June 7, 2021

Veru Announces Positive Phase 2 Clinical Data: Efficacy of Enobosarm Therapy Correlates with Androgen Receptor Levels in AR+ER+HER2- Metastatic Breast Cancer Presented at the 2021 ASCO Annual Meeting

-- In Phase 2 study, enobosarm, an oral selective androgen receptor (AR) agonist, had the most significant antitumor effects in heavily pretreated AR+ER+ metastatic breast cancer subjects with ≥ 40% AR expression in cancer tissue --

-- Companion diagnostic test to measure AR may be used to select AR+ER+HER2- metastatic breast cancer subjects most likely to benefit from enobosarm treatment--

-- Phase 3 ARTEST study to evaluate enobosarm treatment in subjects with ≥ 40% AR expression and estrogen blocking agent and CDK4/6 agent resistant AR+ER+HER2- metastatic breast cancer expected to commence Q3 2021 --

MIAMI, June 07, 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 additional clinical results from the Phase 2 study demonstrating that the anticancer benefits of enobosarm, a selective androgen receptor (AR) targeting agent, were related to the presence and amount of AR expression in breast cancer tissue in subjects with AR+ER+ HER2- metastatic breast cancer, will be presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting being held June 4-8, 2021.

Highlights of presentation:

In preclinical studies, AR has been established as a tumor suppressor in breast cancer. Clinically, AR is expressed in up to 90% of breast cancers and targeting AR with enobosarm, an oral selective AR agonist, would be a major new endocrine therapy for metastatic breast cancer. The positive G200802 Phase 2 clinical study in 136 heavily pretreated women with AR+ER+HER2- metastatic breast cancer who progressed following CDK4/6 inhibitor and/or estrogen blocking agent treatment confirmed that the AR is commonly expressed in breast cancer tissue (86.5-94%) and when activated by enobosarm is acting in these patients as a tumor suppressor.

In the overall Phase 2 study, the presence and the amount of AR receptor expression in breast cancer tissue correlated with a beneficial antitumor response. The best overall target lesion reduction of >30% occurred only in subjects who were AR+. In a post-hoc analysis of 84 women who had AR+ER+HER2- metastatic breast cancer, measurable disease, and centrally confirmed AR status at study entry, an AR positivity threshold of ≥ 40% in breast cancer tissue distinguished patients that responded to enobosarm in both dose arms (9 and 18 mg). AR positivity ≥ 40% was common as 52% of subjects in study met this threshold.

Focusing on the 9mg cohort, the dose selected for the Phase 3 ARTEST study, the best objective tumor response rate (complete + partial responses) was 48% for ≥ 40% AR positivity versus 0% for <40% AR positivity ($p<0.0001$). Similarly, the clinical benefit rate was 79% for ≥ 40% AR positivity versus 18% for <40% AR positivity ($p<0.0001$). The median radiographic progression free survival was 5.5 month for ≥ 40% AR positivity versus 2.75 months for <40% AR positivity ($p<0.001$). Enobosarm was very well tolerated without masculinizing side effects, increases in hematocrit, or liver toxicity.

Conclusions from Phase 2 study:

- Enobosarm, a selective AR agonist, targets AR, a tumor suppressor, in AR+ ER+ HER2- metastatic breast cancer

- Objective tumor responses (efficacy) to enobosarm monotherapy require the presence and a threshold level of AR expression (≥40% AR cutoff) in heavily pretreated AR+ ER+ HER2- metastatic breast cancer

- AR may be used as a biomarker to identify patients with AR+ ER+ HER2- metastatic breast cancer that are most likely to respond to enobosarm

- Enobosarm treatment was well tolerated as an endocrine therapy without masculinizing side effects, increases in hematocrit, or liver toxicity

- Targeting the AR tumor suppressor pathway to be studied prospectively in a 3rd line metastatic setting in the Phase 3 ARTEST registration clinical trial of enobosarm monotherapy versus active control (exemestane everolimus or a SERM) for the treatment of AR+ER+HER2- metastatic breast cancer patients who have failed a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

