June 7, 2021

Veru Announces Positive Phase 1b/2 Clinical Study Update for Sabizabulin (VERU-111) in Men with Metastatic Castration Resistant Prostate Cancer Presented at the 2021 ASCO Annual Meeting

-- Sabizabulin, an oral selective cytoskeleton disruptor, demonstrated good safety, significant evidence of antitumor efficacy, and that chronic administration is feasible in ongoing Phase 1b/2 study of 80 men --

-- Phase 3 VERACITY study to evaluate sabizabulin treatment in men who have metastatic castration prostate cancer and have also progressed following at least one androgen receptor targeting agent planned to start this month --

MIAMI, June 07, 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 the presentation of the Phase 1b/2 clinical trial update of sabizabulin (VERU-111), an oral cytoskeleton disruptor which in prostate cancer also disrupts androgen receptor transport, to treat men with metastatic castration resistant prostate cancer who failed at least one androgen receptor targeting agent, at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting being held June 4-8, 2021.

The Phase 1b/2 clinical study was designed as a dynamic study with an initial 3+3 standard safety study component followed by an expanded study with increases in dose and schedule. The Phase 1b/2 clinical trial enrolled 80 men and is ongoing with patients in both the Phase 1b and 2 components still on study.

Highlights of the study presentation are as follows:

- Sabizabulin oral daily dosing was well tolerated, and the most common adverse events, being mostly Grade 1 and 2, were diarrhea, fatigue, nausea, and decrease in appetite. There was no evidence of clinically relevant neutropenia or neurotoxicity. Safety profile was similar to that reported in package inserts for androgen receptor targeting agents, abiraterone and enzalutamide.

- Clinically meaningful and durable evidence of objective tumor responses were observed in patients on 63mg oral daily dosing schedule:

    - In the ITT population with measurable disease (n=29), the ORR (5 partial responses + 1 complete response) was 20.7%.

    - In the Phase 1b study, ITT population of men that received at least 1 dose of 63mg daily dosing schedule (n=14), the median progression free survival was 10.8 months (2.3-26+ months). Two of these patients on continuous daily dosing of sabizabulin have now reached 27 months and 23 months of treatment without prostate cancer progression.

    - In the Phase 1b/2 study of men that received at least 1 dose of 63mg daily dosing schedule (n=55), the study is still ongoing, the median progression free survival has not been reached as 10 men were still on study at the time of data cut off. The estimated radiographic progression free survival is greater than 7.4 months.

“Our clinical experience with sabizabulin has demonstrated an excellent safety profile along with significant antitumor activity,” said Dr. Mark C. Markowski, M.D., Ph.D., Assistant Professor of Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center the Principal Investigator of this Phase 1b/2 study. “A daily oral agent for men that have had disease progression on an androgen receptor targeting agent but prior to their advancing onto an intravenous chemotherapy would be a major clinical advance.”

“Based on these exciting clinical results, we have reached agreement with FDA on the design of the Phase 3 VERACITY registration trial to evaluate the efficacy and safety of sabizabulin in men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent which is expected to initiate in June 2021,” said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc. “Given that sabizabulin’s safety profile appears similar to what is reported in the package inserts for abiraterone and enzalutamide, sabizabulin oral daily dosing may potentially be prescribed by both urologists and medical oncologists to men with metastatic castration and androgen targeting agent resistant prostate cancer prior to IV chemotherapy. This is a large and growing unmet medical need indication for the treatment of refractory prostate cancer.”

Sabizabulin (VERU-111) Clinical Development Program
Sabizabulin is a novel, oral, new chemical entity that targets microtubules in the cytoskeleton to disrupt androgen receptor transport into the nucleus. Sabizabulin is in clinical development for: (1) Phase 3 VERACITY study for the treatment of men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent but prior to receiving chemotherapy. The open-label, randomized (2:1), multicenter Phase 3 study is expected to begin enrollment this month to evaluate sabizabulin 32mg versus the alternative androgen receptor targeting agent. Based on the recently conducted PK study from the Phase 2 clinical trial, the blood levels of the Phase 3 clinical trial sabizabulin 32mg drug dose formulation were similar to the Phase 1b/2 63mg dosage formulation. The Phase 3 VERACITY clinical trial is expected to enroll approximately 245 patients. (2) Phase 2 clinical study for the treatment of women with metastatic triple negative breast cancer who have become resistant to at least two systemic chemotherapies. The

Phase 2b clinical study will evaluate daily oral dosing of sabizabulin monotherapy, TRODELVY® monotherapy, and sabizabulin + TRODELVY® combination therapy in approximately 156 women. The Phase 2b clinical study is expected to commence in the third quarter of calendar 2021. (3) Phase 3 clinical trial for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for ARDS. Sabizabulin 9mg is being evaluated as a monotherapy versus placebo. The Phase 3 clinical study is actively enrolling patients.

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 androgen receptor transport. 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 expected to commence in June. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, is expected to start the planned Phase 2 clinical study later this month, and the Phase 3 clinical study is planned to initiate in calendar Q4 2021 to treat hormone sensitive metastatic 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 effect 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 receptor 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 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 is also being evaluated in a three arm Phase 2b clinical study 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 trial in approximately 300 subjects for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for acute respiratory distress syndrome.

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 for the administration of tadalafil 5mg and finasteride 5mg combination formulation 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.

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 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 for clinical trials and FDA acceptance of such design and scope, whether sabizabulin, enobosarm, VERU-100 and TADFIN will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere, and whether the enrollment timelines for the 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.

Contact:
Sam Fisch 800-972-0538
Director of Investor Relations

Source: Veru Inc.