April 21, 2021

Veru Announces Presentation of Phase 2 Study of Enobosarm -- a Selective Androgen Receptor Targeting Agent in Metastatic AR+ER+HER2- Breast Cancer at 2021 ESMO Breast Cancer Congress

MIAMI, April 21, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancer, today announced that clinical results from the Phase 2 clinical study of enobosarm, a selective androgen receptor targeting agonist, in heavily pretreated women with AR+ER+HER2- advanced breast cancer including further efficacy data and an analysis of patients who have failed both estrogen blocking agents and CDK 4/6 inhibitors, has been accepted for a poster presentation at the European Society for Medical Oncology (ESMO) Breast Cancer Virtual Congress 2021 to be held May 05-08, 2021. Enobosarm is an oral, first-in-class, selective androgen receptor targeting agonist that activates the androgen receptor, a tumor suppressor, in AR+ER+HER2- metastatic breast cancer. The planned Phase 3 ARTEST study will evaluate enobosarm monotherapy versus an active control (exemestane or SERM) for the treatment of metastatic AR+ER+HER2- breast cancer patients whose disease has progressed after treatment with a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK 4/6 inhibitor and the study is anticipated to commence in Q2 2021.

Presentation details:

Abstract Title: Efficacy of enobosarm, a selective androgen receptor (AR) targeting agent, in patients with metastatic AR+ER+ breast cancer resistant to estrogen receptor targeted agents and CDK 4/6 inhibitor in a Phase 2 clinical study
Presenter: Carlo Palmieri, BSc, MB BS, PhD, FRC, Professor of Translational Oncology & Medical Oncologist, University of Liverpool
Abstract Number: 568

Additional information on the meeting can be found on the ESMO website
https://www.esmo.org/meetings/esmo-breast-2021-virtual

“With the recent validation of the androgen receptor as a tumor suppressor and a therapeutic target in AR+ER+HER2- breast cancer as well as the positive proof of concept efficacy and safety results in the Phase 2 clinical study, we remain very excited about advancing the

clinical development of enobosarm into a Phase 3 ARTEST registration trial and its potential role in the targeted treatment refractory AR+ER+HER2- advanced breast cancer," said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc.

About Veru Inc.

Veru Inc. is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast cancer. Veru's prostate cancer pipeline includes: VERU-111, an oral, first-in-class, targeted cytoskeleton disruptor, is expected to commence in Q2 2021 a Phase 3 VERACITY clinical trial in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer. VERU-100, a novel, proprietary GnRH antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, will start the planned Phase 2 clinical study in Q2 2021 and the Phase 3 clinical study in Q4 2021 to treat hormone sensitive advanced prostate cancer. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects; Phase 3 ARTEST clinical trial to evaluate enobosarm in approximately 210 subjects with AR+ER+HER2- advanced breast cancer who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor is anticipated to commence Q2 2021. The second indication for VERU-111 is for the treatment of taxane resistant metastatic triple negative breast cancer; the planned Phase 2b in 200 subjects is expected to begin Q3 2021. Based on positive Phase 2 results on the reduction of mortality, VERU-111 is being evaluated in a Phase 3 trial in 300 subjects for the treatment of hospitalized patients with COVID-19 who are at high risk for acute respiratory distress syndrome.

The Company's Sexual Health Business commercial product is the FC2 Female Condom® (internal condom) ("FC2"), an FDA-approved product for dual protection against unintended pregnancy and the transmission of sexually transmitted infections. The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple third-party telemedicine and internet pharmacy providers and retail pharmacies. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. The second product expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). An NDA was submitted in February 2021. To learn more about Veru products, please visit www.verupharma.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995: *The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding the potential of enobosarm to treat certain breast cancer patients and whether future clinical development will demonstrate sufficient efficacy and safety to secure FDA approval of the Company's drug candidates and statements regarding the expected timing, design and efficacy of the other*

drug candidates in the Company's development pipeline. Any forward-looking statements in this release are based upon the Company's current plans and strategies 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 release. The Company assumes no obligation to update any forward-looking statements contained in this 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. 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 following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and the time and cost to bring any of our product candidates to market; potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; preclinical or clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company's existing products and any future products, if approved, may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; product demand and market acceptance; competition in the Company's markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; the risk that the Company will be affected by regulatory developments, including a reclassification of products; *price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's product candidates are in development and the Company may fail to successfully commercialize such products, if approved; risks related to intellectual property,*

including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; the risk 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; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; 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; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; 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, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; risks related to the costs and other effects of litigation, including product liability claims; 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 in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2020 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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Source: Veru Inc.