starpharma

SHAREHOLDER Update

DECEMBER 2012

IN THIS ISSUE

Phase 3 clinical trial results for treatment of bacterial vaginosis

Starpharma recently announced the results of its phase 3 studies of VivaGel® for treatment of Bacterial Vaginosis (BV). The studies demonstrated that use of VivaGel®, once daily for seven days, resulted in a statistically significant cure of the clinical signs of BV (Clinical Cure) compared with the placebo gel, and superior effectiveness in treating the patient symptoms of BV at the end of treatment (EOT). However, the primary endpoint of the studies as required by the US Food and Drug Administration (FDA), of Clinical Cure 2-3 weeks after the last dose of product – at Test of Cure (TOC) – was not met. As a result a new drug application (NDA) for BV treatment will not be filed with the FDA at this time.

However, given the clear-cut efficacy shown for VivaGel® at the EOT time point, the excellent and sustained symptomatic relief reported by women using VivaGel®, and its superior acceptability profile, the company is actively exploring alternative claim strategies, such as symptomatic relief, and also other regulatory jurisdictions.

Nearly 500 women participated in the two concurrent clinical trials held at 30 international sites. When assessed by a clinician 2 to 5 days after cessation of treatment with VivaGel® (1% SPL7013), vaginal discharge was resolved in 71% and 74% of women (statistically significant versus placebo, $p<0.001$) in each of the trials.

Vaginal odour, as assessed by the clinician, was resolved in 72% and 70% of women ($p<0.001$) at the EOT assessment, while 76% and 72% of participants reported resolution of unpleasant vaginal odour ($p<0.001$).

The results of these studies, including the statistically significant Clinical Cure, resolution of patient symptoms of BV, and an excellent safety profile, at the EOT assessment shortly after stopping use of the product, strongly support the prevention of BV recurrence indication for VivaGel®. The phase 2 trial of VivaGel® for the prevention of BV recurrence, which is assessing the effectiveness of ongoing use of VivaGel® on the rate of BV recurrence, remains on track. Results are anticipated in Q1 2013.

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"The prevention of BV recurrence market is estimated to be around $1 billion – there are no approved products and VivaGel® would be first in class. Partner interest in the prevention of recurrence indication continues to be very strong."

Starpharma CEO, Dr Jackie Fairley.

Data supports prevention of recurrence of BV

The larger prevention of recurrence market opportunity for VivaGel® is not negatively affected by these recent Phase 3 results but is in fact supported by the findings. In addition, the trial design and endpoints for that indication are quite different. In particular, in the prevention trial there is no equivalent of the TOC assessment as the study involves continued usage of the product every second day for the whole assessment period. In contrast, the Phase 3 TOC endpoint effectively required the product to maintain its cure for a further 2-3 weeks after cessation of dosing (and in spite of potential for re-infection having occurred).

Both market estimates and the majority of potential licensing partners have emphasized the value and importance of prevention of recurrence of BV indication.

Formal patient acceptability research undertaken at the end of the phase 3 trials was also very positive for VivaGel® with those women treated with the product reporting rapid and sustained relief from symptoms.

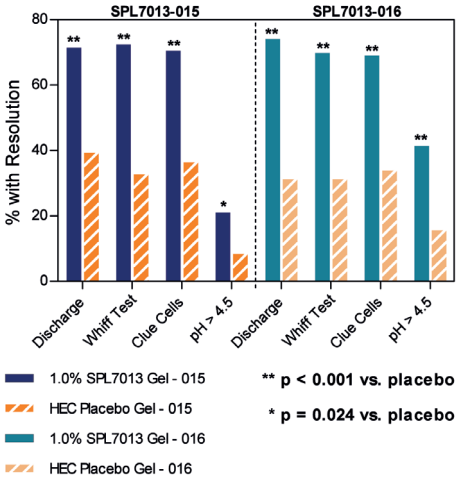
The phase 3 study results also have no negative implications for the condom coating products, as the marketing claims being pursued for condoms relate to the potent antiviral activity of SPL7013, the active dendrimer ingredient in VivaGel®.

