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Veru Acquires Novel Proprietary Formulation for Overactive Bladder

--Addresses Large Population of Men and Women Who Have Overactive BladdersAnd Difficulty Swallowing Tablets--
--FDA Meeting Confirms Single Bioequivalence Study Path to Approval--
--Expands Offering of Drugs for Long-Term Care and Geriatric Urology--

MIAMI, Dec. 11, 2017 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU) today announced that it has acquired world-wide rights to a novel, proprietary oral granule formulation for solifenacin from Camargo Pharmaceuticals Services, LLC. Solifenacin is the active ingredient in a leading drug VESIcare® for the treatment of overactive bladder in men and women.

Solifenacin Delayed Release Granule (DRG) addresses the large population of men and women who have overactive bladder (OAB) and who have dysphagia, or difficulty swallowing tablets. The US Food and Drug Administration (FDA) recently confirmed in a meeting with the company that regulatory approval for Solifenacin DRG will require a single bioequivalence study and that no additional nonclinical, clinical efficacy and/or safety studies will be required to support the approval of Solifenacin DRG product for the treatment of overactive bladder.

A current leading drug for overactive bladder that contains solifenacin carries an FDA label stating that the tablet should be swallowed whole and not chewed, crushed or broken. Solifenacin DRG addresses the significant percentage of patients both in long-term care and geriatric urology that have difficulty swallowing tablets.

“Solifenacin DRG would be the only drug in its class available as an oral granule for both men and women who suffer from overactive bladder and who have difficulty swallowing tablets,” said Mitchell Steiner, M.D., President and Chief Executive Officer of Veru. “We are excited about the significant benefits that this formulation promises not just in a long-term care setting, but in the general population as well, given the high prevalence of overactive bladder. The acquisition of this formulation bolsters our growing portfolio of novel urology drugs.”

Veru plans to begin the Solifenacin DRG bioequivalence study in 2018 and to file the NDA in 2019. Under the terms of the agreement with Camargo, Veru paid an undisclosed upfront fee to acquire the asset and will pay undisclosed milestone fees upon successful clinical development and a low single digit royalty upon commercial sales.

About Solifenacin DRG

Solifenacin DRG is a novel, proprietary oral granule or powdered formulation for the treatment of OAB for people who have difficulty swallowing tablets or capsules. Symptoms of OAB include urinary incontinence, urgency and urinary frequency. The prevalence of OAB in the US is similar in women and men at 17% and 16%, respectively. According to the US Department of Health and Human Services, 37% of short-term nursing home residents and 70% of long-term nursing home residents were not in complete control of their bladder. Worldwide 2017 sales to date for a leading drug for OAB with solifenacin as its active ingredient are greater than $1 billion according to IMS Health sales data. Dysphagia, or swallowing difficulty, is also a growing health issue in our aging population. Up to 38% of the elderly who live independently and up to 68% of elderly nursing home residents have difficulty swallowing whole tablets. Swallowing difficulties are particularly prevalent in patients who have Parkinson's Disease (80%) and Alzheimer's Disease (40-70%) and who have suffered a stroke (50%). These same conditions are associated with OAB.

About Veru Inc.

Veru Inc. (Veru) is a biopharmaceutical company focused on urology and oncology. Veru utilizes FDA's 505(b)(2) regulatory approval pathway to develop and commercialize drug candidates. FDA's 505(b)(2) regulatory approval pathway is designed to allow for potentially expedited, lower cost and lower risk regulatory approval based on a previously established safety and efficacy profile of the product. Veru is developing products under the 505(b)(1) pathway as well, which is the traditional new drug application (NDA) pathway. The company is currently developing drug product candidates for benign prostatic hyperplasia (BPH or enlarged prostate), hot flashes associated with prostate cancer hormone treatment, male infertility and novel oral chemotherapies (alpha and beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast and ovarian cancers. In addition, the company markets and sells the FC2 Female Condom® (now available by prescription in the US including through the virtual doctor smartphone app "HeyDoctor" at www.fc2.us.com) and PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation which is being co-promoted with Timm Medical Technologies, Inc.

The company's division, The Female Health Company, is focused on the global public health sector FC2 business. 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.veruhealthcare.com, www.PREBOOST.com and www.fc2.us.com. For corporate and investor-related information about the Company, please visit https://veruhealthcare.com/investors.

About Camargo Pharmaceuticals Services, LLC

Camargo Pharmaceutical Services is the most experienced team of experts providing comprehensive drug development services specialized for the 505(b)(2) approval pathway and global equivalent processes. By assessing the scientific, medical, regulatory, and commercial viability of product development opportunities, Camargo systematically builds and executes robust development plans that align with business strategies and ensure Agency buy-in every step of the way. With alignment through pre-Investigational New Drug

(pre-IND) meeting planning and preparations, Camargo maintains and ensures consistency throughout the drug development program, which increases the likelihood of NDA and future market success. Routinely holding three to six pre-IND meetings a month, Camargo works with product developers across more than 25 countries. For more about Camargo Pharmaceutical Services, visit http://camargopharma.com

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995: *The statements in this release that are not historical fact are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements in this 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 inherently subject to known and unknown risks and uncertainties. The Company's actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking 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: product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including 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 or restructuring; 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; the Company's reliance on its international partners in the consumer sector and on the level of spending on the female condom by country governments, global donors and other public health organizations in the global public sector; 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; risks related to the costs and other effects of litigation; 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, 2016. These documents are available on the "SEC Filings" section of our website at www.veruhealthcare.com/investors.*

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