October 13, 2021

Veru Enrolls First Patient in International Phase 3 ARTEST Clinical Trial of Enobosarm in Metastatic Breast Cancer

-- Enobosarm is a novel targeted hormone drug to be evaluated in the 3rd line treatment of androgen receptor positive metastatic breast cancer --

-- A companion diagnostic test will be developed, validated, and used to select patients who are most likely to respond to enobosarm treatment --

-- The Phase 3 ARTEST study will be conducted in 49 clinical sites across the United States and Europe --

MIAMI, Oct. 13, 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 it has enrolled the first patient in its Phase 3 ARTEST registration trial of enobosarm, an oral selective androgen receptor (AR) targeting agonist, for patients with AR+ER+HER2- metastatic breast cancer who had tumor progression following treatment with estrogen blocking agents and CDK4/6 inhibitors.

“While endocrine therapies have been the mainstay of breast cancer treatment for decades, these therapies have all focused on the estrogen receptor. Targeting the AR, a demonstrated tumor suppressor, provides us with an opportunity to bring a truly novel hormone treatment approach to patients who have AR+ER+HER2- metastatic breast cancer,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “We already have substantial safety information about enobosarm therapy as it has been evaluated in 25 clinical trials comprising over 2,000 patients with approximately 350 patients dosed at 9mg or higher doses. Enobosarm is well tolerated and has also resulted in improvements in quality of life including reported better physical function, mobility, and pain in metastatic breast cancer patients. Furthermore, a recent Phase 2 study in heavily pretreated patients with metastatic breast cancer confirmed that enobosarm’s efficacy was best in women that had 40% or greater expression of the androgen receptor in their breast cancer.”

“Targeting patients expressing the androgen receptor allows us to focus a new endocrine approach on patients that have become resistant to existing therapies,” said Adam Brufsky, M.D., Ph.D., Professor of Medicine, Associate Chief, Division of Hematology/Oncology and Co-Director, Comprehensive Breast Cancer Center at the University of Pittsburgh Medical

Center. Dr. Brufsky is also the Principal Investigator of the ARTEST study. “I couldn’t be more pleased that Veru is advancing enobosarm into a registration Phase 3 trial for the treatment of hormone receptor positive metastatic breast cancer in an effort to fill an unmet medical need benefitting these patients.”

ARTEST Phase 3 Trial Design

The Phase 3 ARTEST (Androgen Receptor Targeting Agent, Enobosarm, for the Treatment of Metastatic ER+ Breast Cancer) clinical trial is an international, multicenter, open-label randomized, active control pivotal study evaluating the efficacy and safety of enobosarm 9mg oral daily dosing versus active control (exemestane +/- everolimus or SERM – physician’s choice) in the 3rd line metastatic treatment of approximately 210 metastatic AR+ ER+ HER2- advanced breast cancer patients who had tumor progression on a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. Enobosarm is being targeted to patients with positive androgen receptor staining using a threshold of ≥ 40% nuclei staining in tissue samples using a diagnostic test being developed and validated as a companion diagnostic test. The primary efficacy endpoint is median radiographic progression-free survival. Secondary endpoints include overall response rate (CR+PR), duration of response, overall survival, change in short physical performance battery (SPPB), and change in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ). The Phase 3 ARTEST study will be conducted in 49 clinical sites across the United States and Europe.

About the Enobosarm Phase 2 (G200802) Study

The Phase 2 clinical study was an 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% also progressed on 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. A post-hoc AR expression subset analysis of these Phase 2 clinical data was conducted to evaluate the relationship of AR status with enobosarm antitumor efficacy. This subset analysis showed that the presence of the AR and the amount of AR expression in the breast cancer tissue predicted those women who were most likely to have an antitumor response to enobosarm. More specifically, the subset analysis combined randomized subjects from both the 9mg and 18mg cohorts who had known AR status determined by a central lab and who had measurable disease (n=84). The cutoff of 40% AR expression appeared to be the best level to enrich for subjects that were most likely to respond to enobosarm. The clinical benefit rate at 24 weeks was 52% at 40% AR staining versus 14% for <40% AR staining ($p<0.0004$); best objective tumor response (PR + CR) was 34% at

