starpharma

SHAREHOLDER Update

JUNE 2014

IN THIS ISSUE

VivaGel® BV prevention of recurrence: start of phase 3 trials close

Final preparations are underway for the imminent commencement of two pivotal Phase 3 clinical trials of VivaGel® for the prevention of recurrent BV (bacterial vaginosis). Quintiles, a leading global clinical research organisation (CRO) has been appointed and many study preparations, including site identification and engagement, are now either complete or significantly advanced.

Through meetings with the US Food and Drug Administration (FDA) and Scientific Advice from the European Medicines Agency (EMA), Starpharma has reached agreement with the regulators on the design of the Phase 3 trial program. Initial ethics committee approval has also been obtained.

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The phase 3 trial program will comprise two identical trials, each enrolling approximately 600 women at sites in North America, Europe, and Asia. Women will receive 1% VivaGel® or placebo gel. The primary efficacy end point is recurrence of BV over the 16 week treatment period.

There are no approved products for the prevention of recurrent BV, a market estimated to be worth in excess of US$1 billion. The previous Phase 2 trial for prevention of recurrent BV – an exploratory study in 205 US women (VivaGel® vs. placebo) – showed 1% VivaGel® reduced recurrent BV and delayed time to first recurrence. More than 80% of 1% VivaGel® users remained BV free at 16 weeks and the product provided protection against the occurrence of BV symptoms, which include unpleasant vaginal odour and discharge.

R&D tax incentive cash received

Starpharma has received a refund of $4.7 million under the R&D tax incentive for activities undertaken during the 2012-13 financial year.

The R&D tax incentive allows Starpharma to confidently advance development of its proprietary products including the clinical programs for VivaGel® and DEP™ docetaxel. It also supports the conduct of the DEP™ docetaxel clinical trial in Australia with the additional benefit that Australian patients are the first in the world to have access to Starpharma's improved version of the widely used cancer drug, Taxotere®.

Starpharma released its Appendix 4C cash flow summary on 30 April, which reported a cash balance of $27.8 million at 31 March.

DRUG DELIVERY

DEP™ docetaxel clinical trial progressing well

The Phase 1 clinical trial of Starpharma's chemotherapeutic product, DEP™ docetaxel, is underway and progressing well with the first patients enrolled in the dose escalation phase of the trial, with some having already received multiple cycles of therapy. In this trial phase, patients receive increasing doses of DEP™ docetaxel. Results so far indicate very good tolerability for DEP™ docetaxel with no evidence of neutropenia to date. Neutropenia (a low white blood cell count) is one of the most important dose-limiting side effects of standard formulations of docetaxel such as Taxotere® and other forms of chemotherapy.

Approximately 25-30 patients with solid tumours will be enrolled in the trial which has commenced at Nucleus Network in Melbourne. Two additional trial sites, Austin Health/Olivia Newton-John Cancer & Wellness Centre and Royal Brisbane & Women's Hospital (RBWH) have recently received ethics committee approval and will be enrolling patients shortly.

The primary objective of the clinical study is to establish the maximum tolerated dose and dose limiting toxicities of DEP™ docetaxel given intravenously, once every three weeks. The secondary objective is to identify the safety, pharmacokinetic and tolerability profile of DEP™ docetaxel in patients with advanced cancer.

The study will also investigate the impact of the improved dendrimer formulation on problematic side effects seen with Taxotere®, such as neutropenia, which was markedly reduced with the dendrimer formulation in pre-clinical studies, anaphylaxis and hair loss.

DEP™ docetaxel is Starpharma's dendrimer enhanced version of the major chemotherapeutic agent, docetaxel, which is marketed worldwide by Sanofi Aventis under the trade name Taxotere®. Used to treat a wide range of solid tumours including breast, lung and prostate, Taxotere® generated sales in excess of US$3 billion in 2010.

Earlier pre-clinical studies of DEP™ docetaxel demonstrated its significantly superior anti-cancer effectiveness compared to Taxotere® across a range of important cancer types including breast, prostate, lung and ovarian cancer. In addition, DEP™ docetaxel exhibited a lack of the dose-limiting and severe toxicity, neutropenia, which is the most important dose-limiting side effect of Taxotere®.

