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Veru Announces the Presentation of Positive Phase 2 Clinical Data of Enobosarm in AR+ER+HER2- Metastatic Breast Cancer Patients that Have Progressed on Estrogen Blocking Agents and CDK 4/6 Inhibitor at the ESMO Breast Cancer Congress 2021

MIAMI, May 05, 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 the clinical results from the Phase 2 clinical study of enobosarm, an oral 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, will be presented at the European Society for Medical Oncology (ESMO) Breast Cancer Virtual Congress 2021 to be held May 05-08, 2021.

Highlights of presentation:

The subset analysis of patients from the Phase 2 study who were heavily pretreated with estrogen blocking agents and chemotherapy with an average of 3 prior lines of therapy in the metastatic setting and had tumor progression on a CDK 4/6 inhibitor prior to receiving enobosarm.

Enobosarm treatment in evaluable patients with measurable metastatic AR+ER+ breast cancer who had progressed following treatment with an estrogen blocking agent and CDK 4/6 inhibitor (palbociclib) resulted in a clinical benefit rate at 24 weeks of 50% and a best objective tumor response of 30% including 2 complete responses and 1 partial response. The overall mean radiographic progression free survival for the 9mg dose was 10 months. The 9mg dose of enobosarm was selected for the Phase 3 ARTEST study that is anticipated to commence in June 2021.

“Despite progressing on the standard of care, patients treated with enobosarm had significant clinical responses”, said Professor Carlo Palmieri, BSc, MB BS, PhD, FRCP, Professor of Translational Oncology & Medical Oncologist, University of Liverpool and the

presenter of the results at the Congress. “Targeting the androgen receptor, a tumor suppressor in breast cancer, provides us with a potential novel endocrine therapy with an excellent safety profile.”

“Currently, CDK 4/6 inhibitors are standard treatment for metastatic ER-positive breast cancer, and unfortunately, these patients will eventually develop tumor progression. Patients who have metastatic breast cancers that progress on estrogen receptor blocking agent and CDK4/6 inhibitor therapies are a group in which we need to define the most optimal drug treatment. Although a small cohort in this Phase 2 study, the ability of these refractory patients to have significant clinical responses to enobosarm, an AR targeted treatment, is clinically meaningful and promising,” said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc. “Further, enobosarm was very well tolerated and has shown to improve the quality of life as well. We are excited about the Phase 3 registration clinical trial ARTEST evaluating patients in this clinical setting.”

About Enobosarm
Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor, tumor suppressor, in AR+ER+HER2- metastatic breast cancer. Enobosarm is in clinical development for the treatment of metastatic ER+HER2- breast cancer patients whose disease has progressed after treatment with a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The Phase 3 ARTEST clinical trial is expected to begin enrollment during the second quarter of 2021.

About Phase 2 Clinical Trial Design
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 (defined as CR+PR+SD) by RECIST 1.1. Secondary endpoints included objective response rate, best overall response rate, radiographic progression-free survival (rPFS), 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 also disrupts androgen receptor transport, is expected to commence in Q2 2021 with 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, is expected to start the planned Phase 2 clinical study in Q2 2021 and the Phase 3 clinical study is planned to initiate 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. Sabizabulin is also being evaluated for the treatment of taxane resistant metastatic triple negative breast cancer in a planned Phase 2b clinical study in approximately 200 subjects expected to begin Q3 2021. 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 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 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. 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, 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 take 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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