December 14, 2020

Veru Reports Positive Phase 2 Clinical Trial Results for Enobosarm, Selective Androgen Receptor Targeting Agent, for Endocrine Resistant Metastatic Breast Cancer

-- Phase 2 Multicenter, International Clinical Study Selected as Spotlight Presentation at 2020 San Antonio Breast Cancer Symposium –

--Enobosarm Demonstrated Clinically Meaningful Clinical Benefit Rates, Overall Response Rates, Median Radiographic Progression-Free Survival and Well Tolerated Safety Profile in Heavily Pretreated Endocrine and Chemotherapy Resistant Metastatic Breast Cancer Cohorts--

--FDA Agrees to Phase 3 Clinical ARTEST Study for the Treatment of Endocrine Resistant ER+/HER2- Advanced Breast Cancer; Study to Commence in 2Q 2021 --

MIAMI, Dec. 14, 2020 (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, announces positive Phase 2 clinical trial results for enobosarm, an oral, novel selective androgen receptor (AR) targeting agent, for the treatment of endocrine and chemotherapy resistant ER+/HER2- metastatic breast cancer, which was selected as a Spotlight Presentation at the 2020 San Antonio Breast Cancer Symposium.

Estrogen receptor (ER) is present in 85% of all breast cancers, and more than 90% of ER+ positive breast cancers also contain the AR which has been demonstrated to be an important therapeutic target in ER+ breast cancer. Enobosarm is an oral drug that selectively targets the AR in breast cancer without having the unwanted virilizing androgen adverse side effects including facial hair, acne, increase in hematocrit, or liver toxicity, while having potential clinical benefits including increasing muscle and physical function as well addressing cancer treatment induced bone loss and fractures. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies with 2,091 enrolled patients, including three Phase 2 clinical studies in advanced breast cancer. There are also at least two enobosarm investigator-initiated Phase 2 clinical studies in advanced breast cancer.

In the first enobosarm Phase 2 clinical study (G200801), enobosarm 9mg oral daily dosing was evaluated in 22 heavily pretreated women who have confirmed AR+/ER+/HER2- metastatic breast cancer and who have developed resistance to estrogen receptor targeted endocrine therapies and chemotherapy. In this first Phase 2 clinical study, enobosarm demonstrated a clinically meaningful six-month clinical benefit rate (complete responses (CR)+partial responses (PR)+ stable disease (SD)) of 35.3% and had a good safety profile with no reports of virilization, increased hematocrit, or liver toxicity.

Today Veru announces the clinical results of the second enobosarm Phase 2 clinical study (G200802) which were presented at the 2020 San Antonio Breast Cancer Symposium. This was an international, Phase 2, open label, parallel design, randomized study to investigate the efficacy and safety of enobosarm 9mg and 18mg oral daily dosing in 136 heavily pretreated women with ER+/HER2- metastatic breast cancer who had breast cancer progression being treated with multiple lines of endocrine therapy and 90% who had also failed chemotherapy. Patients were randomized to receive enobosarm 9mg (n=72) or 18mg (n=64) oral daily dosing. The primary endpoint was clinical benefit rate at 6 months (defined as CR+PR+SD) by RECIST 1.1. Secondary endpoints included objective response rate, best overall response rate (complete responses + partial responses), radiographic progression-free survival (rPFS), and duration of clinical benefit. Median age was 60.8 years (35-83) for 9mg and 62.1 years (42-81) for the 18mg cohort. AR positivity (>10%) was centrally confirmed in 94.0% and 86.5% of the 9mg and 18mg cohorts, respectively.