Application of Starpharma's DEP™ technology to this drug has also improved the water solubility of docetaxel. This improvement has allowed the omission of the detergent, polysorbate 80, from DEP™ docetaxel's formulation. Polysorbate 80 is toxic and can cause life threatening anaphylaxis. It is a necessary inclusion in Taxotere® and other marketed formulations of docetaxel (but not DEP™ docetaxel). The serious nature of anaphylaxis means that Taxotere® and other marketed formulations of docetaxel must carry a "black box" FDA warning. The presence of polysorbate 80 also necessitates the pre-treatment of patients with steroids, which cause additional side effects. This pre-treatment with steroids has not been required in patients receiving DEP™ docetaxel. This creates another advantage for patients receiving DEP™ docetaxel because they avoid steroid pre-treatments which are associated with side effects such as insomnia, mood changes, fluid retention and worsening of diabetes.

Key outcomes of the study will inform a recommended dose for future studies as well as exploring the preliminary anti-tumour efficacy of the product. The study will also employ a variety of imaging techniques and specific investigations aimed at exploring anti-tumour efficacy. These include CT scans and bone scans, as well as tumour markers.

Oncology agreement with AstraZeneca expanded

A second, expanded agreement with AstraZeneca in the field of cancer medicine using Starpharma's proprietary DEP™ technology is a strong validation of the interest in the Company's drug delivery technology.

The agreement follows an earlier agreement with AstraZeneca to access Starpharma's delivery technology. The new agreement will see the application of Starpharma's technology to a cancer drug, from AstraZeneca's pipeline.

"As a leading discovery-led company this alliance represents an exciting collaboration with an Australian-based company to combine the oncology treatments of tomorrow that AstraZeneca is developing using innovative delivery mechanisms," said Mark Fladrich, Managing Director, AstraZeneca Australia.

Under the new agreement, AstraZeneca will provide funding for a pre-clinical stage cancer research program to be conducted jointly.

VIVAGEL®

›› VivaGel®-coated condom: preparing for launch

Okamoto Industries, Starpharma's exclusive marketing partner for the VivaGel®-coated condom in Japan, has received regulatory certification ahead of launch of this innovative product. Japan is the world's second largest condom market.

"This receipt of the world's first marketing approval for a VivaGel®-coated condom in Japan marks a major milestone for this product, our company and for our strategically important partnership with Okamoto," said Starpharma Chief Executive Officer, Dr Jackie Fairley.

Okamoto is Japan's leading marketer of condoms with approximately 60% share of the Japanese condom market. The value of the Japanese condom market has been estimated to be around US$500 million.

Okamoto's senior Managing Director Mr Seiji Takeuchi said earlier this year that condoms with functional coatings and gels represent the next wave of innovation in the Japanese condom market following on from a decade-long focus on condom thinness.

"We are very pleased to be in a partnership with Starpharma for this product," Mr Takeuchi said following the announcement of certification for a VivaGel®-coated condom.

Okamoto, based in Tokyo, has total revenues of more than US$740 million and over 1,500 employees.

Starpharma will receive an ongoing royalty based on the sale of these VivaGel®-coated condoms.

Starpharma also has a separate licensing agreement with Ansell Limited that provides marketing rights to a VivaGel®-coated condom in countries outside Japan. The company is also working closely with Ansell on pre-launch activities ahead of regulatory approval in other jurisdictions under that partnership. These pre-launch activities include final packaging and preparations for public relations activities.

Extensive market research confirms strong consumer interest

Consumer research for the VivaGel®-coated condom has now been conducted in more than 1800 condom users from markets which include the US, Europe, Asia and South America. This work adds to the previous positive market research undertaken during the development phase of the VivaGel®-coated condom.

The latest research was conducted by a leading European firm highly experienced in condom research. Participants were aged between 18 and 54 with an equal split of men and women in each market. Most participants were in a monogamous relationship and had never suffered from a sexually transmitted infection.

The research results support the concept that a VivaGel®-coated condom will have broad applicability and strong consumer appeal and the findings will inform the marketing materials and launch activities. The research showed the product concept performs very well and compares favourably against other product concepts in that market. In particular, the VivaGel®-coated condom scored at the top end of the scale for 'likelihood to buy' and scored 'outstanding' with respect to being 'new and different'.

Other findings of the consumer research include:

- More than 80% of participants rated the VivaGel®-coated condom as very interesting and more than 90% said they would buy it;
- There was very little difference between men and women with a high 'likelihood to buy';
- There was little difference in opinion and acceptance of the VivaGel®-coated condom by age group and relationship status.

This consumer feedback confirms the consumer research already undertaken by Starpharma that showed strong interest in a condom with a coating to inactivate STIs.

