December 8, 2021

Veru Announces Presentation of Preclinical Evidence Supporting the Therapeutic Benefit of Enobosarm Alone or in Synergistic Combination with a CDK4/6 Inhibitor Against Palbociclib Resistant Metastatic Breast Cancer at the 2021 San Antonio Breast Cancer Symposium

MIAMI, Dec. 08, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast cancer and prostate cancer, today announced that human preclinical data will be presented demonstrating that enobosarm treatment alone as well as in combination with a CDK4/6 inhibitor increased androgen receptor (AR) expression resulting in the synergistic suppression of breast cancer cell and tumor models that are resistant to CDK4/6 inhibitors and estrogen blocking agents. Enobosarm is an oral, first-in-class, selective androgen receptor targeted agonist for the androgen receptor, a tumor suppressor, being evaluated in Phase 3 clinical studies to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects. The presentation was selected as a spotlight presentation at the San Antonio Breast Cancer Symposium being held December 07-10, 2021, in San Antonio, TX.

Highlights of the presentation:

Utilizing a human PDX model (CTPx4353) that was derived from a liver metastasis in a patient that had received and progressed on fulvestrant, palbociclib and an aromatase inhibitor (resistant to both a CDK 4/6 inhibitor and estrogen blocking agents), enobosarm monotherapy significantly reduced the growth of the tumors. The combination of palbociclib and enobosarm treatment was synergistic and resulted in the almost complete inhibition of the growth of the tumors in the human PDX AR+ER+ breast cancer model (CTPx4353). Palbociclib treatment alone had no effect on tumor growth. Interestingly, both palbociclib and enobosarm each had the ability to significantly increase the expression of the androgen receptor in breast cancer cell lines and tumors.

This study provides preclinical evidence to support the synergistic therapeutic benefit of the CDK4/6 inhibitor and enobosarm combination therapy in clinically relevant models of CDK4/6 inhibitor and estrogen blocking agent resistance breast cancer.

This treatment strategy is being evaluated in the Phase 3 ENABLAR-2 clinical study of abemaciclib + enobosarm combination for the 2nd line treatment of patients with AR+ER+HER2- metastatic breast cancer that has become resistant to 1st line palbociclib and estrogen blocking agent (NCT05065411).

Presentation details:

Presentation Date/Time: Spotlight Poster Discussion 2; Wednesday, December 08, 2021, 07:00 AM -08:30 AM CT
Abstract Title: Combination CDK4/6 inhibition and AR agonism suppresses the growth of CDK4/6 inhibitor resistant breast cancers
Presenter: Allegra Freelander. Garvan Institute of Medical Research, University of New South Wales, Sydney, Australia
Presentation Number: PD2-02

“These new findings, in conjunction with the preclinical data published earlier this year (Hickey et al, Nature Medicine), demonstrate that the combination of a CDK4/6 inhibitor and the AR targeted agonist, enobosarm, activates the androgen receptor and provides therapeutic synergy,” said Professor Elgene Lim, the senior author of the presentation. “We are excited that Veru is conducting Phase 3 trials in breast cancer patients informed by our preclinical findings with the goal of providing a much-needed novel form of endocrine therapy,” said Professor Lim.

“These findings provide direct support for both our enrolling Phase 3 ARTEST clinical study evaluating enobosarm monotherapy in the 3rd line treatment of AR+ER+HER2- metastatic breast cancer patients who received CDK4/6 inhibitor, fulvestrant, and an aromatase inhibitor, and the Phase 3 ENABLAR-2 study evaluating the combination of enobosarm and the CDK4/6 inhibitor, abemaciclib, in the 2nd line metastatic setting in AR+ER+HER breast cancer patients which is expected to commence during the first quarter of calendar year 2022,” said Dr. Mitchell S. Steiner, Chairman, President and CEO of Veru Inc. “Further, the studies presented here further solidify the scientific rationale for pursuing enobosarm in patients with hormone receptor positive breast cancer. We remain extremely excited about the potential of enobosarm as both a 2nd line and a 3rd line treatment for AR+ metastatic breast cancer.”

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 is comprised of enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor, and includes: the ongoing Phase 3 ARTEST study of enobosarm in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting); the planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting); the planned Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a

CDK 4/6 inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting); and the planned Phase 2 study of sabizabulin + enobosarm combination therapy in metastatic triple negative breast cancer after two systemic chemotherapies.

The Company has identified that patients who have ≥ 40% androgen receptor nuclei staining by immunohistochemistry, which is a measure of AR expression, in their breast cancer tissue are the patients that are most likely to respond to enobosarm. Based on this observation, the Company is developing a companion diagnostic test to determine a patient's AR expression status. Consequently, the Company has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostic tests, who will develop and, if approved, commercialize the companion diagnostic AR test. The companion diagnostic test is being developed in parallel with the Phase 3 ARTEST clinical study.

The Company's late-stage prostate cancer development portfolio is comprised of sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist and includes: the ongoing Phase 3 VERACITY and Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy; the ongoing Phase 2 dose finding study of VERU-100 in advanced hormone sensitive prostate cancer; and the planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer on androgen deprivation therapy who suffer from hot flashes.

One of the Company's anticancer drugs, sabizabulin, also has dual antiviral and anti-inflammatory effects and is currently enrolling in a Phase 3 study for the potential treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS).

Veru also has a commercial Sexual Health Division which includes a drug candidate, ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia with a December 2021 PDUFA date, and a commercial product, the FC2 Female Condom® (Internal Condom), an FDA-approved product 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 whether the Company's current and planned clinical trials in its breast cancer program, including the ARTEST and ENABLAR-2 studies of enobosarm, and its prostate cancer programs or any future clinical development and their respective 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; whether sabizabulin, enobosarm, VERU-100, zuclomiphene citrate or ENTADFI will serve any unmet need; and whether and when ENTADFI will be approved by the FDA an. 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.

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Source: Veru Inc.