Female Pelvic Health Panel Investigates a Medication for HSDD, Low Serum Testosterone's Association with SUI and Issues Surrounding Transvaginal and Vaginal Mesh

BOSTON, May 14, 2017 /PRNewswire-USNewswire/ -- Four studies examining female pelvic and sexual health, show promising results for women with hypoactive sexual desire disorder (HSDD), an association between low testosterone levels and incontinence and refutes theories linking synthetic mesh and autoimmune disease and cancer. All four studies will be presented at the 112th Annual Scientific Meeting of the American Urological Association (AUA) during a joint press conference at the Boston Convention and Exhibition Center, Boston, MA on Sunday, May 14 at 7:30 a.m.

**Study Details**

**Effect of Flibanserin on Sexual Functioning: An Analysis of Female Sexual Function Index Domains (#PD40-11):**

In 2015, the U.S. Food and Drug Administration approved Flibanserin (Addyi) to treat HSDD in premenopausal women. HSDD is characterized by a low sex drive that causes women personal distress and occurs regardless of the type of sexual activity, situation or sexual partner. Prior to Flibanserin's approval, there were no FDA-approved treatments for HSDD in women. Utilizing the Female Sexual Function Index (FSFI), researchers set out to examine the effect of Flibanserin on the following six FSFI domains: desire, arousal, lubrication, orgasm, satisfaction and pain. Utilizing patient-level data from more than 2,360 women, researchers analyzed three, 24-week, double-blind, placebo-controlled studies in premenopausal women with HSDD. Results showed

Flibanserin produced significant improvement not only in the FSFI 'desire' domain, but also across the other domains of sexual function assessed by the FSFI.

**Low Serum Testosterone is Associated with Increased Stress and Mixed Incontinence in Women (#PD50-07):** The association between testosterone levels and urinary incontinence has not been extensively studied, which is why researchers examined the relationship between testosterone levels and self-reported urinary incontinence in women. Data from 2,123 females who self-reported stress, urge or mixed urinary incontinence as part of the 2012 cycle of National Health and Nutrition Examination Survey, and who also underwent measurement of their testosterone levels, were analyzed. Researchers first examined each participant's testosterone levels in a weighted variance-corrected univariate model for association with incontinence, and then in a weighted variance-corrected model adjusted for age, body mass index, diabetes, race, parity and the time of day their blood was drawn for testosterone level measurement.

Results showed:

- The higher the testosterone level in women, the lower likelihood for having urinary incontinence.
- After adjusting for age, results also revealed lower levels of testosterone were associated with an increased likelihood of only stress and mixed incontinence.

Investigators concluded that given the role of pelvic musculature in maintaining urethral support and the anabolic effect of androgens on skeletal muscle, a physiologic mechanism for this relationship could be proposed and further evaluated in prospective and translational studies.

**Is Vaginal Mesh a Stimulus of Autoimmune Disease (#PD17-08) and Transvaginal Mesh Does Not Cause Carcinogenesis (#PD02-10):**
Two separate studies refuted claims against mesh as a cause of systemic disease and a cause of cancer. In the first study, researchers looked for the potential link between the development of systemic/autoimmune disorders and synthetic polypropylene mesh repairs. A total of 2,257 patients who underwent mesh based pelvic organ prolapse (POP) surgery were analyzed. When patients were matched, based on demographics, comorbidities and procedure time, mesh-based surgery was not associated with an increased risk of developing autoimmune disease. Similarly, in the second study, an investigation sought to find a potential link between carcinogenesis and synthetic polypropylene mesh repairs using statewide administrative data. A total of 2,301 patients who underwent mesh based POP surgery were analyzed. The results showed mesh-based surgery was not associated with an increased risk of developing a cancer diagnosis at 1-year and during the entire follow up of up to 5 years.

"These studies show promise in understanding more about a woman's sexual and urologic health" said Tomas L. Griebling, MD, MPH, AUA spokesperson and session moderator. "The favorable outcomes associated with such new treatments as Flibanserin, as well as data indicating synthetic vaginal mesh does not cause either systematic disease or cancer, are important factors in patient diagnosis, treatment and survival variances and is beneficial information for physicians to discuss with their patients."

NOTE TO REPORTERS: Experts are available to discuss this study outside normal briefing times. To arrange an interview with an expert, please contact the AUA Communications Office at 410-689-3932 or e-mail cfrey@AUAnet.org.

About the American Urological Association: The 112th Annual Meeting of the American Urological Association takes place May 12 – 16 at the Boston Convention & Exhibition Center in Boston, MA.

Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology and has more than 21,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

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