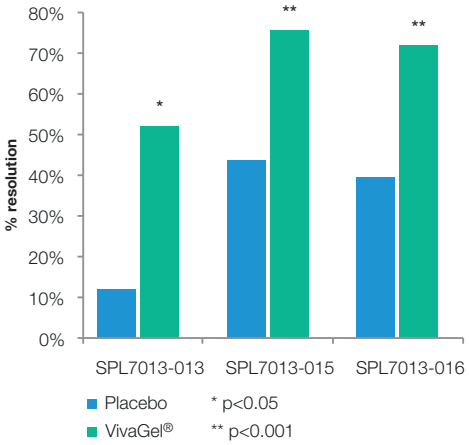
"The level of interest in the condom is very high and likelihood to buy remains high even when positioned as "not available with your current brand", supporting the ability of the VivaGel®-coated condom to generate brand switching behaviour," said CEO Jackie Fairley.

VIVAGEL®

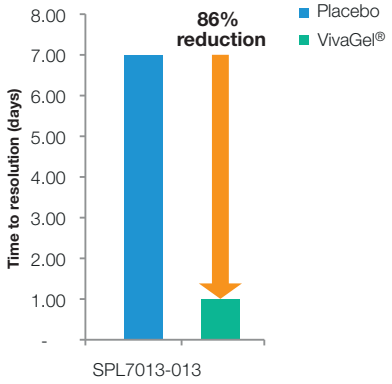
VivaGel® BV symptomatic relief product: commercial and regulatory progress

Strong clinical data and high levels of patient demand for a product to treat the symptoms of BV underpin Starpharma's strategy to seek regulatory approval for VivaGel®, with a claim of symptomatic relief in multiple geographies in parallel with ongoing commercial partnering discussions. The regulatory documentation for this product is currently being prepared ahead of submission in the second half of calendar year 2014. This short term use of VivaGel® in BV is an additional application to that of prevention of recurrence which will commence Phase 3 trials shortly.

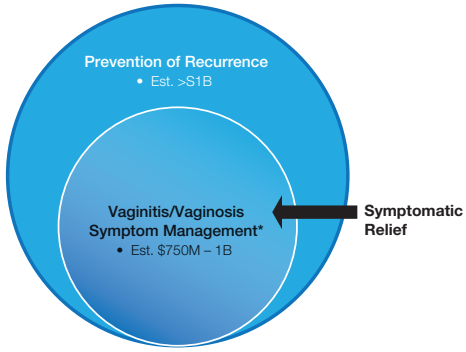
Starpharma's VivaGel® has already demonstrated statistically significant clinical cure and effectiveness in treating symptoms of BV across multiple clinical trials when measured at the end of treatment.



VivaGel® consistently provided statistically significant results replicated in three separate VivaGel® trials (SPL7013-013, 015, 016) showing greater odour resolution as compared to placebo.



Time to resolution of odour showed that VivaGel® resolved odour in 1 day, compared to 7 days for placebo.



Market research suggests odour is one of the most bothersome symptoms for women suffering BV. Results from the company's clinical trials showed VivaGel®, when applied once a day for seven days, offered patients both rapid resolution and sustained relief from odour. Patients reported an improvement as quickly as one day following application. They also noted VivaGel® performed better than other products.

Market research in BV patients has also shown a high patient acceptance and desire to purchase and use VivaGel® once it is available to the market.

The market for management of BV symptoms is estimated to be between US$750 million and US$1 billion annually. Currently available products have limited efficacy with little or no clinical evidence to support their effectiveness.

AGROCHEMICALS

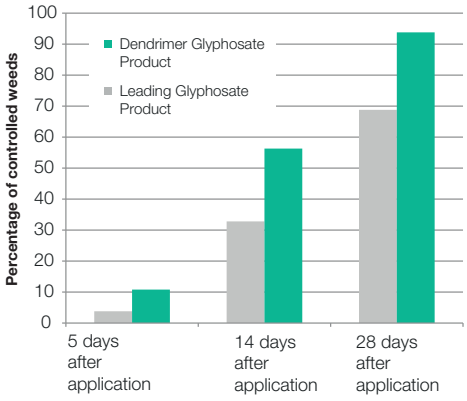
Strong results for dendrimer-enhanced agrochemicals

Starpharma has completed further field trials demonstrating the effectiveness of its dendrimer technology when applied to glyphosate. Results from the latest field trials show that Starpharma's dendrimer enhanced glyphosate formulations are more effective on hard to control weeds than marketed glyphosate alone. Glyphosate is currently sold under a number of brands, including Roundup®.

The trials saw two key benefits: faster evidence of effect and better overall effectiveness with the dendrimer formulation across a number of weed species. For example certain hard to kill weeds showed more than a 30% survival rate with commercial glyphosate, but averaged less than 10% survival with the dendrimer-enhanced formulation.

In addition, the Starpharma formulations showed three to four times as much visible effect five days after application, giving growers reassuring feedback that the formulation is working effectively.

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



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