VIVAGEL®

›› Phase 3 clinical trial results for treatment of bacterial vaginosis (continued from page 1)

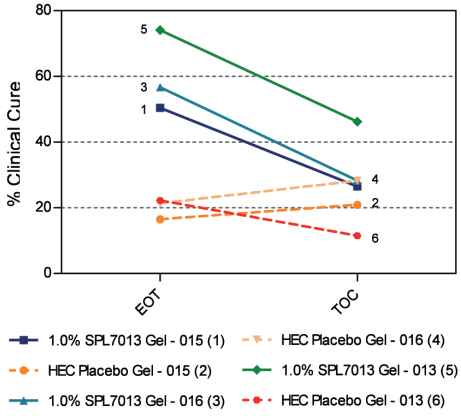
As shown in the graph (below) highly statistically significant resolution of symptoms (referred to as resolution of Amsel criteria) was achieved with 1% SPL7013 Gel (VivaGel®) compared with the placebo. The Amsel criteria are used to quickly diagnose bacterial vaginosis. These criteria require at least three findings (vaginal discharge, a vaginal pH greater than 4.5, a positive "whiff" test, or a saline wet preparation that microscopically shows clue cells).

RESOLUTION OF AMSEL CRITERIA AT EOT



In the graph (below) Placebo Clinical Cure rates behaved differently in the phase 3 compared with expected and actual Phase 2 results. The potential factors include changes in behaviour such as increased sexual activity, alternative therapy, differences between sites).

CLINICAL CURE IN PHASE 2 (013) AND PHASE 3 (015 AND 016)



VIVAGEL®

›› Rapid resolution of symptoms; strong patient acceptability for VivaGel®

With any new pharmaceutical, a critical success factor is the likelihood of patient uptake and acceptability. One of the many positive elements in the phase 3 BV treatment trials was the statistically significant, very rapid and sustained, resolution of patient symptoms for the majority of women in the VivaGel® arm of the study. This factor is considered to account for the high acceptability rating

The following are real excerpts from the user research undertaken:

It takes a lot away from your self-esteem, you know, especially when you're in a relationship because it's just not pleasant all the way around… it's really uncomfortable, and it kind of brings down your self-esteem a little bit and makes you feel inadequate at times… BV SUFFERER

And then I think it pretty much started to go away right when I started to use it. My symptoms weren't – I wasn't irritable and itchy and irritated. My second day I could tell it was working.

VIVAGEL® USER

Like I said, I thought it was effective 'cause within the first day I noticed a change already. It was like gone almost overnight. No itching, no discharge.

VIVAGEL® USER

I've been going through bacterial vaginosis for a few years now. On and off, on and off, it comes it goes, it comes it goes… and I have it now, a whole headache, dealing with it… BV SUFFERER

women gave VivaGel® in post-treatment formal market research that was undertaken.

Bacterial vaginosis is an insidious condition that is difficult to treat, and both the disease itself and the symptoms it causes can have a very significant impact on a woman's health and wellbeing, particularly for the many women who suffer from recurring infections.

The Metronidazole pills upset my stomach. Yeah, that was one thing I did have to deal with as well was an upset stomach. I also dealt with a hives breakout from oral Metronidazole. So I just dealt with, and I dealt with it, and I just kept popping Benadryl, Benadryl, and Benadryl, and you know, I never put two and two together until I really like just paid attention, but it had been like 10 years later, you know? I had been dealing with the hives.

METRONIDAZOLE USER

The next day I noticed a huge difference. And I told her that when I saw her, like, it's actually working already. VIVAGEL® USER

DRUG DELIVERY

Taxotere's anti-cancer effect boosted with Starpharma's dendrimer technology

Starpharma's dendrimer-enhanced version of docetaxel had significantly superior anti-cancer effects across a range of the most common cancer types when compared to Taxotere® (the commercial product name for docetaxel), latest pre-clinical trials have shown.