The Phase 2 primary endpoint demonstrated clinically meaningful clinical benefit rate of 32% and 29% in the 9mg and 18mg daily enobosarm AR+ cohorts, respectively. At the time the study was terminated, the median duration of clinical benefit was not reached (NR) in the 9mg group (range 8.2 months to NR) and 14.1 months (range 11.0 to 16.5) in the 18mg group. Best overall response rates, AR+ patients that had complete or partial responses, were 35.3% and 25.6% for 9mg and 18mg, respectively. The median progression-free survival was 5.6 months (2.9 to >27.5) and 4.2 months (2.8 to 11) in the 9mg and 18mg groups AR+, respectively. Women being treated with 9mg or 18mg of enobosarm also reported significant improvements in quality of life measurements including mobility, anxiety/depression and pain discomfort.

Overall, enobosarm was well tolerated with most of the observed adverse events being grade 1 and 2. Drug related severe adverse events (SAEs) (Grades 3-4) were observed in 6 patients (8.0%) at the 9mg and 10 patients (16.4%) at the 18mg dose. There were no reports of virilization, increased hematocrit, and liver toxicity.

In both Phase 2 clinical studies, enobosarm demonstrated clinically meaningful efficacy and was well tolerated with no unwanted virilization, no increased hematocrit, and no liver toxicity in a combined 150 women heavily pretreated women with ER+/HER2- metastatic breast cancer who have failed estrogen targeted endocrine therapies and chemotherapy. As the 9mg and 18mg had similar efficacy, but the 9mg had slightly better tolerability, the enobosarm 9mg oral daily dose is the recommended dose for the Phase 3 study.

Based upon the efficacy and safety from these clinical studies, the FDA recently agreed to the Company’s Phase 3 registration open label, randomized, ARTEST clinical study to evaluate efficacy and safety of enobosarm 9mg versus an active comparator (exemestane or tamoxifen) for the treatment of ER+/HER2- metastatic breast cancer in approximately 240

patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The primary endpoint will be radiographic progression-free survival. In the Phase 3 ARTEST study design, the primary endpoint assumptions anticipate, as this is an earlier treatment cohort (2nd line of treatment for metastatic disease and prior to chemotherapy), the median radiographic progression-free survival will be 7 months for enobosarm treatment group and 3.5 months for the active comparator treatment group. As a comparison from the scientific literature, the observed median radiographic progression-free survival for chemotherapy in this treatment setting is approximately 3.1-3.5 months.

“This Phase 2 study confirms that targeting the androgen receptor with enobosarm results in clinical efficacy. Furthermore, enobosarm was well tolerated as evidenced by improvement in quality of life. These results clearly support the further clinical development in a Phase 3 study of enobosarm for the treatment of metastatic endocrine resistant breast cancer. For breast cancer patients, enobosarm represents a novel class of targeted endocrine therapy that alternatively targets the androgen receptor when endocrine therapies targeting the estrogen receptor stop working,” said Dr. Carlo Palmieri, BSc, MB BS, PhD, FRC, Professor of Translational Oncology and Consultant Medical Oncologist, Clatterbridge Cancer Centre NHS Foundation Trust/University of Liverpool, UK.

“We are extremely excited to have exclusively licensed worldwide rights to enobosarm to add to our oncology pipeline. Enobosarm is a large market opportunity as it represents the first new class of targeted endocrine therapy in ER+ advanced breast cancer in decades. Enobosarm targets AR in ER+ HER2- metastatic breast cancer as a potential second line and/or third line oral daily dosing endocrine therapy option in breast cancer patients that have exhausted endocrine therapies targeting ER, but prior to chemotherapy,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “We expect enobosarm, as a second line drug for metastatic ER+HER2- breast cancer, will have a median radiographic progression-free survival of at least 7 months versus 3.5 months for further estrogen receptor targeted endocrine therapy. Furthermore, based on the scientific literature, when women receive chemotherapy, their radiographic progression-free survival was also about 3.5 months, but with all the chemotherapy side effects. If enobosarm demonstrates efficacy, a good safety profile, and has the potential additional benefits of improving quality of life, increasing bone strength, and increasing muscle and physical function, then it is clear to me that enobosarm as an AR targeted agent could be the next drug women would consider after failing ER targeted endocrine therapy and before having chemotherapy.”

