

## Viagra for women? Drug developed as antidepressant effective in treating low libido

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This is John M. Thorp Jr., M.D., from the University of North Carolina School of Medicine. Credit: UNC-Chapel Hill School of Medicine

The drug flibanserin, which was originally created as an antidepressant, is effective in treating women with low libido, pooled results from three separate clinical trials have found.

These trials were the first ever to test a therapy that works at the level of the brain to enhance libido in women reporting low sexual desire, said John M. Thorp Jr., M.D., McAllister distinguished professor of obstetrics and gynecology at the University of North Carolina at Chapel Hill School of Medicine and the principal investigator for North America in the studies.



"Flibanserin was a poor antidepressant," Thorp said. "However, astute observers noted that it increased libido in laboratory animals and human subjects. So, we conducted multiple <u>clinical trials</u> and the women in our studies who took it for <u>hypoactive sexual desire disorder</u> reported significant improvements in sexual desire and satisfactory sexual experiences.

"It's essentially a Viagra-like drug for women in that diminished desire or libido is the most common feminine sexual problem, like erectile dysfunction is in men," Thorp said.

Studies have shown that the prevalence of hypoactive sexual desire disorder in the U.S. ranges from 9 percent to 26 percent of women, depending on age and menopausal status. Flibanserin is currently an investigational drug and is available only to women taking part in clinical trials.

The results reported here were presented Monday, Nov. 16, at the Congress of the European Society for Sexual Medicine in Lyon, France. The presentation was given by Elaine E. Jolly, M.D., overall principal investigator and a professor at the University of Ottawa in Canada.

Jolly, Thorp and colleagues pooled data from four clinical trials of flibanserin conducted in the U.S., Canada and Europe. A total of 1,946 pre-menopausal women ages 18 and older were randomized to receive either flibanserin or placebo for 24 weeks, with 4 weeks of pre-treatment baseline measurement and 4 weeks of post-treatment follow-up.

Initially, four different dosing regimens were used in the trials: 25 milligrams twice a day, 50 milligrams once a day at bedtime, 50 milligrams twice a day and 100 milligrams once a day at bedtime. The dosing regimens totaling 50 milligrams a day were not effective while



the regimens totaling 100 milligrams were. So, the results being reported are from only three of the four trials and are based on the 100 milligrams once a day dosing regimen only.

The trials measured mean changes from baseline on the following six variables as reported by the women each week: number of satisfactory sexual encounters (SSE), electronic diary (eDiary) desire score, female sexual function index (FSFI) desire domain score, FSFI total score, female sexual distress scale-revised (FSDR-R), and FSDR-R Item 13 (which focuses specifically on desire/libido).

The researchers concluded that treatment with 100 milligrams of flibanserin once a day was associated with significant improvements versus placebo in the number of satisfactory sexual encounters (SSE) reported, <u>sexual desire</u> (as measured by eDiary and FSFI desire domain), a reduction in distress associated with sexual dysfunction (as measured by FSDS-R and its Item 13), and sexual functioning as measured by FSFI.

"These results point to a novel approach to pharmacologic treatment of the sexual problem that plagues reproductive age women the most, and may over time prove to be an effective treatment without the side effects of androgen replacement therapy, which is the only treatment currently available," Thorp said.

Source: University of North Carolina School of Medicine (<u>news</u>: <u>web</u>)

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