

## USFDA approves 'Female Viagra'

19 August 2015 | News | By BioSpectrum Bureau

### USFDA approves 'Female Viagra'



US-based Sprout Pharmaceuticals gained USFDA's approval for Addyi, whose chemical name is Flibanserin, created to enhance sex drive in premenopausal women or women suffering from hypoactive sexual desire disorder (HSDD).

Addyi is the first and only FDA-approved treatment for this condition, the most common form of female sexual dysfunction, affecting up to 1 in 10 women in the United States, voiced Sprout.

The approval has been granted with strong warnings of effects including low blood pressure and fainting when taken with alcohol.

The company said, the most common adverse events among patients treated with Addyi were dizziness, somnolence, nausea, fatigue, insomnia and dry mouth.

Hypotension and syncope were seen rarely with Addyi alone but more frequently when Addyi was taken in the morning and when co-administered with alcohol or certain other drugs.

"It has been a remarkable journey to get to this breakthrough moment. Today we celebrate what this approval means for all women who have long awaited a medical treatment option for this life impacting condition," said Ms Cindy Whitehead, CEO, Sprout Pharmaceuticals. "We applaud the FDA for putting the patient voice at the center of the conversation and for focusing on scientific evidence."

Previously, the drug failed twice to obtain USFDA's approval owing to its side effects.

The drug was initially developed by German-based drug maker Boehringer Ingelheim.

Once the drug failed FDA's nod, Sprout purchased the drug from Boehringer.

In 1998, Pfizer marketed Viagra, a drug designed to address erectile dysfunction in men. Now Addyi is being dubbed as 'Female Viagra'.

Palatin Technologies, a New Jersey-based biopharmaceutical company coming up with a similar drug to address HSDD in women.

A few groups in the US have raised their opposition against Addyi as a result of its side effects.

Addyi is anticipated to be available by October 17, 2015, said Sprout in a statement.