Earlier this month, the company announced the results of studies which tested its dendrimer-enhanced version of docetaxel in breast, prostate, lung and ovarian tumour types.

It was seen to significantly outperform the off-patent Taxotere® in each tumour type, expanding on the result of studies announced earlier this year which had focussed solely on breast cancer. If the dendrimer formulation's superiority to Taxotere® across these cancers is maintained in the clinic, then it could have very wide application, benefiting many more cancer patients and providing an expanded commercial opportunity for Starpharma.

Docetaxel is a leading chemotherapy drug used to treat a wide range of tumours including breast, lung, ovarian and prostate. The original formulation is commercially registered as Taxotere® and marketed by Sanofi Aventis with sales in excess of US$1 billion in 2011 and more than $3 billion prior to its patent expiry.

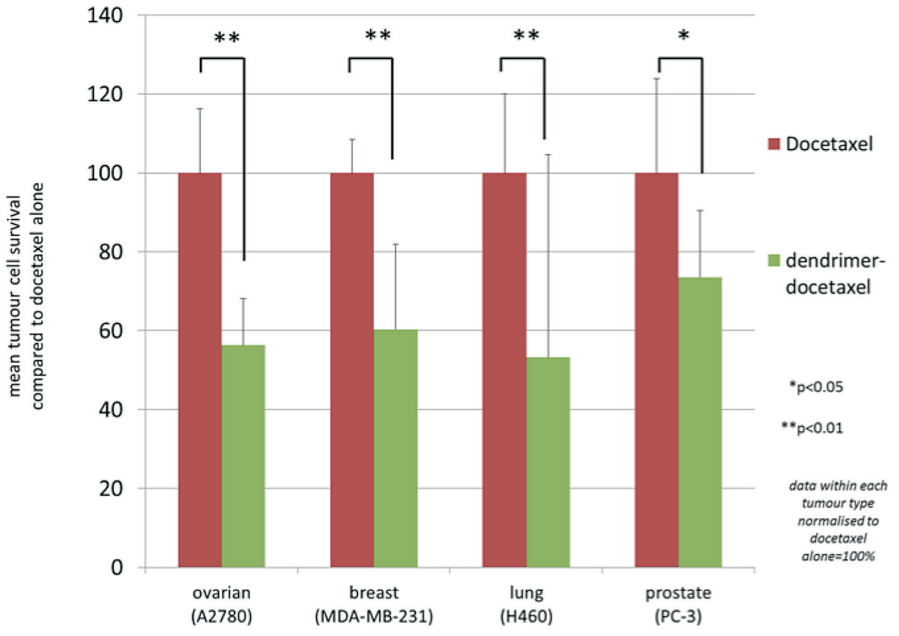
The dendrimer-enhanced version of docetaxel is a major element of Starpharma's internal drug delivery program, which runs in parallel with the partnered program.

Anti-cancer collaboration signed with AstraZeneca

In September, the company also announced the signing of an agreement with global pharmaceutical company AstraZeneca. Under the agreement, AstraZeneca will undertake oncology studies using specific Starpharma drug-dendrimer molecules within the cancer field.

Starpharma's partnering model continues to be a very effective strategy to progress multiple potential product lines. Starpharma now has partnerships with five of the world's major pharmaceutical companies and has signed agreements for the agrochemical use of dendrimer technology with more than half of the top 10 leading crop protection companies globally.

(COMPARATIVE) ANTI-TUMOUR EFFICACY– DENDRIMER-DOCETAXEL V'S TAXOTERE®



Above: Starpharma's dendrimer-docetaxel formulation showed a significantly superior tumour cell killing effect compared to Taxotere® (docetaxel) alone over several test cancer types. (N=6 for each bar)

AGROCHEMICALS

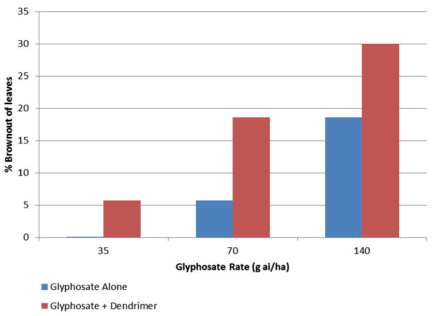
Turning over a new leaf in the world of agrochemicals

In October, Starpharma reported additional positive results from its internal program of testing the way leading agrochemicals can be improved using Starpharma's dendrimer technology.

