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Starpharma readies U.S. NDA for Vivagel on positive phase III results in bacterial vaginosis

By Tamra Sami
Staff Writer

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PERTH, Australia – Melbourne-based biotech Starpharma Ltd [2]. expects to file its rolling NDA with the FDA in the next month following positive phase III results for Vivagel BV [3] for preventing recurrent bacterial vaginosis.

Starpharma CEO Jackie Fairley told *BioWorld* that Vivagel met the primary endpoint as well as five secondary endpoints for reducing recurrent bacterial vaginosis (rBV) in two pivotal trials.

The placebo-controlled trials enrolled 1,223 women who had a history of rBV and were randomized to use either Vivagel or placebo gel on alternate days for 16 weeks. A history of rBV was defined as at least three episodes of BV in the preceding 12 months.

In the U.S. trial, the rate of BV recurrence at week 16 was 44.2 percent in the Vivagel group compared to 54.3 percent in the placebo group. In the European trial, the rate of BV recurrence at week 16 was 15.7 percent.

Fairley noted that recurrence is higher among African-American and Hispanic women, and that was the main reason for the higher rates of recurrence in the U.S. trial. She said that any patients who failed to attend the week 16 visit were treated as if they had a recurrence.

BV is the most common cause of vaginal infection for women of childbearing age and can lead to infertility and premature birth delivery, and women with BV are more susceptible to HIV and other sexually transmitted infections.

BV is currently treated with antibiotics such as metronidazole, clindamycin and tinidazole, but existing treatments have low cure rates, high rates of recurrence and high levels of bacterial resistance.

Vivagel is an antimicrobial dendrimer formulated as a water-based gel and delivered vaginally. It inhibits biofilm, the mechanism that causes the BV condition and, unlike antibiotics, isn't absorbed into the bloodstream.

The FDA granted Vivagel fast track designation and qualified infectious disease product status, which allows five additional years of market exclusivity.

No option for recurrent BV

"One-third of the U.S. population has BV," Fairley said, "and roughly 50 percent to 60 percent of those have it recurrently, and women have nothing they can use to prevent the recurrence. The only therapeutic option they have is to take antibiotics repeatedly."

She said the unmet need for recurrence is quite high, and key opinion leaders "reported situations where patients were treated with multiple treatments of metronidazole with little success but had immediate success with Vivagel." She added that metronidazole has numerous side effects and is a carcinogenic, so "Vivagel presents an opportunity to have something that is not an antibiotic and not absorbed into the bloodstream."

The company is submitting a rolling NDA for both indications of treatment of BV and preventing recurrence of BV under a special protocol assessment with the FDA, Fairley said. She anticipates approval in six to eight months. The company had earlier announced positive results for treatment of BV, and that data package will be submitted first, with the recurrence of BV indication following on its heels, the CEO said.

Vivagel is approved in the EU for treatment of BV, and the company will file for the additional indication of recurring BV with the new data, Fairley said. Marketing applications have been filed in other markets using the EU data, including Australia. The product has not yet been launched, and Starpharma is in numerous partnering discussions in different geographies.

The underlying technology is built around dendrimers – a type of synthetic nanoscale polymer. Starpharma has two core development programs: its Vivagel portfolio and its DEP drug delivery portfolio.

Starpharma has signed a license agreement with Aspen Pharmacare Australia Pty for marketing Vivagel BV in Australia and New Zealand. It has separate license agreements with Ansell Ltd. globally, Okamoto Industries in Japan, Shenyang Sky and Land in China, and Koushan Pharmed Co. in Iran to market a Vivagel condom. The company claims the Vivagel condom is the world's first antiviral condom.

The Vivagel condom has been shown to inactivate up to 99.9 percent of HIV, HPV and HSV-2 and provide "near complete" protection against the Zika virus, Starpharma said.

Enhancing existing drugs

The other major part of Starpharma's business is its DEP drug delivery platform using its dendrimer scaffold to enhance existing drugs. The most advanced of those is DEP

docetaxel, a dendrimer-enhanced version of docetaxel, which is in phase I trials in solid tumors.

Because the dendrimer is larger than the small-molecule drug, by attaching to the dendrimer, the drug accumulates in the tumor for a more targeted effect, Fairley said. "We're also able to get improved pharmacokinetics because you get a larger area under the curve, so larger tissue exposure."

Starpharma has a partnership with Astrazeneca plc for the use of its DEP drug delivery platform for developing and commercializing a number of Astrazeneca oncology compounds.

"All of the drugs we've looked at, including Astrazeneca's drugs, are more efficacious with less toxicity when you put them on a dendrimer."

She explained that when the drug is bound to the dendrimer, it's like a prodrug and is less toxic.

The company's market cap is roughly A$270 million (US$213 million). Starpharma shares on the Australia Stock Exchange (ASX:SPL; OTCQX:SPHRY) were up 10.5 percent to A84 cents on the clinical trial news.

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