

Bayer invests in 'Viagra for women'

Research costs, clinical trials; Puts \$300M into Quebec firm developing product to treat sexual dysfunction

BY MARIANNE WHITE, POSTMEDIA NEWS OCTOBER 6, 2010

- The development of a treatment for sexual dysfunction in women drew a step closer yesterday as Bayer Pharmaceuticals invested \$300 million in Quebec City-based Endoceutics, a company that claims to have discovered what it dubs "Viagra for women."

Bayer will foot the bill for research costs and Phase 3 clinical trials in Canada and the United States on 1,500 women. The treatment, tentatively called Vaginorm, is a compound that liquefies immediately when inserted in the vagina to treat vaginal dryness and thinning.

Although Endoceutics president Dr. Fernand Labrie said his treatment can be seen as "Viagra for women," he noted it is not a pill like Viagra and works differently because there are major differences between the causes of sexual dysfunction in men and in women.

Endoceutics said the treatment is not hormone-based, but relies on DHEA, a naturally secreted molecule whose levels decrease as women age.

Researchers at Endoceutics have found that lower levels of DHEA are responsible for some menopausal symptoms, including vaginal atrophy and sexual dysfunction.

Vaginal atrophy refers to soreness and inflammation caused by thinning and shrinking of vaginal tissues, as well as decreased lubrication. The condition can make intercourse painful and lead to bleeding afterward.

"We bring levels of DHEA higher and by doing that, the sexual function comes back to normal," said Labrie, who has been doing research on the topic for 19 years.

He noted that 75 per cent of post-menopausal women - more than 360 million women worldwide and 4 million to 5 million in Canada - suffer from vaginal atrophy and could benefit from this new treatment.

The market could stretch into the billions of dollars, and Bayer said yesterday if all clinical studies are conclusive, the product could be commercialized within two to three years.

The company declined to say whether the compound would be produced in Quebec or in Canada.

The agreement does allow royalties for Endoceutics based on the sale of the treatment by Bayer.

Labrie, who published his findings earlier this year in the journal *Menopause*, stressed that his treatment is very different from other drugs in development designed to boost women's libido.

These drugs rely on hormones such as estrogen and have proven to have serious side effects, Labrie said.

"Our preparation, that we call an ovule, transforms locally into estrogen and androgens and these are not released into the blood," he noted, adding that unlike Viagra, Endoceptics's match for women is not a pill that is assimilated by the blood.

"It will eliminate all the risks and side effects that are associated with estrogens," he said.

The safety of hormone replacement therapy for menopause -formulated with estrogen -has been called into question after studies linked the treatment with an increased risk of stroke, heart attack and invasive breast cancers.

Labrie is confident that Vaginorm will receive approval from health authorities. He noted that earlier clinical trials have shown that the DHEA compound eliminated vaginal atrophy within one week of use without side effects.

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