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Veru Announces the Appointment of Louis Aronne MD as Chief Medical Advisor for its Enobosarm Program for High Quality Weight Loss

MIAMI, March 12, 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 (ARDS), today announced the appointment of Louis Aronne, MD, as Chief Medical Advisor and a member of the Scientific Advisory Board to support the advancement of enobosarm, an oral novel selective androgen receptor modulator (SARM), to avoid muscle loss and augment fat loss when combined with a Glucagon-like peptide-1 receptor agonist (GLP-1 RA) drug for potentially higher quality weight loss.

Dr. Louis Aronne is a leading authority on obesity and its treatment. He is the Sanford I. Weill Professor of Metabolic Research and the director of the Comprehensive Weight Control Center, a state-of-the-art, multidisciplinary obesity research, education, and treatment center in the division of Endocrinology, Diabetes & Metabolism at Weill Cornell Medicine. A graduate of Johns Hopkins University School of Medicine, Dr. Aronne is a founder and past chairman of the American Board of Obesity Medicine and a past president of The Obesity Society. He is founder and Chief Scientific Advisor of *Intellihealth* a cloud-based weight management system which delivers obesity treatment online as *flyte*.

He completed his internship and residency at Albert Einstein College of Medicine and Jacobi Medical Center, followed by a Henry J. Kaiser Family Foundation Fellowship in General Internal Medicine at New York-Presbyterian/Weill Cornell Medical Center.

Dr. Aronne has been an investigator on more than 65 trials of obesity treatment modalities including medications, devices, and diets. He has authored more than 150 papers and book chapters on obesity and edited the National Institutes of Health's Practical Guide to Obesity Treatment. He served as a consultant to the VA Weight Management/Physical Activity Executive Council in the development of the MOVE! Program, the nation's largest medically based weight control program. Dr. Aronne has won many awards, including the 2015 Atkinson-Stern Award for Distinguished Public Service and 2021 Clinician of the Year from The Obesity Society, and several for medical teaching, including the Davidoff Prize from Albert Einstein College of Medicine and the Elliot Hochstein Award from Weill Cornell Medical College. Since 2001, he has appeared annually in Castle-Connolly's Top Doctors directory as a specialist in obesity and internal medicine.

Dr Aronne has served as a consultant/advisor to many companies developing treatments for obesity including Boehringer Ingelheim Pharmaceuticals, Inc. (USA), Mediflix Inc. Pfizer, Inc., Altimmune, Inc., Amgen, Inc., Eli Lilly and Company, Janssen Pharmaceutical Company, Novo Nordisk Pharmaceuticals, Inc., Senda Biosciences, and Versanis Bio.*

“The weight loss and health benefits of the new generation of anti-obesity medications, the GLP-1 receptor agonists, are clear. Weight loss through any modality produces muscle loss, and there is an unmet need to minimize that in certain groups of patients in order to produce better quality weight loss. In conjunction with a GLP-1 drug, enobosarm has the potential to deliver better quality weight loss while utilizing lower doses of the GLP-1 drug. This should not only produce fewer side effects and better functioning, but potentially lead to longer term maintenance of weight loss.”

“We are pleased that Dr. Aronne, a world-renowned obesity expert, will be our Chief Medical Advisor to help us develop enobosarm as a treatment for chronic weight management,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru Inc. “Enobosarm is a drug candidate that may provide higher quality weight loss for obese or overweight patients by preferentially increasing fat loss while preserving muscle. We are fortunate that Dr. Aronne and the other senior expert members of our Scientific Advisory Board will help guide the enobosarm development program.”

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 frailty in older obese or overweight elderly patients.

About Enobosarm

Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), a novel daily oral 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 of both muscle and fat mass like that seen with GLP-1 RA treatment. The totality of the clinical data from these five clinical trials demonstrates that enobosarm treatment leads to preservation of muscle mass with improvements in physical function as well as significant reductions in fat mass.

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.

The efficacy and safety clinical data that were generated from 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 with higher quality total weight loss while preserving muscle and physical function.

Planned Phase 2b enobosarm clinical trial design for potentially high 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 preserve muscle and augment fat loss in 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), and the key secondary endpoints are total body fat mass and physical function at 16 weeks. The IND has received FDA clearance, and the clinical study is expected to begin in April 2024 with the topline clinical results from the trial expected 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 that occurs after stopping a GLP-1 RA drug. The topline results of the separate Phase 2b extension clinical study is expected in calendar Q2 2025.

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 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 other members of the Company’s Scientific Advisory Board, receives certain 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 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, whether the Scientific Advisory Board will make valuable contributions to the Company’s metabolic development program, 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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