May 24, 2021

Veru Announces Acceptance of Two Abstracts for Presentation at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting

-- Presentation of Phase 2 trial clinical trial data from patients with AR+ER+HER2- metastatic breast cancer demonstrating that the antitumor efficacy of enobosarm, a selective androgen receptor targeting agent, treatment is dependent on the magnitude of expression of androgen receptor (AR) in breast cancer tissue --

-- Presentation of Phase 1b/2 updated clinical trial results of sabizabulin (VERU-111), an oral androgen receptor transport disruptor, in metastatic castration and androgen receptor targeting agent resistant prostate cancer --

MIAMI, May 24, 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 two abstracts were accepted for presentation at the 2021 American Society of Clinical Oncology Annual Meeting which will be held virtually from June 4-8, 2021.

Poster Discussion Session – Breast Cancer (Metastatic)
Abstract #1020: Efficacy of enobosarm, a selective androgen receptor (AR) targeting agent, correlates with degree of AR positivity in advanced AR+/estrogen receptor (ER)+ breast cancer in an international Phase 2 clinical study
Presenter: Carlo Palmieri, BSc, MB BS, PhD, FRCP, Professor of Translational Oncology & Medical Oncologist, University of Liverpool

Poster Presentation - Genitourinary Cancer—Prostate, Testicular, and Penile
Abstract #5056: Sabizabulin (VERU-111), an oral cytoskeleton disruptor, to treat men with metastatic castration resistant prostate cancer (mCRPC) who failed an androgen receptor targeting agent
Presenter: Dr. Mark C. Markowski, Assistant Professor of Oncology, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University School of Medicine

Additional information on the meeting can be found on the ASCO website https://conferences.asco.org/

“These exciting clinical results have allowed us to advance two novel agents, enobosarm and sabizabulin into Phase 3 registration trials. The Phase 3 ARTEST clinical trial of

enobosarm monotherapy in the 3rd line metastatic setting in subjects with AR+ER+ metastatic breast cancer is expected to begin enrolling in June 2021 and the Phase 3 VERACITY trial for sabizabulin in men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent is expected to initiate in early June 2021," said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc. "We are a step closer to potentially bringing these important drugs to large and growing unmet medical need indications in treatment of refractory breast and prostate cancers."

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 early 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 and activates the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects; Phase 3 ARTEST clinical trial to evaluate enobosarm in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- advanced breast cancer who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor is anticipated to commence Q2 2021. In a separate clinical development program, a Phase 2 study to evaluate the efficacy and safety of enobosarm in combination with CDK 4/6 inhibitor (abemaciclib) compared to estrogen receptor blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer in a 2nd line metastatic setting in approximately 106 patients who have failed an estrogen receptor blocking agent plus a CDK 4/6 inhibitor (palbociclib) 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 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 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. 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, whether and when a companion diagnostic test for AR will be developed and used successfully for enobosarm in breast cancer, 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 TADFIN. 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.

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Source: Veru Inc.