Latest tests confirmed earlier results which showed a dendrimer-version of the herbicide glyphosate (sold as Roundup®) had higher efficacy than conventional glyphosate.

ENHANCED EFFICACY

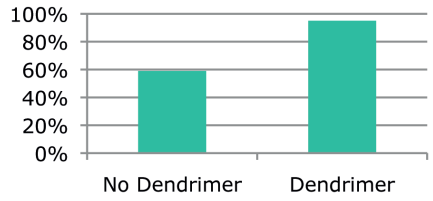
Glyphosate only (blue) or Glyphosate with Starpharma Priostar Dendrimer



Not only that, the dendrimer version was also more "rain-fast" showing a 150% to 250% improvement in efficacy compared to conventional glyphosate when "rain was applied four hours after treatment".

IMPROVED RAIN-FASTNESS

Retention of Effect: rain at 4 hours



Glyphosate has global sales of approximately US$5 billion annually and as an off-patent chemical it represents a huge opportunity for enhanced formulation in the US$44 billion agrochemical market.

AGROCHEMICALS

Crop Protection deal signed with Nufarm

In August, a deal was signed that will see Starpharma's Priostar® dendrimer technology used to develop innovative crop protection formulations within Nufarm's product portfolio, in another sign of the company's burgeoning agrochemical program.

Lachlan McKinnon, Nufarm Australia's General Manager said: "This collaboration with Starpharma reflects Nufarm's renewed emphasis on technological innovation. We are seeking innovative ways to differentiate our products so that growers are offered a wider range of control options tailored to their particular needs."

Starpharma wins Janssen Company of the Year Award

Starpharma was last month named the Janssen "Company of the Year" at Australia's annual gathering of the biotechnology and life sciences sector.

From left to right:
Janssen-Cilag MD Chris Hourigan, Starpharma VP Business Development Malcolm McColl, Janssen Senior Manager, Innovation and Investment, ANZ Kathy Connell, Starpharma CEO Jackie Fairley, Starpharma CFO Nigel Baade, Starpharma VP, Development and Regulatory Affairs Jeremy Paull, Starpharma Company Secretary Ben Rogers at the Janssen Industry Excellence Awards

2012 A YEAR OF KEY ACHIEVEMENTS

- THE COMPLETION OF TWO CONCURRENT PHASE 3 CLINICAL TRIALS OF VIVAGEL® AS A TREATMENT FOR BACTERIAL VAGINOSIS (BV)
- A PHASE 2 CLINICAL TRIAL OF VIVAGEL® USED AS A PREVENTIVE AGAINST BV RECURRENCE FULLY RECRUITED WITH RESULTS EXPECTED NEXT YEAR
- A DEAL THAT WILL SEE STARPHARMA'S DENDRIMER TECHNOLOGY USED TO DEVELOP INNOVATIVE CROP PROTECTION FORMULATIONS FOR NUFARM'S PRODUCT PORTFOLIO
- A DEAL ALLOWING GLOBAL PHARMACEUTICAL COMPANY ASTRAZENECA TO TEST WHETHER STARPHARMA DENDRIMER MOLECULES COULD ENHANCE THE EFFECTIVENESS OF EXISTING CANCER DRUGS. COLLABORATION WITH LILLY EXPANDED
- IMPROVED EFFICACY AND SIGNIFICANT TUMOUR-TARGETING RESULTS WITH STARPHARMA'S PROPRIETARY DENDRIMER-DOCETAXEL FORMULATION ACHIEVED
- A NEW DENDRIMER-GLYPHOSATE FORMULATION WHICH DEMONSTRATED IMPROVED EFFICACY AND RAIN-FASTNESS ACHIEVED

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