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## **Veru Adds Breakthrough Novel Androgen Deprivation Therapy Formulation to its Advancing Prostate Cancer Drug Pipeline Following Successful Meeting with FDA**

*— VERU-100 Is a Proprietary Peptide Formulation Designed with Multiple Beneficial Clinical Attributes Addressing the Shortfalls of the Current Multi-Billion-Dollar Androgen Deprivation Therapy Market —*

*— Reached Agreement with FDA on an Expedited Regulatory Pathway and Clinical Development Strategy —*

MIAMI, June 04, 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 it has added to its robust prostate cancer drug development pipeline, a proprietary biologic drug candidate, VERU-100, for the treatment of hormone sensitive advanced prostate cancer, an established multi-billion-dollar global market.

VERU-100 was internally developed in collaboration with Drug Delivery Experts, LLC of San Diego, California (DDE Labs).

“The target product profile for VERU-100 is most compelling having a number of advantages over currently available androgen deprivation therapies. 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. As a GnRH antagonist, it will immediately suppress testosterone with no testosterone surge upon initial or repeated administration and no testosterone micro-increases which may adversely affect patient outcomes --- a problem which potentially occurs with approved LHRH agonist drugs like LUPRON®, ZOLADEX® and ELIGARD®,” said Peter N. Schlegel, M.D., James J. Colt Professor and Chairman of the Department of Urology at Weill Cornell Medicine and Urologist-in-Chief at New York-Presbyterian / Weill Cornell Medical Center. “Currently, there are no GnRH antagonists commercially approved beyond 1 month, making VERU-100, if approved, the only commercially available GnRH antagonist 3-month depot -- an attractive choice for androgen deprivation therapy.”

The Company recently met with the FDA and received agreement that VERU-100 qualifies for an expedited regulatory pathway. Based on FDA input, the Company plans to commence a single open label, multicenter dose-finding Phase 2 clinical trial in approximately 50 men, followed by a single open label, multicenter Phase 3 clinical trial in approximately 100 men. Veru is in the process of scaling up GMP manufacturing of drug product to prepare for the clinical trials of VERU-100. The Company plans to submit an Investigational New Drug application by no later than calendar Q1 2020.

Based on current cash on hand and expected cash from current sales forecasts, along with existing sources of capital, the Company does not anticipate the need for a new equity financing until at least fiscal 2021, even with additional costs related to the VERU-100 clinical development.

“We continue to execute on our strategy to become The Prostate Cancer Company by expanding and advancing our deep pipeline of late-stage proprietary oncology drugs for men with advanced prostate cancer,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “VERU-100 is a unique biologic formulation that complements our portfolio of drug candidates advancing in clinical development to provide a continuum of care for prostate cancer patients. As VERU-100 qualifies for an expedited FDA regulatory pathway, it represents a lower-cost investment opportunity for a major product that could address the shortfalls of the current \$2.6 billion global ADT market. I am particularly pleased that VERU-100 was internally developed by the Company in collaboration with DDE Labs and not acquired from a third party.”

Chris Rhodes, Chief Executive Officer of DDE Labs commented, “Veru has been a great collaborator and we look forward to this exciting new therapy becoming available to patients.”

#### **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 zuclomiphene citrate (also known as VERU-944, *cis*-clomiphene), VERU-111 (bisindole) and VERU-100. Zuclomiphene citrate is an 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-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. 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 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 co-administration of tadalafil 5mg and finasteride 5mg 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. 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<sup>®</sup> ("FC2"), an FDA-approved product for the dual protection of unwanted pregnancy and sexually transmitted infections, and the PREBOOST<sup>®</sup> 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. including through the virtual doctor smartphone app “HeyDoctor” at [www.fc2.us.com](http://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 PREBOOST, the Company has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company has also 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](http://www.getroman.com). To learn more about Veru products please visit [www.verupharma.com](http://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, the effects and market potential for the Company's drug candidates, and the Company's anticipation that it will not need a new equity financing until at least fiscal year 2021. 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](http://www.verupharma.com/investors).*

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