“There is an urgent need for new therapies for patients whose metastatic breast cancer disease progresses following treatment with ER directed endocrine therapy and CDK 4/6 inhibitor. This current exploratory analysis from the Phase 2 study of enobosarm demonstrates that the amount of AR expressed may be important in defining patients who are most likely to have an antitumor response to enobosarm, an oral selective AR agonist. Furthermore, enobosarm had positive effects on quality of life and was well tolerated. These key Phase 2 clinical findings will be tested in the Phase 3 ARTEST clinical study, which is comparing enobosarm to physician’s choice of endocrine therapy in patients progressing following a CDK4/6 inhibitor and if positive would open up a new treatment option for women with ER+AR+ metastatic breast cancer,” said Professor Carlo Palmieri, BSc, MB BS, PhD, FRCP, Professor of Translational Oncology & Medical Oncologist, University of Liverpool and lead presenter for this study.

“We have transformed our company into a late clinical stage oncology company. The enobosarm breast cancer clinical development program is growing and is led by the Phase 3 ARTEST clinical trial of enobosarm monotherapy in the 3rd line metastatic setting in subjects with AR+ER+HER2- metastatic breast cancer which is expected to begin enrolling in the third quarter of this year,” said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc. “We are also advancing enobosarm into a Phase 2 clinical study, in the 2nd line metastatic setting, to evaluate the combination of enobosarm and abemaciclib in AR+ER+HER2- metastatic breast cancer patients who progressed following treatment with palbociclib, a CDK4/6 inhibitor, in combination with an estrogen blocking agent. This is also a large market and unmet medical need. We expect the Phase 2 to commence in calendar Q3 2021.”

Enobosarm Clinical Development Program

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor, a tumor suppressor, in AR+ER+HER2- metastatic breast cancer. The enobosarm clinical development program is initially focusing on two indications: (1) Phase 3 ARTEST clinical study of enobosarm in the 3rd line metastatic setting for AR+ER+HER2- metastatic breast cancer patients (≥ 40% AR positivity) whose disease has progressed after treatment with a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor which is expected to begin enrollment calendar third quarter 2021; (2) Phase 2 clinical study of enobosarm + CDK4/6 inhibitor, abemaciclib, in the 2nd line metastatic setting for AR+ER+HER2- metastatic breast cancer patients (≥ 40% AR positivity) whose disease has progressed after treatment with a 1st line CDK 4/6 inhibitor, palbociclib, in combination with either a nonsteroidal aromatase inhibitor or fulvestrant which is expected to begin enrollment during the third quarter of calendar 2021.

About the Enobosarm Phase 2 Clinical Trial

The Phase 2 clinical study (G200802) was an international, 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 including CDK 4/6 inhibitors 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 24 weeks determined by RECIST 1.1. Secondary endpoints included objective response rate, best overall response rate, radiographic progression-free survival, and duration of clinical benefit.

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 disruptor which in prostate cancer also disrupts androgen receptor transport. 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 expected to commence in June. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, is expected to start the

planned Phase 2 clinical study later this month, and the Phase 3 clinical study is planned to initiate in calendar Q4 2021 to treat hormone sensitive metastatic prostate cancer. 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 effect 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 anticipated to commence calendar Q3 2021. 2) Phase 2 study to evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor, abemaciclib, combination compared to estrogen receptor 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 106 patients who have failed 1st line treatment with CDK 4/6 inhibitor, palbociclib, in combination with either an aromatase inhibitor or fulvestrant which is expected to commence in calendar Q3 2021. Sabizabulin is also being evaluated in a three arm Phase 2b clinical study in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy, TRODELVY® monotherapy, and sabizabulin + TRODELVY combination therapy in approximately 156 women with metastatic triple negative breast cancer that have become resistant to at least two systemic chemotherapies including a taxane. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 trial in approximately 300 subjects for the treatment of hospitalized patients with moderate to severe 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 potential commercial product, if approved, 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 filed by FDA in April 2021 with a PDUFA date in December 2021. The Company plans to 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 future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates, 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, whether and when a companion diagnostic test for AR will be developed and used successfully for enobosarm in breast cancer, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including whether and when TADFIN will be approved by the FDA and the ability of the Company to successfully launch TADFIN, if approved. 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.

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Source: Veru Inc.