Veru Announces Successful Completion of Pre-NDA Meeting with FDA for TADFIN (Tadalafil 5mg and Finasteride 5mg) Combination for the Treatment of Benign Prostatic Hyperplasia

–Reached Agreement with FDA on Regulatory Package for NDA Submission Utilizing the 505(b)(2) Expedited Regulatory Pathway— — TADFIN is a First Novel Combination Formulation of Tadalafil and Finasteride for the Treatment of BPH with NDA Submission Anticipated in Summer of 2020–

MIAMI, June 26, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and prostate cancer supportive care, today announced that the Company concluded its pre-New Drug Application ("NDA") meetings with the U.S. Food and Drug Administration ("FDA") for TADFIN® (tadalafil 5mg and finasteride 5mg combination) formulation for the treatment of benign prostatic hyperplasia (BPH). The purpose of the meeting was to discuss the proposed NDA and to confirm the clinical, non-clinical, and chemistry, manufacturing and controls (CMC) requirements for the Company's NDA submission utilizing the FDA expedited 505(b)(2) regulatory pathway.

Veru submitted a pre-NDA briefing document to the FDA that outlined the Company's preliminary data package being prepared for the NDA submission, including bioequivalence and bioavailability clinical study results, CMC and other regulatory elements for a 505(b)(2) submission. The Company believes it has reached agreement with FDA on the regulatory data package requirements that will be sufficient for submission. FDA requested that the company submit 12-month stability data on manufacturing batches to support the expiry date of TADFIN at the time of the NDA submission.

Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment 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.

"Based upon Veru's in-person meeting and written communications with FDA regarding our pre-NDA briefing package, we believe that all the requested components of our upcoming TADFIN NDA will be available to fulfill the FDA's requirements for submission after we have reached 12-months of stability data for the TADFIN manufacturing batches," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "Veru is excited to advance our 505(b)(2) development program to an NDA submission by the summer of 2020. We look forward to working with FDA to bring this novel and differentiated treatment option that combines both tadalafil and finasteride into one formulation for men suffering from BPH."

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and prostate cancer supportive care as well as urology specialty pharmaceuticals.
The Veru prostate cancer pipeline includes VERU-111, zuclomiphene citrate, and VERU-100. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. Zuclomiphene citrate is an oral estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-100 is a novel, proprietary peptide formulation designed with multiple beneficial clinical attributes addressing the shortfalls of the current multi-billion-dollar androgen deprivation therapy market for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration — a problem which occurs with currently approved LHRH agonists. Currently, there are no GnRH antagonists commercially approved beyond 1 month. VERU-100 is anticipated to enter a Phase 2 dose finding study in early 2020.

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®) formulation 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 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. Expected submission of the NDA for TADFIN is

summer of 2020. Veru is also developing Tamsulosin DRS granules and Tamsulosin XR capsules which are formulations 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 of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the prevention of premature ejaculation (also marketed as Roman Swipes). 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. FC2 is available by prescription and OTC in the U.S. at www.fc2.us.com. 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. For our premature ejaculation product, marketed as "Roman Swipes", the Company has entered into a U.S. distributor agreement with Roman Health Ventures Inc., a premier and fast-growing men's health and telemedicine company that discreetly sells men's health products via the internet website www.getroman.com. 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 relating to the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated process and timeframe for clinical studies, clinical study results and FDA submissions, and the effects and market potential for the Company's drug candidates. 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, and 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 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; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company's markets and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; 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 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 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 facilities, 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 year ended September 30, 2018. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

Contact:Sam Fisch800-972-0538
