

US regulators to decide on 'female Viagra'

August 18 2015

US regulators are expected to decide Tuesday whether to approve a drug nicknamed the "female Viagra," which would be the first pill on the market to raise women's sex drive.

In June, an advisory panel to the Food and Drug Administration urged regulators to approve the drug, flibanserin, after previously voting against it twice in years past.

This time, the experts voted 18-6 in favor of allowing the drug on the market, but with some additional risk-control measures to make sure doctors prescribe it only to patients who need it and that [women](#) are aware of the risks.

The FDA is not required to follow the advice of the panel, but it often does.

A spokeswoman for Sprout Pharmaceuticals in North Carolina told AFP that the FDA decision was expected Tuesday but was unsure what time. An FDA spokeswoman declined to comment.

If approved, flibanserin would be sold under the name "Addyi," and marketed toward pre-menopausal women.

It can have significant side effects including nausea, dizziness and sleepiness.

Safety concerns include sleepiness, fainting, [low blood pressure](#) and the

potential for hormonal contraceptives and alcohol use to make side effects worse.

Experts also raised questions about the increased risk of breast cancer seen in one of two studies on lab animals.

Most commonly diagnosed disorder

The drug is a non-hormonal agent that acts on neurotransmitters in the brain, and aims to treat a condition known as [hypoactive sexual desire disorder \(HSDD\)](#), or loss of interest in sex, among women who have not yet entered menopause.

Rebecca Zucconi, an assistant professor of medical sciences at the Frank H. Netter School of Medicine at Quinnipiac University, said the condition is the most commonly diagnosed sexual dysfunction in women.

"Until now, physicians have been limited to recommending education, counseling, psychotherapy and, in some cases, off-label usage of testosterone and estrogen therapy as treatment options for otherwise healthy women with HSDD," Zucconi said.

"Importantly, the [advisory panel](#) gave its approval with specific concerns regarding flibanserin's safety when combined with certain medications or with alcohol.

"If approved by the FDA, flibanserin will likely be marketed and prescribed with explicit restrictions to this effect."

Two attempts at bringing the drug to market failed in 2010 and 2013, given what experts described as inconclusive advantages when compared to a placebo.

According to documents on the FDA website, women taking flibanserin reported on average 4.4 sexually satisfying encounters per month, compared to 3.7 in a placebo group and 2.7 before beginning the study.

© 2015 AFP

Citation: US regulators to decide on 'female Viagra' (2015, August 18) retrieved 5 May 2024 from <https://medicalxpress.com/news/2015-08-female-viagra.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.