January 10, 2022

Veru Announces FDA Grant of Fast Track Designation for Enobosarm for the Treatment of AR+ ER+ HER2- Metastatic Breast Cancer

-- FDA Fast Track Designation is Intended to Expedite the Development and Review of New Drugs to Treat Serious Medical Conditions that Fill Unmet Medical Need --

-- Phase 3 ARTEST Registration Study of Enobosarm in Patients with AR+ ER+ HER2- Metastatic Breast Cancer Who Have Shown Previous Disease Progression on a Nonsteroidal AI, Fulvestrant, and a CDK 4/6 Inhibitor is Currently Enrolling --

MIAMI, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast and prostate cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Phase 3 registration program for the investigation of enobosarm, a selective androgen receptor targeting agonist, for the treatment of androgen receptor positive, estrogen receptor positive, human epidermal growth factor receptor 2 negative (AR+ER+HER2-) metastatic breast cancer patients who have shown previous disease progression on a nonsteroidal AI, fulvestrant, and CDK 4/6 inhibitor therapy, and who have AR% nuclei staining ≥40% in breast cancer tissue (third-line metastatic setting).

“We are very pleased that enobosarm has received Fast Track designation from the FDA, a distinction that underscores the urgent need for new, novel, targeted therapies for this important patient population suffering from this aggressive disease,” said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc. “We look forward to ongoing, productive regulatory interactions with the FDA, which are further enabled with this designation.”

About Fast Track Designation
Fast Track designation aims to expedite the development and review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to fill unmet medical needs. The purpose is to get important new drugs to patients faster. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Drugs that are granted this designation are given the opportunity for more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug

approval: more frequent written communication with FDA about such things as the design of the proposed clinical trials and use of biomarker; Eligibility for *Accelerated Approval and Priority Review, if relevant criteria are met;* and, *Rolling Review*, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

About Enobosarm
Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor in AR+ ER+ HER2- metastatic breast cancer without unwanted masculinizing side effects. Enobosarm is in clinical development for three 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 with an androgen receptor nuclei staining of ≥40% which is enrolling; (ii) a planned 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 with an androgen receptor nuclei staining of ≥40%; and (iii) a planned Phase 2 clinical study of enobosarm + sabizabulin combination therapy in metastatic triple negative breast cancer after two systemic chemotherapies.

About Breast Cancer
Breast cancer is the most commonly diagnosed cancer in women with an estimated 284,200 new cases and 44,130 deaths expected for 2021 in the U.S. It is expected that one in eight women will develop invasive breast cancer in their lifetime. Breast cancer is a heterogenous disease with diverse clinical and molecular characteristics. Estrogen is one of the main drivers of breast cancer proliferation, tumor progression, and metastasis. Consequently, treatments that target the estrogen receptor (ER) have been the mainstay of breast cancer therapy, but unfortunately almost all women will eventually develop resistance to endocrine therapies and alternative treatment approaches will be required including IV chemotherapy.

About Veru Inc.
Veru is an oncology biopharmaceutical company with a principal focus on developing novel medicines for the management of breast and prostate cancers.

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with AR ≥ 40% (third-line metastatic setting)

- Planned Q1 2022 Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (second-line

metastatic setting)

- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (third-line metastatic setting)

- Planned Q2 2022 Phase 2 study of sabizabulin + enobosarm combination therapy in metastatic triple negative breast cancer after two systemic chemotherapies.

The Company has determined that patients who have ≥ 40% androgen receptor nuclei staining by immunohistochemistry in their breast cancer tissue, a measure of AR expression, are most likely to respond to enobosarm. Consequently, Veru is developing a companion diagnostic to determine a patient's androgen receptor expression status. We have partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostics, which will develop and, if it is approved, commercialize the companion AR diagnostic.

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY and ongoing Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy

- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone-sensitive prostate cancer

- Planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer undergoing androgen deprivation therapy who suffer from hot flashes

In addition, sabizabulin, which has dual antiviral and anti-inflammatory effects, is currently enrolling in a Phase 3 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, also known as the cytokine storm.

Veru also has a commercial sexual health division, the proceeds of which help fund our drug development programs. Its two main products are:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia

- FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

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 regarding: whether and when enobosarm will be approved by FDA for the treatment of certain breast cancers and the timing of the Company's submissions to FDA and FDA's review of such submissions;

whether the Company's current or future clinical development program results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates; and whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use. 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, 2021 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 and Media Contact:
Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Source: Veru Inc.