40% AR staining versus 2.7% for <40% AR staining (p<0.0003); and the median rPFS was 5.47 months at 40% AR staining versus 2.7 months for <40% AR staining (p<0.001). Using this 40% cutoff, 57% of all women with AR+ER+HER2- metastatic breast cancer would qualify for treatment with enobosarm. Thus, the presence and degree of AR expression in breast cancer tissue was important for enobosarm's antitumor activity which is consistent with enobosarm being a targeted agent, or biomarker, that could select or enrich for subjects most likely to respond to enobosarm therapy.

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 masculinizing side effects, increased hematocrit, and liver toxicity.

Enobosarm Clinical Development Program
Enobosarm is in clinical development for two indications: (i) a Phase 3 ARTEST clinical study evaluating enobosarm for the treatment of 3rd line metastatic AR+ER+HER2- breast cancer patients whose disease has progressed after treatment with a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor which is enrolling; and (ii) a Phase 3 ENABLAR-2 clinical study evaluating enobosarm + abemaciclib combination therapy as treatment of 2nd line metastatic AR+ER+HER2- breast cancer patients whose breast cancer has progressed after treatment with palbociclib and either a nonsteroidal aromatase inhibitor or fulvestrant combination. The Phase 3 ENABLAR-2 clinical trial is expected to begin enrollment in calendar Q4 2021.

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: sabizabulin, an oral, first-in-class, new chemical entity that targets the cytoskeleton which in prostate cancer also disrupts the transport of the androgen receptor. A Phase 3 VERACITY clinical trial evaluating the efficacy and safety of sabizabulin in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer is enrolling. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy to treat hormone sensitive advanced prostate cancer, is currently enrolling in a dose finding Phase 2 clinical trial, and the Phase 3 clinical trial is planned to initiate in calendar Q4 2021. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects. The enobosarm clinical program is initially focusing on 2 indications: 1) Phase 3 ARTEST clinical trial to evaluate enobosarm monotherapy in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- metastatic breast cancer (≥ 40% AR positivity) who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor which is currently enrolling; and 2) Phase 3 ENABLAR-2 study to evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor, abemaciclib, combination compared to estrogen blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer (≥ 40% AR positivity) in a 2nd line metastatic setting in approximately 186 patients who have failed 1st line treatment in a

metastatic setting with CDK 4/6 inhibitor, palbociclib, in combination with either an aromatase inhibitor or fulvestrant which is expected to commence in calendar Q4 2021. Sabizabulin will also be evaluated in a single arm Phase 2b clinical study planned to initiate in calendar Q1 2022 to evaluate oral daily dosing of sabizabulin + enobosarm in approximately 111 women with metastatic triple negative breast cancer that have become resistant to at least two systemic chemotherapies. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 clinical trial for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for acute respiratory distress syndrome in approximately 300 subjects and is currently enrolling in the United States and South America.

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 potential commercial product, if approved, expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg capsule) dosed daily for benign prostatic hyperplasia (BPH). PDUFA date for the NDA is in December 2021. The Company plans to initially launch through telemedicine and telepharmacy sales channels. To learn more about Veru products, please visit www.verupharma.com.

Forward-Looking Statements

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 whether the ARTEST study or any future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates, whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, whether sabizabulin, enobosarm, VERU-100 and TADFIN will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere, and whether the enrollment timelines for the clinical trials will be met, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including the ability of the Company to successfully launch TADFIN. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly

taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; the Company's ability to protect and enforce its intellectual property; the potential 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; 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; the concentration of accounts receivable with our largest customers and the collection of those receivables; 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; 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 from time to time 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. The Company disclaims any intent or obligation to update these forward-looking statements.

Investor Contact:
Sam Fisch 800-972-0538

Phase 3 Clinical Trial Contact:
veruclinicaltrials@verupharma.com
Domingo Rodriguez MD 800-606-9382

Source: Veru Inc.