Enobosarm to Treat Muscle Loss Associated with Weight Loss Drugs

FDA IND clearance is an important development milestone in advancing enobosarm in combination with GLP-1 drugs for potentially higher quality weight loss than has been shown with GLP-1 drug alone

Randomized Phase 2b clinical trial aims to show enobosarm preserves muscle and physical function while augmenting fat loss in sarcopenic obese or overweight elderly patients on GLP-1 drug for weight loss

Phase 2b clinical trial is expected to initiate by April 2024

Phase 2b clinical trial final topline results are anticipated by year-end

MIAMI, FL, Feb. 06, 2024 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for potentially higher quality weight loss, oncology, and viral induced acute respiratory distress syndrome (ARDS), today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for its Phase 2b clinical study to evaluate enobosarm, an oral novel selective androgen receptor modulator (SARM), to preserve muscle mass and physical function and further increase fat loss in patients receiving a Glucagon-like peptide-1 receptor agonist (GLP-1 RA) drug for potentially higher quality weight loss.

GLP-1 RA drugs are very effective drugs that result in significant weight loss. Unfortunately, studies have shown that up to 50% of the total weight loss comes from muscle which is problematic as muscle is essential for metabolism, strength, and physical function.

Planned Phase 2b enobosarm clinical trial design for potentially higher quality weight loss

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 augment fat loss and to prevent muscle loss in 90 sarcopenic obese or overweight elderly 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), and the key secondary endpoint is total body fat mass at 16 weeks. The clinical study is expected to begin by April 2024 with the topline clinical results from the trial expected in the end of the fourth calendar quarter of 2024.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, participants will then continue into an open label extension trial where all patients will receive 6 mg of enobosarm monotherapy for 12 weeks to determine the ability of enobosarm to rescue, or reverse muscle loss and prevent fat and weight rebound after stopping a GLP-1 RA. The results of the separate Phase 2b open label extension clinical study is expected in calendar Q2 2025.

“FDA clearance of our IND will allow us to evaluate enobosarm as a combination treatment with GLP-1 drugs to prevent the loss of muscle, while preferentially reducing fat in not only overweight or obese patients, but especially for the large subpopulation of sarcopenic obese or overweight elderly patients who are at-risk for developing muscle atrophy and muscle weakness leading to frailty,” stated Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. “We look forward to starting the Phase 2 clinical study to further validate enobosarm’s ability to preserve muscle and physical function while augmenting fat loss to provide for a potentially higher quality weight loss.”

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.

Metabolic pipeline: Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), an oral daily novel selective androgen receptor modulator (SARM), is being developed as a treatment in combination with weight loss drugs to augment fat loss and avoid muscle loss in overweight or obese patients for chronic weight management. Initially, enobosarm will be developed in a Phase 2b clinical study to address the large subpopulation of sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness leading to physical function mobility disability and frailty.

Oncology pipeline: Phase 3 clinical development of enobosarm for 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.

Infectious disease pipeline: 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 Veru's expectations regarding whether and when the planned phase 2b trial of enobosarm discussed above will commence by April 2024, the planned design, timing, endpoints, patient population and patient size of such Phase 2b trial and whether such trial will successfully meet any of its endpoints; whether enobosarm will be shown to preserve muscle and physical function while augmenting fat loss in the specified patient populations; whether the Phase 2b data will be available by the end of 2024; whether the data will warrant continued study and whether and when the clinical trial participants will continue into an open-label extension study and when those results will be available; whether enobosarm will meet any unmet need for obesity patients; the planned timing, design, endpoints, patient population and expected funding of the Company's breast cancer and infectious disease pipeline; 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 Veru Inc. (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, uncertainties related to market conditions and the satisfaction of customary closing conditions related to the proposed public offering and the Company's expectations regarding the completion, timing and size of the proposed public offering and the use of proceeds therefrom. This list is not exhaustive and other risks 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.

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