
COMPANIES

S1 Biopharma starts trial of female libido drug

PHARMACEUTICALS

**By Clive Cookson
in London**

A new drug called Lorexys, which aims to rekindle sexual desire in women, is beginning a clinical trial in the US. Its developer, S1 Biopharma, is one of several biotech companies competing to produce the first authorised treatment for what is known officially as “hypoactive sexual desire disorder” or HSDD.

S1, based in New Jersey, will today announce details of the trial and the composition of Lorexys. It combines two well-established antidepressants, bupropion and trazodone, in a ratio designed to alter the balance of brain chemicals that regulate sexual excitation and inhibition.

“Lorexys may provide the first safe and effective treatment option for those whose lives . . . are affected by the disorder,” said Nicolas Sitchon, chief executive of S1. “By restoring the balance of the key neurotransmitters that regulate sexual desire in the

brain, we expect Lorexys will help women with sexual desire and arousal disorders regain a healthy sexual life.”

Although the US Food and Drug Administration has not approved any treatment for women with HSDD, it can expect several candidates over the next few years. First in line will be flibanserin, a drug originally submitted to the FDA by Boehringer Ingelheim of Germany and rejected in 2010, on the grounds that its benefits did not outweigh its side effects.

After the rejection, Boehringer Ingelheim sold rights to the drug to Sprout Pharmaceuticals, a new company in North Carolina, which has conducted further clinical trials – showing more significant benefits – and recently resubmitted flibanserin to the FDA.

In addition, Emotional Brain, based in the Netherlands and New York, is developing two HSDD drugs, confusingly called Lybrido and Lybridos. And Palatin Technologies of New Jersey has bremelanotide in clinical trials for female sexual dysfunction.

Although phrases such as “lady Viagra” and “pink Viagra” have been applied to these new drugs, their developers say that such descriptions are misleading because they work in completely different ways. Pfizer’s Viagra treats erectile dysfunction by increasing genital blood flow in men who want to have sex. By contrast, the HSDD drugs arouse sexual desire in the female brain.

Yet they may have something in common with Viagra: a huge potential market of sexually dissatisfied people.

According to Robert Pyke, chief medical officer of S1 Biopharma, studies show that 10 per cent of women in the US meet the criteria for HSDD – a lack of desire for sex “causing marked distress or interpersonal difficulties”, as judged by a doctor.

S1 Biopharma expects results from its current study of the effect of Lorexys on 30 women with HSDD in the first quarter of 2014. A much larger trial would follow, with an application to the FDA for marketing approval in 2017 if all goes well.