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# SHAREHOLDER Update

OCTOBER 2014



**DRUG DELIVERY**

## ›› Encouraging clinical data for DEP™ docetaxel

Encouraging early data has been seen in the DEP™ docetaxel Phase 1 trial both in terms of tolerability and activity.

Patients in the Phase 1 trial are currently being enrolled in the dose escalation phase with a number having now completed multiple cycles of treatment. This is an open label study (an unblinded clinical study where all patients receive treatment with DEP™ docetaxel) of the drug allowing progressive results to be evaluated.

Despite not having yet reached the maximum tolerated dose (MTD) in the study, a number of patients treated with DEP™ docetaxel have exhibited potential anti-cancer activity with one exhibiting stable disease over many weeks. This is an encouraging sign especially given the doses are lower than the MTD.

In addition, DEP™ docetaxel has been well tolerated to date. No neutropenia (a low white blood cell count) or hair loss has been observed so far.



The expansion phase of the study will follow once the MTD is determined. This expansion phase provides opportunity for dosing of multiple patients at the MTD level.

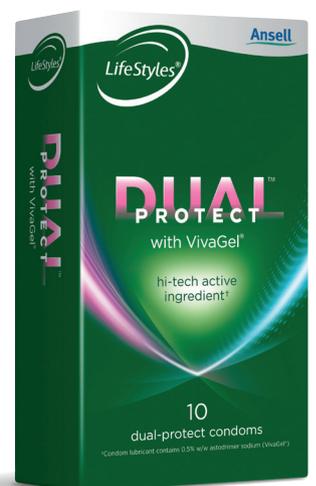
Dr Jackie Fairley, Starpharma CEO said: "It is very encouraging to see such good tolerability and signs of potential anti-cancer activity with DEP™ docetaxel below the maximum tolerated dose. Whilst in the early stages of this trial, it is also very positive to see that the patients treated so far have shown no signs of neutropenia, the most important, dose-limiting side effect of docetaxel."

**VIVAGEL®**

## ›› VivaGel® condom approved for sale in Australia – Launch imminent

Starpharma recently announced that the VivaGel® condom has been included in the Australian Register of Therapeutic Goods (ARTG). This inclusion is the final step before the market launch in Australia by Starpharma's partner Ansell.

The antiviral VivaGel® condom will be marketed under the LifeStyles® brand as the Dual Protect™ condom with VivaGel®, and will be available in Australian retail outlets including Woolworths from October. The VivaGel® condom is a world-first product based on an Australian innovation. It is the only condom which incorporates the additional benefit of an antiviral lubricant.



**DEP™ docetaxel benefits**

<b>Improved efficacy</b>	Higher level of docetaxel delivery preferentially to the tumour Longer duration of effect leading to higher tissue exposure
<b>Improved side effects and safety</b>	No neutropenia – Avoids risks & need for expensive rescue therapies (including GCSF) and hospitalisation  No detergent (polysorbate 80) required for solubilisation – Avoids potentially fatal toxicities of polysorbate 80 and does not require cortisone pre-treatment

›› continued on page 2



## >> VivaGel® condom approved for sale in Australia – Launch imminent (continued from page 1)

LifeStyles® Dual Protect™ condoms will also carry the VivaGel® brand and Starpharma will receive royalties based on sales.

“We are very pleased with the achievement of this final milestone ahead of launch. It is the result of working closely with Ansell on the preparations for product rollout”, said Starpharma CEO, Dr Jackie Fairley.

*“Ansell looks forward to the imminent launch of this innovative product, with LifeStyles® Dual Protect™ condoms expected on retail shelves in Australia in October.”*

Chris Kalaitzis, Ansell VP of Sales and Marketing for Asia Pacific

Following the earlier announcement of the TGA Certification for the VivaGel® condom, there was a high level of traditional and social media coverage. There was a very strong level of interest in the VivaGel® condom with the news reaching more than 10 million people via social media in the days after the announcement. This overwhelmingly positive media sentiment is in keeping with the strong consumer appeal identified in formal market research, which confirmed strong interest and purchase intent across genders and age brackets.

International market research of the VivaGel® condom was conducted with 1800 condom users which showed 85% of condom users overall (82% men and 88% of women) were interested in the product.

The launch of the LifeStyles® Dual Protect™ condom is the first marketed product for Starpharma’s VivaGel® franchise, and the first of three women’s health and sexual wellness VivaGel® products that are in various advanced stages of development and commercialisation.

