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Veru Enrolls First Patient in Phase 2 Clinical Trial of VERU-100, Novel Long-acting GnRH Antagonist Decapeptide Injection Formulation, for the Treatment of Hormone Sensitive Advanced Prostate Cancer

--VERU-100 formulated to address the clinical limitations of currently available androgen deprivation therapy--

--The Phase 2 clinical trial is expected to be completed by 2H calendar 2021--

MIAMI, June 10, 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 2 clinical trial of VERU-100, a novel, proprietary gonadotropin-releasing hormone (GnRH) antagonist decapeptide, three-month subcutaneous depot injection formulation, for the treatment of hormone sensitive advanced prostate cancer.

Androgen deprivation therapy, also known as ADT, is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease. Furthermore, ADT is continued even as other endocrine, chemotherapy, or radiation treatments are added or stopped. The ADT market is well-established for advanced prostate cancer and is estimated to be approximately $2.8 billion worldwide. Standard medical practice for urologists and medical oncologists is to administer ADT every 3-4 months which coincides with follow-up office medical visits and ensures maximum compliance with ADT for patients with advanced prostate cancer.

Androgen deprivation therapy using a GnRH antagonist is preferred because castration occurs rapidly within a week with no surges or flares in testosterone levels. Testosterone also tends to reach lower levels which may improve tumor control. GnRH antagonist ADT also lowers FSH levels which is thought to be the reason why, in published studies, there are fewer cardiovascular side effects with GnRH antagonists versus GnRH agonists (LUPRON and ELIGARD). Unfortunately, there are no GnRH antagonist depot injection formulations for ADT approved by FDA for treatment beyond a one-month duration. VERU-100 is a novel, proprietary long-acting peptide, 3-month subcutaneous depot formulation injection that does

not require a loading dose designed to address these current limitations of commercially available androgen deprivation therapies.

VERU-100 Phase 2 Trial Design

The Phase 2 clinical trial is an open label, multicenter, dose finding study evaluating the efficacy and safety of subcutaneous injected doses of VERU-100 in 35 men with hormone sensitive advanced prostate cancer. The primary efficacy endpoint is percent of men that reach castrate levels of total testosterone (<50 ng/dL) by Day 28 and maintain castrate testosterone levels beyond 90 days. The secondary endpoint is the percent of men that reach <20 ng/dL of total testosterone levels by Day 28 that are maintained at <20 ng/dL through Day 91.

“I am excited about the clinical development of VERU-100. While GnRH antagonists are the preferred approach, a long-acting injectable alternative does not exist. VERU-100 would fill an unmet clinical need and provide an opportunity for the urologist to maintain the continuity of care with our patients and maximize drug compliance for their cancer treatment,” said Ronald Tutrone, MD, FACS, CPI, Chair, William H. Kalhert Endowment for Urological Research and Medical Director, Chesapeake Urology Research Associates.

“If successful and approved, VERU-100 could address an unmet medical need by providing a long-acting GnRH antagonist formulation as a low volume injection treatment option with immediate castration, drug compliance, and potentially less concerns for cardiovascular safety events without disrupting current standard of medical care. We expect the Phase 2 clinical results to be available in the second half of this calendar year. Further, we have already reached FDA agreement on the Phase 3 registration trial design. It will be an open label multicenter study to evaluate the efficacy and safety of VERU-100 in approximately 100 men with hormone sensitive advanced prostate cancer and is anticipated to start towards the end of calendar year 2021,” said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc.

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 anticipated to start in early calendar Q3 2021. 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.

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 potential for VERU-100 as an androgen deprivation therapy for advanced prostate cancer; what share of the worldwide ADT market in advanced prostate cancer VERU-100, if successful and approved, might achieve; whether VERU-100 will fill an unmet need in prostate cancer treatment or will be safe; when the Phase 2 data will be available and when the planned Phase 3 study for VERU-100 will commence; 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 TADFIN to treat BPH; whether the VERU-100 studies, the VERACITY study or any other current or future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to warrant further development or 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.

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