February 17, 2022

Veru Announces the Presentation of Updated Data from the Phase 1b/2 Sabizabulin Study in Men with Metastatic Castration Resistant Prostate Cancer at the 2022 ASCO Genitourinary Cancers Symposium

MIAMI, Feb. 17, 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 updated clinical data from the positive Phase 1b/2 study of sabizabulin in 80 men with metastatic castration resistant prostate cancer who have progressed on at least one novel androgen receptor targeting agent will be presented at the 2022 ASCO Genitourinary Cancers Symposium being held February 17-19, 2022 in San Francisco, CA. Sabizabulin is an oral new chemical entity that represents a novel class of agents that target unique binding sites on microtubules to disrupt the cytoskeleton.

Highlights of the Presentation:
In this updated analysis of all 80 patients in the Phase 1b/2 clinical study, sabizabulin treatment demonstrated both cytotoxic and cytostatic antitumor activity. Evidence of antitumor activity was observed with PSA reductions and objective and durable tumor responses. For patients with measurable disease at baseline (n=29), the overall response rate was 20.7%. The best clinical response (stable disease or objective tumor response) in patients with measurable disease at study entry was 59% (17/29). At the time of data cut off for this presentation, 5 of the responders remain on study with the longest approaching 3 years on sabizabulin. Chronic daily dosing with sabizabulin was feasible and well tolerated with no clinically relevant neutropenia or neurotoxicity. This Phase1b/2 clinical study supports the efficacy and safety assumptions for the ongoing Phase 3 VERACITY clinical study evaluating sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy.

Presentation details:
Presentation Date/Time: February 17, 2022
Abstract Title: Sabizabulin has both cytotoxic and cytostatic activity in Phase 1b/2 clinical trials of men with metastatic castration-resistant prostate cancer who progressed on androgen receptor-targeting agents.

Presenter: Mark C. Markowski MD, PhD, Assistant Professor, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University
Abstract Number: 110

Additional information on the meeting can be found on the ASCO Genitourinary Cancers Symposium website: https://conferences.asco.org/gu/attend

“There have been significant advances in the treatment of metastatic castration resistant prostate cancer with the use of the latest generation of novel agents that target the androgen receptor axis. Despite this, almost all patients will have tumor progression on these agents. An oral, well tolerated drug that can be utilized prior to patients moving on to intravenous chemotherapy is needed,” said Mark Markowski, MD, PhD who is presenting the study. “Based upon these Phase 1b/2 data and assuming that the Phase 3 study continues to support these findings, sabizabulin appears to have the appropriate efficacy and safety to fill this unmet medical need.”

“In this further analysis, we are excited that sabizabulin continues to demonstrate long-term efficacy in patients from our Phase 1b/2 study. This may be attributed to its cytotoxic and cytostatic effects with chronic oral administration of the sabizabulin which appears to translate to long-term clinical responses,” said Mitchell S. Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc. “We are excited about the ongoing Phase 3 VERACITY study and moving sabizabulin closer to potentially providing a novel oral therapy prior to IV chemotherapy.”

In addition to the presentation on the additional analysis from the Phase 1b/2 study, a trials in progress presentation will be given on the Phase 3 VERACITY study that is currently underway.

Presentation details:
Presentation Date/Time: February 17, 2022
Abstract Title: Phase 3 VERACITY clinical study of sabizabulin in men with metastatic castrate resistant prostate cancer who have progressed on an androgen receptor targeting agent.
Presenter: Robert Dreicer MD, University of Virginia Cancer Center
Abstract Number: TPS217

About VERACITY Phase 3 Clinical Trial
Sabizabulin is a novel oral new chemical entity that targets unique binding sites in microtubules to disrupt both the cytoskeleton. In June 2021, the Company initiated the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical trial evaluating sabizabulin 32 mg versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent. The 32 mg dose formulation being studied in the VERACITY study has similar bioavailability to the 63 mg dose formulation used in the Phase 1b/2 study. The primary endpoint is median radiographic progression free survival. The Phase 3 VERACITY clinical trial is anticipated to enroll approximately 245 patients from 45 clinical centers.

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% expression (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) combination in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% expression (second-line metastatic setting). The Company has entered into a clinical study collaboration and supply agreement with Lilly regarding Lilly's supply of Verzenio® (abemaciclib) for the ENABLAR-2 study.

- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% expression (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 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 COVID-19 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, and which has been granted Fast Track designation by the FDA.

Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, 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 whether current and 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; whether the drug candidates will be approved for the targeted line of therapy, including sabizabulin in metastatic castration resistant prostate cancer; the anticipated design and scope for clinical studies and FDA acceptance of such design and scope, whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met, including the Phase 3 VERU-100 clinical study and the sabizabulin clinical study for the treatment of hospitalized Covid-19 patients at high risk of ARDS; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the US or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; 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 studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies 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

studies, 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; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; 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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