



Female Health Company / Veru Healthcare Announces Advancement of Male Infertility Drug Candidate Following FDA Advisory Committee Meeting

MIAMI, FL, December 7, 2016 -- The Female Health Company/Veru Healthcare ([FHCO](#)) today announced its plan for a Phase 2 clinical trial for MSS-722, the company's proprietary oral drug candidate for the treatment of male infertility, following the company's recent presentation at the U.S. Food and Drug Administration (FDA) meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee on December 6, 2016.

"We are pleased with the outcome of the meeting and the direction received from the FDA Advisory Committee," said Mitchell Steiner, M.D., President and Chief Executive Officer of The Female Health Company / Veru Healthcare. "We now have a path forward to advance the development of MSS-722 for the treatment of male infertility. Our team is mobilizing quickly and we intend to file an Investigational New Drug application for MSS-722 next quarter."

As previously announced, the company accepted an invitation from the FDA to present at the meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee on December 6, 2016. The FDA uses advisory committees to obtain independent expert advice on scientific, technical and policy matters. At the meeting, the committee discussed appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism (low testosterone levels) while preserving or improving testicular function, including spermatogenesis. MSS-722 is being developed as the first oral agent for the treatment of low sperm count (impaired spermatogenesis) in men who have secondary hypogonadism as a cause of male infertility.

At the meeting, the FDA Advisory Committee provided guidance for clinical trial design and endpoints. The committee accepted the intended patient population, recommended a short-term study, and supported the use of improvement of semen quality for such clinical endpoints as avoidance of aggressive assisted reproductive procedures such as in vitro fertilization or achieving pregnancy.

"Based on the FDA Advisory Committee guidance, we are now a significant step closer to bringing a new treatment option for male infertility to couples desiring to become parents," said Edward Kim, M.D., Professor of Urology, University of Tennessee Graduate School of Medicine and a Veru Healthcare consultant. "This patient population is poorly served with current medications, and because Veru Healthcare is utilizing the 505(b)(2) regulatory pathway, MSS-722 has the potential for accelerated development."

The Female Health Company recently completed a transformational merger with Aspen Park Pharmaceuticals, a company focused on the development and commercialization of pharmaceutical and consumer health products for men's and women's health and oncology. APP's drug development portfolio includes MSS-722, an oral drug product candidate for the treatment of hypogonadism. The company intends to utilize the 505(b)(2) regulatory pathway, which has the potential to significantly accelerate and substantially lower the cost and risk of developing MSS-722.

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About MSS-722

MSS-722 is a new, proprietary, first-in-class oral agent being developed for the treatment of male infertility. MSS-722 is being developed as the first oral agent for the treatment of low sperm count (spermatogenesis) in men who have secondary hypogonadism (low testosterone levels) as a cause of male infertility. MSS-722 is designed to increase both luteinizing hormone as well as follicle-stimulating hormone (FSH) levels to restore sperm production. The only current FDA approved therapy is human chorionic gonadotropin and FSH injections, which are very expensive and inconvenient compared to MSS-722. FDA has previously confirmed that MSS-722 qualifies for the 505(b)(2) accelerated regulatory approval pathway and an orphan drug status request for MSS-722 is pending, which could allow additional years of exclusivity. The US market for male infertility is estimated to be approximately \$700 million annually.

About The Female Health Company / Veru Healthcare

The Female Health Company / Veru Healthcare is a medical therapeutics company, with a focus on the development and commercialization of pharmaceuticals that qualify for the FDA's 505(b)(2) accelerated regulatory approval pathway as well as the 505(b)(1) pathway. The Company does business both as "Veru Healthcare" and as "The Female Health Company" and is organized as follows:

- Veru Healthcare manages the Pharmaceuticals Division, which develops and commercializes pharmaceutical products for men's and women's health and oncology.
- Veru Healthcare manages the Consumer Health/Medical Devices Division, which is focused on commercializing sexual healthcare products and devices for the consumer market, including the Company's Female Condom (FC2), which is referred to as the FC2 Female Condom[®] in the consumer health products sector and as the Female Disposable Contraceptive Device (FC2) in the U.S. prescription market, and PREBOOST[®] medicated individual wipes which is a male genital desensitizing drug product that helps in the prevention of premature ejaculation.
- The Female Health Company manages the Global Public Health Division, which is focused on the global public health sector FC2 business. This division markets the Company's Female Condom (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.

More information about the Female Health Company and its products can be found at www.femalehealth.com, www.veruhealthcare.com and www.femalecondom.org. For corporate and investor-related information about the company, please visit www.FHCinvestor.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

The statements in this release which are not historical fact 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 Company's analysis, assessment and conclusions around the future development and commercial potential of MSS-722, and the timing of future clinical trials. These statements 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 as a result 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: timing and expected completion of the Phase 2 clinical trial for MSS-722, success of the Phase 2 clinical trial or future clinical trials, product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions; 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; 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, 2015. Actual events affecting the Company and the impact of such events on the Company's operations may vary from those currently anticipated.

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