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Veru Enters into Clinical Trial Collaboration and Supply Agreement with Eli Lilly and Company to Evaluate Enobosarm in Combination with Verzenio® in Phase 3 ENABLAR-2 Trial

-- Phase 3 ENABLAR-2 Clinical Trial for 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer Expected to Commence During First Quarter of 2022 --

MIAMI, Feb. 01, 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 it has entered into a clinical trial collaboration and supply agreement with Eli Lilly and Company. The objective of the collaboration is to evaluate the efficacy and safety of enobosarm, Veru's oral, first-in-class, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor (AR), a tumor suppressor, in combination with Lilly's Verzenio® (abemaciclib), a CDK4/6 inhibitor, as a second line therapy in the treatment of AR+ER+HER2- metastatic breast cancer.

"Independently conducted proof of concept preclinical studies in human breast cancer models have demonstrated that the combination of enobosarm with a CDK4/6 inhibitor had greater antitumor synergistic activity in tumor samples from patients who had breast cancer progression following treatment with palbociclib, a CDK4/6 inhibitor, and an estrogen blocking agent. The ENABLAR-2 trial will evaluate the efficacy and safety of the enobosarm and abemaciclib combination in patients that have previously received first line therapy of palbociclib and estrogen blocking agent combination in AR+ER+HER2- metastatic breast cancer," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. "We are excited about potentially being an oral 2nd line therapeutic option in combination with abemaciclib for patients who have AR+ER+HER2- metastatic breast cancer. We are looking forward to our collaboration with Lilly on the ENABLAR-2 clinical trial."

Under the terms of the non-exclusive clinical trial collaboration and supply agreement, Veru is responsible for conducting the clinical trial while Lilly will supply Verzenio for the study. Veru maintains full exclusive, global rights to enobosarm.

Phase 3 ENABLAR-2 Trial Design
The Phase 3 ENABLAR-2 clinical trial is an open-label, multicenter, randomized, active control pivotal study evaluating the efficacy and safety of enobosarm 9mg oral daily dosing in combination with Verzenio®, a CDK4/6 inhibitor, versus active control (alternative estrogen blocking agent) in the 2nd line treatment of 186 metastatic AR+ ER+ HER2- breast cancer patients who had previously received an estrogen blocking agent in combination with palbociclib. Enobosarm is being targeted to patients who have androgen receptor staining levels ≥ 40% in their breast cancer tissue samples. The primary efficacy endpoint is median radiographic progression free survival. Secondary endpoints include overall response rate (CR+PR), change in short physical performance battery (SPPB), and change in DEXA-body composition muscle and bone. The Phase 3 ENABLAR-2 study will be conducted in approximately 35 clinical sites across the United States.

About Enobosarm
Enobosarm is an oral, first-in-class, new chemical entity that is a member of a new class of endocrine drugs called selective androgen receptor targeting agonists, which means it is both an agonist and an antagonist depending on the tissue type. Enobosarm binds to the AR in breast tissue and inhibits AR+ ER+ breast cancer cell proliferation and tumor growth in animal models. Unlike testosterone, enobosarm cannot be aromatized to estrogen. Enobosarm has selective clinical properties that could have potential benefit in women with AR+ ER+ HER2- breast cancer. Preclinical studies have shown that enobosarm builds and heals cortical and trabecular bone with the potential to treat osteoporosis and skeletal related cancer events. Enobosarm has been shown to build muscle and improve physical function as well as reduce fat in clinical studies involving elderly subjects and patients with cancer cachexia including breast cancer. Furthermore, clinical studies have shown that the tissue selectivity of enobosarm results in a favorable side effect profile with no masculinizing adverse effects (facial hair and acne), no increase in hematocrit and thrombosis, and no liver toxicity. Enobosarm has extensive nonclinical and clinical experience, having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced AR+ ER+ HER2- metastatic breast cancer involving more than 250 patients.