The Principal Investigator for both Phase 2 studies, including the G200802 study, was Dr. Beth Overmoyer, Founder and Director of the Inflammatory Breast Cancer Program at the Dana-Farber Cancer Institute, and Assistant Professor of Medicine, Harvard Medical School. Presentation was made by Professor Carlo Palmieri of the Clatterbridge Cancer Centre NHS Foundation Trust / University of Liverpool, UK.

The authors and affiliations of those included on the study include Carlo Palmieri[1], Hannah Linden[2], Stephen Birrell[3], Elgene Lim[4], Lee S Schwartzberg[5], Hope S Rugo[6], Patrick Cobb[7], Kirti Jain[8], Charles Vogel[9], Joyce A O’Shaughnessy[10], Adam Brufsky[11] and Beth Overmoyer[12]. [1]The Clatterbridge Cancer Center NHS Foundation Trust, Liverpool, United Kingdom; [2]University of Washington/ Seattle Cancer Care Associates, Seattle, WA;

[3]Wellend Health/Burside Hospital, North Adelaide, Australia; [4]University of New South Wales, Australia and Garvan Institute of Medical Research, Darlinghurst, Australia; [5]The West Clinic, Memphis, TN;[6]University of California San Francisco, San Francisco, CA;[7]Cancer Centers of Montana, Billings, MT;[8]Ashland Bellefonte Cancer Center, Ashland, KY; [9]University of Miami Sylvester Comprehensive Cancer Center, Miami, FL;[10]Baylor University Medical Center, Texas Oncology, US Oncology, Dallas, TX; [11]Magee-Womens's Hospital, University of Pittsburgh Medical Center, Pittsburgh, PA;[12]Dana Farber Cancer Institute, Boston, MA

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. The Veru prostate cancer pipeline includes VERU-111, VERU-100, and Zuclomiphene citrate. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical trials in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical trial completed enrollment of 39 men and is ongoing. The Phase 2 clinical trial has completed the enrollment of 40 men who have metastatic castration resistant prostate cancer and who have also become resistant to at least one novel androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to IV chemotherapy, and is ongoing. The Company anticipates proceeding to its Phase 3 VERU-111 VERACITY registration clinical trial in the first quarter of calendar 2021.VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 in subjects at high risk for ARDS. VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration — a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. A Phase 2 trial to evaluate VERU100 dosing is anticipated to begin in the first quarter of calendar year 2021 and a Phase 3 registration clinical trial is anticipated to begin the second half of calendar year 2021. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. Following an End of Phase 2 meeting with the FDA, the Company plans to advance Zuclomiphene citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

The Veru breast cancer pipeline includes enobosarm for hormone sensitive metastatic ER+/HER2- metastatic breast cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor (AR) in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. In October 2020, the FDA agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agent, versus physician’s choice

of either exemestane or tamoxifen as an active comparator for the treatment of metastatic ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control trial is anticipated to commence in the first half of calendar year 2021. VERU111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules and is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane resistance in TNBC. Using the safety information from the Phase 1b and Phase 2 VERU111 prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in the first half of calendar year 2021 and to commence a Phase 2b registration clinical trial in the second half of calendar year 2021 to evaluate oral daily dosing of VERU111 in approximately 100 women with metastatic TNBC that have become resistant to taxane IV chemotherapy.

Veru is also advancing a new drug formulation in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFYN®) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company expects to submit the NDA for TADFYN® in early calendar year 2021.

The Company’s Sexual Health Business commercial product is the FC2 Female Condom / FC2 Internal Condom® (“FC2”), an FDA-approved product for the 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. 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 regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, clinical study results including potential benefits and the absence of adverse events and anticipated results of future clinical trials, and the anticipated design and scope for clinical trials and FDA acceptance of such design and scope. 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 time and cost to bring 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 COVID19, 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; 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; 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 products 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 products are in development and the Company may fail to successfully commercialize such products; 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.

Contact:
Sam Fisch, Director of Investor Relations
800-972-0538

Source: Veru Inc.