**International consumer research of the VivaGel® condom confirms strong interest and purchase intent – Strong consumer interest was seen across genders, ages and relationship status.**

	TOTAL			18-30 years	31-40 years	41-50 years
<b>Level of interest*</b>	<b>85%</b>	<b>88%</b>	<b>82%</b>	<b>87%</b>	<b>86%</b>	<b>82%</b>

\* Percentages as shown are scores from respondents that said they were “very interested” or “interested” in the condom.

*“I would buy this product right now if I could ...”*

*“I like the idea of a condom doing more for us than just being a barrier ... seems more reassuring to know it’s doing extra”*

*“I would definitely buy this product without a shadow of a doubt ...”*

VivaGel® Condom Consumer Research

*“I think that this product is amazing ... This product is very special and interesting.*

*“I have rated this product a 5/5 as this is a major breakthrough in the condom market and for world health ...”*

VivaGel® Condom Consumer Research

### Social Media Coverage



> 2,000 Tweets;

Twitter  
Google  
Facebook  
YouTube  
News Sources

2,196 mentions reached  
10,213,793 potential audience

AUDIENCE



> 83,000 Likes;  
shared > 18,000 times

At last count the VivaGel® condom had featured on Twitter more than 2,000 times as well as on Facebook, Tumblr and YouTube. It has also featured on the very popular IFL Science website where it gained more than 83,000 “likes” and was shared a further 18,000 times.



## >> VivaGel® for BV: SPA agreement for Phase 3 Recurrent BV trial and commercialisation activities for Symptomatic Relief

### Recurrent BV

In July, the US Food and Drug Administration (FDA) granted Special Protocol Assessment (SPA) agreement on the design and planned analyses of the Phase 3 clinical studies of the VivaGel® bacterial vaginosis (BV) product for the prevention of recurrent BV (R-BV).

This favourable SPA outcome provides a binding agreement from the FDA that the Phase 3 clinical study design, endpoints, statistical analyses and other aspects of the planned studies adequately address objectives in support of a US regulatory submission for approval of the product.

Starpharma CEO, Dr Jackie Fairley said: "Receiving agreement on the SPA is an important and very positive development as it effectively eliminates the US regulatory risk associated with clinical development by specifying upfront the FDA's agreed trial design."

"SPA agreement from the FDA is protected by US law and gives Starpharma certainty and confidence that the studies will support a regulatory submission for the approval of VivaGel® for the prevention of R-BV in the US."

The granting of SPA agreement by the FDA follows earlier agreement by

the European Medicines Agency (EMA) on the design of the Phase 3 trials.

Starpharma has since commenced its two pivotal Phase 3 clinical trials of VivaGel® for the prevention of R-BV at sites in North America, Europe, Asia and Latin America. The two Phase 3 double-blind, randomised, placebo-controlled trials are identical in design and will compare the rate of BV recurrence in women using VivaGel® to the rate of recurrence in women using a placebo gel during a 16-week treatment period. Approximately 600 women will be recruited into each study.

There are no approved products for the prevention of R-BV, a market estimated to be worth in excess of US\$1 billion.

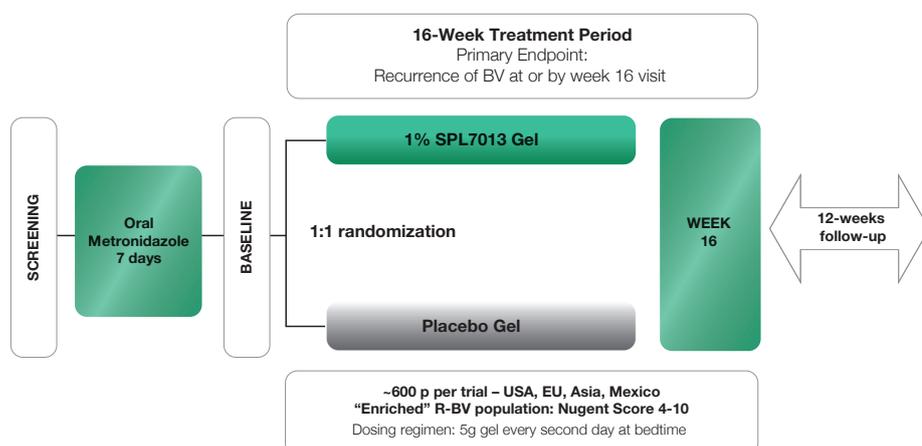
### Symptomatic Relief

Starpharma's VivaGel® has already demonstrated statistically significant clinical cure and effectiveness in treating symptoms of BV when assessed at the end of 7 days' dosing in multiple clinical trials.