In the two Phase 2 clinical studies conducted in women with AR+ ER+ HER2- metastatic breast cancer, enobosarm demonstrated clinically significant objective tumor responses, improvement in quality of life, and favorable safety profile in a heavily pretreated population of women with AR+ER-HER2- metastatic breast cancer. Higher % AR nuclei staining in breast cancer tissue correlated with a greater antitumor activity. By targeting and activating AR in breast cancer tumors with sufficient AR expression (≥40% AR nuclei staining), women with metastatic breast cancer may be identified who are most likely to respond to enobosarm therapy. Consequently, Veru is developing a companion diagnostic to determine a patient's androgen receptor expression status, and has 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.

Overall, these studies of enobosarm clearly establish the clinical relevance of targeting the AR with a selective AR agonist. Enobosarm introduces a novel endocrine therapy to patients with breast cancer that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy.

About Verzenio® (abemaciclib)
Verzenio® abemaciclib is a targeted treatment known as a CDK4/6 inhibitor. Verzenio is a non-chemotherapy oral tablet. Verzenio works inside the cell to block CDK4/6 activity and help stop the growth of cancer cells, so they may eventually die (based on preclinical studies). Cyclin-dependent kinases (CDK)4/6 are activated by binding to D-cyclins. In estrogen receptor-positive (ER+) breast cancer cell lines, cyclin D1 and CDK4/6 promote phosphorylation of the retinoblastoma protein (Rb), cell cycle progression, and cell proliferation. In vitro, continuous exposure to Verzenio inhibited Rb phosphorylation and blocked progression from G1 to S phase of the cell cycle, resulting in senescence and apoptosis (cell death). Preclinically, Verzenio dosed daily without interruption resulted in reduction of tumor size. Inhibiting CDK4/6 in healthy cells can result in side effects, some of which may be serious. Clinical evidence also suggests that Verzenio crosses the blood-brain barrier. In patients with advanced cancer, including breast cancer, concentrations of Verzenio and its active metabolites (M2 and M20) in cerebrospinal fluid are comparable to unbound plasma concentrations. Verzenio is Lilly's first solid oral dosage form to be made using a faster, more efficient process known as continuous manufacturing. Continuous manufacturing is a new and advanced type of manufacturing within the pharmaceutical industry, and Lilly is one of the first companies to use this technology.

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), and which has been granted Fast Track designation by the FDA.

- 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). The Company has entered into a clinical trial collaboration and supply agreement with Lilly regarding Lilly’s supply of Verzenio (abemaciclib) in connection with the ENABLAR-2 trial.

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

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, and has 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, and which has been granted Fast Track designation by the FDA.

Veru also has a commercial sexual health division, the proceeds of which help fund its drug development programs, comprised of:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, for which commercialization launch plans are underway.

- 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: the expected commencement timing of the Phase 3 ENABLAR-2 study; whether enobosarm in combination with abemaciclib will demonstrate sufficient safety and efficacy to ever be approved by the FDA or any other regulatory as an oral 2nd line therapeutic option for patients who have AR+ER+HER2- metastatic breast cancer; whether and when enobosarm will be approved by FDA for the treatment of any other breast cancers and the timing of the Company's submissions to FDA and FDA's review of such submissions; whether any of the selective clinical properties previously observed in clinical studies of enobosarm will be replicated in the current and planned clinical development program for enobosarm and whether any such properties will be recognized by the FDA in any potential approvals and labeling; 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 and companion diagnostic, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, whether any accelerated regulatory pathways, including Fast Track designation, to secure FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are available, when clinical results from the ongoing sabizabulin COVID-19 Phase 3 trial will be available, whether sabizabulin, enobosarm,

VERU-100, zuclomiphene, and ENTADFI will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere, and whether the commencement or enrollment timelines for the clinical trials and development of the companion diagnostic 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 ENTADFI, 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 any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm or other drug candidates will be replicated in the current and planned clinical development program for such drug candidate and whether any such properties will be recognized by the FDA in any potential approvals and labeling; when commercial launch of ENTADFI will occur; the magnitude of any potential revenues generated by ENTADFI; 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; including the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S.; 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.

Verzenio® is a trademark owned by or licensed to Eli Lilly and Company, its subsidiaries, or affiliates.

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