The Female Health Company / Veru Healthcare Reports Interim Analysis of Independent Placebo Controlled Clinical Study of PREBOOST®, Its Proprietary Premature Ejaculation Medication

MIAMI, FL November 17, 2016 -- The Female Health Company / Veru Healthcare (FHCO) today announced top line interim analysis of an independent, double-blind, randomized, controlled clinical study of the company's novel PREBOOST® product (topical 4% benzocaine wipes) for the management of premature ejaculation (PE). The scientific abstract that describes the full interim analysis results has been submitted to a major urological medical conference. The company plans to launch PREBOOST® in the US before year-end.

The independent clinical study was conducted by Jed Kaminetsky, M.D., Medical Director at Manhattan Medical Research, Clinical Assistant Professor of Urology at New York University Medical Center, and practicing urologist with University Urology Associates; Michael Yang, Clinical Research Coordinator at Manhattan Medical Research and University Urology Associates; Michael Perelman. M.D., Clinical Professor Emeritus of Psychology in Psychiatry at Weill Cornell Medical College; and, Ridwan Shabsigh, M.D., Professor of Urology at Weill Cornell Medical College, and President of the International Society of Men's Health. The clinical study was supported by Veru Healthcare.

The top line results of the interim analysis from 21 men show:

- After two months, men treated with PREBOOST® had statistically significant improvement in their ability to control ejaculation, with a mean increase in duration of almost four minutes, which was significantly greater than men on placebo. After treatment with PREBOOST, 80% of men were no longer considered to have PE;
- Men treated with PREBOOST® reported a statistically significant better sense of ejaculation control, confidence, satisfaction, sexual pleasure, length of intercourse and reduced frustration;
- PREBOOST® was well tolerated and no transference was reported;
- The interim clinical study met the primary endpoint of change in average intravaginal ejaculatory latency time (IELT) at two months and secondary outcomes of change in questionnaire assessments, such as global rating of distress, medication assessment, and Index of Premature Ejaculation (IPE).

PREBOOST® is a new, proprietary over-the-counter (OTC) male genital desensitizer used for the treatment of PE. Unlike currently available OTC anesthetic sprays using lidocaine or gels using benzocaine, PREBOOST® is an individually packaged wipe containing 4% benzocaine, which allows for direct and precise application of the same dosage each time.

"Our interim results in men with PE show that PREBOOST® appears to prolong time to ejaculation, supporting the clinical validity of PREBOOST® for the management of PE," said Mitchell Steiner, M.D. President and Chief Executive Officer of The Female Health Company / Veru Healthcare. "These interim analysis results show that PREBOOST® improved both objective and subjective symptoms of PE compared to placebo. We believe PREBOOST® has significant advantages over currently available therapies, especially with regard to ease of use, delivery system and convenience."

"Our plan is to launch PREBOOST® in the US later this quarter through digital and social media marketing," said Shiao Zhu, Vice President of Marketing of Veru Healthcare. "We look forward to being able to provide a tested medical therapy to men and couples who suffer from PE."

-more-

For more information about PREBOOST®, please visit www.preboost.com.

About Premature Ejaculation (PE):
PE is defined by the International Society for Sexual Medicine as, persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the person wishes it. PE is the most common sexual dysfunction, even more common than erectile dysfunction, according to numerous epidemiological studies. It is a problem for couples and the most commonly observed sexual disorder in men below 40 years of age. PE is a self-reported diagnosis with a prevalence rate of 20-30 percent. The estimated prevalence of PE is 50 million men in the US and 60 million men in Europe. Total worldwide market for premature ejaculation drugs and consumer health care products is estimated to be greater than $500 million annually.

About PREBOOST®:
PREBOOST® is a new, proprietary OTC male genital desensitizer used for the treatment of PE. There are no prescription products for PE approved by the United States FDA. Off label use of antidepressants and PDE-5 inhibitors have been used with limited success because of inconsistent efficacy and unacceptable side effects. Psychological counseling and behavioral therapy are also used with mixed results. Of the consumer health products, the topical anesthetics are administered as sprays and gels. The drawbacks of these approaches include inconsistent dosing leading to too much anesthetic and transference of the anesthetics to the partner. PREBOOST® is compliant with the FDA monograph and is approved in the United States. PREBOOST® is the only individually packaged medicated wipe that contains a desensitizing agent (benzocaine 4.0%). The advantages are: 1) Convenient individually wrapped wipes so it is easier to carry and to be discreet, 2) The correct dose is delivered each time 3) The medicine is applied topically and dries quickly which prevents the potential for transference to partner, and 4) Benzocaine at 4.0% temporarily desensitizes, but does not numb the penis.

The Company plans to implement a sampling program targeting urologists, co-promoting with a marketing partner, introducing the product through Walmart, CVS, Walgreens and other OTC distribution outlets, optimizing its internet ecommerce capabilities and digital marketing via www.preboost.com, as well as through out-licensing opportunities for markets outside the U.S.

About The Female Health Company
The Female Health Company is a specialty pharmaceutical and medical device company, with a focus on pharmaceutical products that qualify for the 505(b)(2) FDA regulatory pathway that can result in more rapid approval than a full new drug application. The company is organized as follows: Veru Healthcare manages the Pharmaceuticals and Medical Devices division, which develops and commercializes pharmaceutical and medical device products for men's and women's health and oncology, as well as the Consumer Health division, which is focused on commercializing sexual health products, including FC2 Female Condom® (FC2) and PREBOOST®, for the consumer market. The Female Health Company through its Global Public Health Division manages the global public health sector FC2 business. This division markets FC2 to entities, including ministries of health, government health agencies, non-profit 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. 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: 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; the length, cost and uncertain results of the Company's clinical trials; the potential of adverse side effects or other safety risks that could preclude the approval of the Company's product candidates; 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 global public health 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 health sector; the economic and business environment and the impact of government pressures; the Company's reliance on its major customers and risks related to delays in payment of accounts receivable by major customers; 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 and 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 and the Company's proxy statement filed on August 8, 2016. These documents are available on the "SEC Filings" section of our website at www.femalehealth.com/investors*.*

Contact:
Kevin Gilbert
312-366-2633

The Female Health Company

###