

Veru Announces Additional Information Regarding its South Africa Female Condom Tender Award

MIAMI, Aug. 29, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU), a urology and oncology biopharmaceutical company, today announced additional information regarding its recent award of 75% of a 120 million-unit South Africa female condom tender.

"The anticipated total revenue of the South Africa tender awarded to Veru is \$31 million with the first-year revenue expected to be \$10.4 million with up to another \$10.4 million of revenue for each of years two and three," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer. "The revenue and positive operating margin from this tender award will help fund development of Veru's drug pipeline to make us a leading oncology and urology biopharmaceutical company. We are proud of our team for receiving this significant tender award."

About Veru Inc.

Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

The Veru prostate cancer pipeline includes zuclomiphene citrate (aka VERU-944, *cis*-clomiphene) and VERU-111 (bisindole). 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 who have advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class, antitubulin agent targeting alpha and beta tubulin of microtubules to treat castration and novel androgen blocking agent (abiraterone or enzalutamide) resistant metastatic prostate cancer that Veru expects to enter Phase 1/2 development in late 2018.

Veru is advancing four new drug formulations in our specialty pharmaceutical pipeline addressing unmet medical needs in urology. Tamsulosin DRS granules and XR capsules are formulations of a super selective alpha-1 adrenergic receptor antagonist for the treatment of benign prostatic hyperplasia (BPH) without a food effect, allowing for potentially safer administration and improved drug compliance (NDA filing expected in 2018). Tadalafil/finasteride combination tablets are for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate, treat symptoms of BPH and treat erectile dysfunction (NDA filing expected in 2019). Solifenacin DRG slow release granules are a formulation of a selective M3 muscarinic receptor antagonist for the treatment

of overactive bladder in patients who have difficulty with swallowing tablets (NDA filing expected in 2019).

The company markets and sells the PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation being copromoted with Timm Medical Technologies, Inc. The company also markets and sells the FC2 Female Condom® (now available by prescription in the U.S. including through the virtual doctor smartphone app "HeyDoctor" at https://fc2.com) in the United States and through The Female Health Company Division in the global public health sector. The Female Health Company Division markets 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. More information about Veru and its products can be found at www.verupharma.com, www.verupharma.com, www.verupharma.com, For corporate and investor-related information about the Company, please visit https://verupharma.com/investors.

"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. Forwardlooking statements in this release include statements relating to the amount of the tender award, the anticipated timeframe for filling the award and anticipated revenue and operating margin from the award, and statements relating to the regulatory pathway to secure FDA approval of the Company's drug candidates and the anticipated timeframe for clinical studies and FDA submissions. These South Africa tender awards could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to the Company, and the awards indicate acceptance of the price rather than an order or guarantee of the purchase of any minimum number of units. If fewer orders are placed under the tender award than expected the Company's revenue and operating income from the award would be less than currently anticipated. As with other government tenders, ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount. In addition, the timing of orders under the South Africa tender award is uncertain, and any delay in orders under the award could result in lower revenue and operating margin than anticipated in the earlier part of the three-year period covered by the tender. 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;; 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 due to labor unrest or strikes; 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, 2017. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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Source: Veru Inc.