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Veru Announces ESMO Congress 2020 Oral Presentation of Positive Clinical Results from its VERU-111 Phase 1b Study in Metastatic Prostate Cancer

—Advancing VERU-111 to a Pivotal Phase 3 Clinical Program—

MIAMI, Sept. 18, 2020 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer, today announced that positive clinical results from its Phase 1b study of VERU-111 were orally presented at the European Society for Medical Oncology (ESMO) Congress 2020.

The results of the Phase 1b study evaluating VERU-111, a novel oral microtubule targeting agent that selectively inhibits alpha and beta tubulin, in 39 men with metastatic castration resistant prostate cancer that have also failed at least one androgen receptor targeting agent (enzalutamide or abiraterone) and a large and growing unmet medical need in advanced prostate cancer, have been presented as an oral presentation by Mark Markowski, MD, Assistant Professor of Oncology from the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. The oral presentation is entitled “Phase 1b/2 study of VERU-111, novel, oral tubulin inhibitor, in men with metastatic castration resistant prostate cancer (mCRPC) who failed an androgen blocking agent.″

The highlights of the study were as follows:

- Phase 1b portion of the study enrolled 39 men in 7 clinical sites in the United States and used a two-part dosing schedule with a standard 3+3 dose escalation strategy followed by an expanded dose and dose schedule of VERU-111 daily continuous dosing until disease progression or toxicity.
- Patient demographics: 44% failed both abiraterone and enzalutamide; 55% had bone only metastatic disease.
- The Maximum Tolerated Dose (MTD) of VERU-111 was 72mg (3 /11 men had Grade 3 diarrhea). No Grade 3 diarrhea was observed at doses <72 mg per day. At doses < 72mg/d, the most common adverse events (AEs) were mild to moderate nausea, vomiting, diarrhea, and fatigue, with no observed neurotoxicity or neutropenia.
- Antitumor activity was assessed by PSA as well as bone and CT scans in 10 men that were treated for ≥ 4 continuous 21-day cycles which represents 33% of all men enrolled in the Phase 1b who were chemotherapy naive.

    - 6/10 had PSA declines: 4/10 had ≥ 30% and 2/10 ≥ 50% declines compared to their 21-day cycle baseline.
    - Based on PCWG3/RECIST 1.1 criteria, objective tumor responses were seen in 2/10 (soft tissue and bone) and 7/10 (70%) had stable disease.
    - Median duration of treatment without radiographic progression was greater than 11+ months (range 6-17+ months) as 5/10 men are still on study.
- Median duration of treatment without progression in all men who received any 63mg oral dosing was 9.8+ (range 2-15.4+ months).
- For point of reference from the scientific literature, in similar men with mCRPC who have failed at least one androgen receptor targeted agent, the median radiographic progression free survival was 3.6 months on an alternative androgen receptor targeting agent and for men with mCRPC who failed both abiraterone or enzalutamide the radiographic progression free survival was 2.6 months.
- Phase 2 clinical study has almost completed enrollment of 40 men with mCRPC who have failed at least one androgen blocking agent.
- In conclusion, the recommended Phase 2 dose is 63mg oral daily continuous dosing for 21-day cycles and daily chronic drug administration is feasible and safe in the Phase 1b study. At the recommended Phase 2 dose, there were no reports of neutropenia, neurotoxicity, or Grade 3 diarrhea.

Based on these promising clinical data, VERU met with FDA on the Phase 3 clinical trial design in July 2020. The plan is to submit a final Phase 3 clinical protocol to evaluate VERU-111 in men with mCRPC and who have also failed one androgen receptor targeting agent in the 4th calendar Quarter 2020 and initiate a Phase 3 study in the 1st calendar Quarter 2021.

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer. The Veru prostate cancer pipeline includes VERU-111, VERU-100, and Zuclomiphene citrate. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules. VERU-111 is being evaluated in an open label Phase 1b/2 clinical study in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 2 clinical study will enroll 40 men who have metastatic castration resistant prostate cancer and who have also become resistant to at least one novel androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to IV chemotherapy. VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19. VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration — a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. An IND is expected to be submitted for the Phase 2 study to evaluate VERU-100 dosing in the fourth quarter of calendar year 2020 and a Phase 2 clinical trial is anticipated to commence Q1 2021. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect

caused by ADT in men with advanced prostate cancer. Following an End of Phase 2 meeting with the FDA, the Company plans to advance Zuclomiphene Citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN®) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is the fourth quarter of calendar year 2020 or early 2021. Veru is also developing Tamsulosin XR capsules which is a formulation of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the "food effect" inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance.

The Company's commercial products include the FC2 Female Condom / FC2 Internal Condom® ("FC2"), an FDA-approved product for the dual protection against unwanted pregnancy and the transmission of sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. 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. PREBOOST® is marketed through online sales in the U.S. under the Roman Swipes brand name by Roman, the digital men's health clinic. Roman offers online treatment for a variety of men's health conditions. 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 regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, and clinical study results including potential benefits and the absence of adverse events. Any forward-looking statements in this release are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and

unknown risks, uncertainties and assumptions. If any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company's products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; product demand and market acceptance; competition in the Company's markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; the risk that the Company's products, demand for products, manufacturing and/or development will be affected by regulatory developments, including a reclassification of products; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; the risk 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; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; 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; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; 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; risks related to the 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 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, 2019 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.

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Source: Veru Inc.