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Veru Announces Tamsulosin DRS Bioequivalence Clinical Trial Results

Veru Remains on Schedule to File 505(b)(2) Tamsulosin DRS New Drug Application in First Half Calendar 2018

MIAMI, Nov. 13, 2017 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU) today announced the results of the bioequivalence (BE) clinical trial of the company's proprietary Tamsulosin Delayed Release Sachet (DRS) (Tamsulosin HCl extended-release oral suspension) formulation versus FLOMAX®. Tamsulosin DRS is a new, proprietary, slow release oral granule formulation that addresses the large population of men who have benign prostatic hyperplasia (BPH) and who have dysphagia (difficulty swallowing tablets or capsules).

Dosing with Tamsulosin DRS fasted and Tamsulosin DRS fed were successfully shown to be bioequivalent with FLOMAX Fed based on AUC. The AUC equivalence is the key determinant of drug exposure over time. The Tamsulosin DRS formulation did not meet the remaining bioequivalence criterion for the peak value (Cmax). The BE clinical trial was a 21-day single dose comparison of Tamsulosin DRS slow release granule formulation versus FLOMAX® capsules in 36 patients who have either fasted or eaten prior to dosing. 34 subjects completed the study.

"Having met bioequivalence for AUC, we have the ability to adjust the blend of particle sizes in the proprietary granule formulation to address the Cmax difference, because Cmax is dependent upon particle size," said Lynn Gold PhD, Vice President of Scientific and Regulatory Affairs, Camargo Pharmaceutical Services. Veru licensed Tamsulosin DRS and has a co-development agreement with Camargo. "We are enthusiastic about the results and look forward to advancing Tamsulosin DRS based on this new data."

The current formulation registration batch that is undergoing stability testing is still acceptable for NDA submission. The time required to test stability remains our time limiting step. The new BE study to validate the revised formulation should be accomplished by the first quarter of calendar 2018 which is within the current stability time window that will allow us to remain on track with our planned NDA submission.

"Today's announcement supports the clinical advancement of Tamsulosin DRS. The expected timing of the additional formulation adjustment should allow us to remain on track for a pre-NDA meeting in early 2018 and an NDA submission in the first half of calendar 2018," said Mitchell Steiner, M.D., President and Chief Executive Officer of Veru.

“Tamsulosin DRS compared to FLOMAX® has the potential to improve patient compliance and the safety profile by not having to be taken with meals. Tamsulosin DRS granule formulation addresses the unmet medical need of men who have BPH but who also have difficulty swallowing capsules or tablets. FDA approval of Tamsulosin DRS would allow us to participate meaningfully in the multi-billion dollar BPH market.”

Supported by the Stage 1 and Stage 2 BE clinical trial results, the company also plans to request a meeting with the European Medicines Agency in the first half of calendar 2018.

“Because Veru has a novel slow release granule formulation of Tamsulosin that does not have a food requirement, we will also begin development of an oral capsule containing these granules. The planned NDA filing would be for both drug products - the granule formulation and the capsules,” said Harry Fisch, M.D., Chief Corporate Officer at Veru. “This will allow us to also expand this advantage to men who have BPH and who can swallow capsules in the larger urology and primary care markets.”

About Tamsulosin DRS (Tamsulosin HCl extended release for oral suspension)

Tamsulosin DRS is a new granule formulation containing the active pharmaceutical ingredient in FLOMAX® (tamsulosin HCl) capsules. FLOMAX® is indicated for the treatment of BPH, also known as enlargement of the prostate. Tamsulosin is a selective $alpha_1$ adrenoreceptor antagonist specific to receptors located in prostate and bladder smooth muscle. Symptoms associated with BPH occur because of a change in the functioning of the prostate and bladder smooth muscle that can lead to constricted urinary flow, urinary retention, urinary infection, kidney damage and a life-threatening blood infection called urosepsis. Blocking $alpha_1$ adrenoreceptors relaxes smooth muscle resulting in improved urinary flow and reduction of BPH symptoms.

According to IMS Health sales data, FLOMAX® and their generics have 84% market share of the multi-billion dollar $alpha_1$ blocker market for BPH in the United States. FLOMAX® and their generics are only available as slow release capsules. As stated in the FDA approved package insert, FLOMAX® capsules should not be crushed, chewed or opened, because they cannot be reliably absorbed into the bloodstream. Men with high FLOMAX® drug levels in their bloodstream are placed at risk for postural hypotension (sudden drop in blood pressure upon standing that can lead to fainting) and dizziness. Tablets and capsules are problematic for approximately 15% of men over the age of 60 who have difficulty swallowing tablets and capsules and the up to 68% of men in long term facilities who have difficulty swallowing tablets and capsules because of certain medical conditions, including degenerative neurological diseases like Parkinson's and Alzheimer’s disease or having suffered a stroke. Not being able to take $alpha_1$ blockers for BPH because of difficulty swallowing tablets and capsules, may lead to an increased risk of acute urinary retention, urinary catheterization, urosepsis and death. Because Tamsulosin DRS is a new proprietary slow release granule formulation containing the active pharmaceutical ingredient in FLOMAX®, it would provide a more reliable way to deliver therapeutic levels of tamsulosin to men who have BPH and who have difficulty swallowing tablets and capsules.

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 & beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast and ovarian cancers.

To help support these clinical development programs, 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 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. In addition, the company markets and sells the PREBOOST® medicated individual wipe which is a male genital desensitizing drug product for the prevention of premature ejaculation that is being co-promoted with Timm Medical Technologies LLC. 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 Pharmaceutical Services

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

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