June 25, 2021

Veru Enrolls First Patient in Phase 3 VERACITY Clinical Trial of Sabizabulin (VERU-111) in Metastatic Castration Resistant and Androgen Receptor Targeting Agent Resistant Prostate Cancer

--Sabizabulin is a novel oral androgen receptor transport disruptor--

-- In Phase 1b/2 clinical study, sabizabulin was well tolerated with significant antitumor efficacy in metastatic castration resistant prostate cancer patients who have also become resistant to abiraterone or enzalutamide, but prior to IV chemotherapy--

--Phase 3 clinical study will be conducted in 45 clinical centers across the United States--

MIAMI, June 25, 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 it has enrolled the first patient in its Phase 3 VERACITY clinical trial of sabizabulin, an oral, first-in-class, new chemical entity, androgen receptor transport disruptor (targets and inhibits microtubules to disrupt androgen receptor transport into the nucleus), for metastatic castration and androgen receptor targeting agent resistant prostate cancer.

The Phase 3 VERACITY clinical trial is an open label, randomized (2:1), multicenter registration study to evaluate the efficacy and safety of sabizabulin 32mg oral daily dosing versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have progressed on at least one androgen receptor targeting agent. The primary endpoint is median radiographic progression free survival and key secondary endpoints are overall response rate, duration of objective response, overall survival, time to chemotherapy, and pain progression. The study is expected to enroll 245 patients and will be conducted in over 45 clinical sites across the United States.

“Unfortunately, advanced prostate cancer patients receiving androgen receptor targeting agents in combination with standard ADT will eventually have tumor progression. There is a significant need for new therapies with novel mechanisms of action. Sabizabulin is a novel,

oral agent with provocative levels of activity and safety in early studies and we are now prospectively evaluating this agent in a Phase 3 study," said Robert Dreicer, M.D., Deputy Director, UVA Cancer Center, Director of Solid Tumor Oncology, Professor, Medicine: Hematology and Oncology and lead principal investigator for the VERACITY study.

"We are excited to begin enrolling patients in our open label Phase 3 VERACITY clinical trial," said Mitchell Steiner, MD, Chairman, President and CEO of Veru Inc. "As we have previously reported, in the Phase 1b/2 clinical trial sabizabulin had significant evidence of tumor efficacy including PSA declines and responses as well as objective and durable tumor responses. Furthermore, sabizabulin was well tolerated without neutropenia. In fact, the safety profile of sabizabulin appears to be similar to what is reported in the package inserts for an androgen receptor targeting agent such as enzalutamide or abiraterone. If the Phase 3 is successful, sabizabulin could be the next 'go to drug' in the largest and growing unmet medical need in men who have metastatic castration resistant prostate cancer and who have developed progression of prostate cancer while being treated with an androgen receptor targeting agent, but prior to using IV chemotherapy."

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 in prostate cancer also disrupts the transport of the androgen receptor. A Phase 3 VERACITY clinical trial evaluating the efficacy and safety of sabizabulin in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer is enrolling. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, is currently enrolling, and the Phase 3 clinical study is planned to initiate in calendar 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 the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects. The enobosarm clinical program is initially focusing on 2 indications: 1) Phase 3 ARTEST clinical trial to evaluate enobosarm monotherapy in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- metastatic breast cancer (≥ 40% AR positivity) who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor which is anticipated to commence calendar Q3 2021; 2) Phase 2 study to evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor, abemaciclib, combination compared to estrogen blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer (≥ 40% AR positivity) in a 2nd line metastatic setting in approximately 106 patients who have failed 1st line treatment in a metastatic setting with CDK 4/6 inhibitor, palbociclib, in combination with either an aromatase inhibitor or fulvestrant which is expected to commence in calendar Q3 2021. Sabizabulin will also be evaluated in a three arm Phase 2b clinical study planned to initiate in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy, TRODELVY® monotherapy, and sabizabulin + TRODELVY combination therapy in approximately 156 women with metastatic triple negative breast cancer that have become resistant to at least two systemic chemotherapies including a taxane. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 clinical trial for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for acute

respiratory distress syndrome in approximately 300 subjects and is currently enrolling.

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 commercial product, if approved, expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule dosed daily for benign prostatic hyperplasia (BPH). An NDA was filed by FDA in April 2021 with a PDUFA date in December 2021. The Company plans to launch through telemedicine and telepharmacy sales channels. To learn more about Veru products, please visit www.verupharma.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995: *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 potential of sabizabulin to treat metastatic castration and androgen receptor targeting agent resistant prostate cancer, taxane resistant metastatic triple negative breast cancer and COVID-19 and prevent deaths in patients with moderate to severe COVID-19 disease who are at risk for ARDS; the potential for enobosarm to treat AR+ER+HER2- metastatic breast cancer; the potential for VERU-100 as an androgen deprivation therapy for advanced prostate cancer; the potential for TADFIN to treat BPH; whether the VERACITY study or any other current or 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 of the Company's clinical trials and FDA acceptance of such design and scope; whether sabizabulin, enobosarm, VERU-100 or TADFIN will serve any unmet need and the potential size of any patient population; what dosage, if any, might be approved for use in the US or elsewhere; whether the enrollment timelines for the Company's clinical trials will be met; and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including whether and when TADFIN might be approved by the FDA and the ability of the Company to successfully launch TADFIN, if approved.*

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, 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.

Investor Contact:
Sam Fisch 800-972-0538

Phase 3 Clinical Trial Contact:
veruclinicaltrials@verupharma.com
Domingo Rodriguez MD 800-445-6348

Source: Veru Inc.