Commercialisation activities are already underway for this product opportunity with regulatory dossiers in preparation for the VivaGel® for Symptomatic Relief BV product for submission in selected territories in the next few months. In parallel, Starpharma is now in active discussions with a number of companies pursuing marketing rights to the VivaGel® for the Symptomatic Relief BV product.

Formal market research with patients, clinicians and Key Opinion Leaders strongly supports the demand for a product such as VivaGel® in the management of BV.

### Recurrent BV Phase 3 Program Two double-blind, multi-centre, randomised trials



## >> Starpharma completes \$18M placement; launches \$5M SPP

In late September, Starpharma raised A\$18 million via a placement to international and domestic institutional, sophisticated and professional investors and plans to raise up to a further A\$5 million through a share purchase plan (SPP) currently underway.

The placement was significantly oversubscribed and saw strong demand from existing institutional shareholders as well as a number of new international and domestic funds.

The money raised will significantly strengthen the company's balance sheet allowing it to fund advancement of programs across all areas of the business including:

- >> Completion of Phase 3 trials of VivaGel® prevention of recurrence of BV;
- >> Commercialisation of VivaGel® for Symptomatic Relief of BV;
- >> Accelerating DEP™ docetaxel through completion of Phase 1 and into Phase 2;
- >> Completion of pre-clinical development for another DEP™ candidate; and
- >> Commercialisation of Agrochemical products.

The SPP offers all eligible Starpharma shareholders the opportunity to subscribe for a maximum of \$A15,000 worth of shares at \$A0.65, the same price as in the institutional placement and without brokerage costs.



**AGROCHEMICALS**

**>> Dendrimer-enhanced agrochemicals—strong results continue**

Starpharma's partnered agrochemicals programs continue to progress well with a number of dendrimer-improved formulations being the subject of international field trials by partners.

Active licence discussions are also underway with partners for dendrimer-improved agrochemical formulations based on Priostar® dendrimers.

Starpharma's internal programs have yielded commercially interesting findings in a number of product categories, including herbicides and fungicides. Extensive field trials of Starpharma's dendrimer-glyphosate formulation have been completed recently with a total of 16 weed species having been assessed in a number of regulatory-compliant field trials in Australia and overseas in 2013/14.

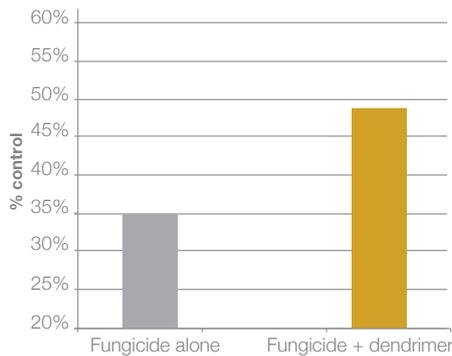
Starpharma's dendrimers-glyphosate formulation continues to show that it is more effective on hard-to-kill weeds than the comparable marketed glyphosate formulations and also exhibited faster



onset of effect. Glyphosate is currently sold under a number of brands, including Roundup® with global sales of approximately US\$5 billion annually.

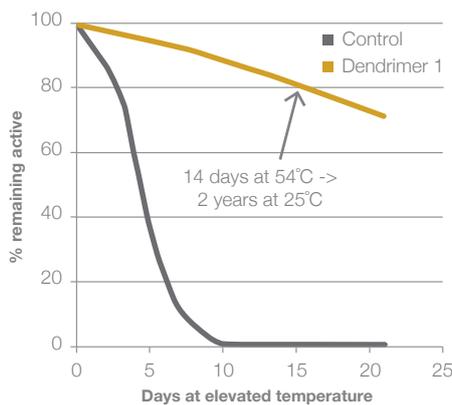
In addition, recent field trials have also shown that Starpharma's dendrimers enhanced the performance of a major currently marketed fungicide with the dendrimer version providing better systemic control of fungal infections than fungicide alone.

**Systemic control of fungal infection**



Data from another fungicide study shows that Starpharma's dendrimers also reduced degradation of the active ingredient thus providing the potential for a longer shelf life and/or a longer effect on plants. Both shelf life extension and prolonged effect have the potential to yield valuable product improvements.

**Protection of fungicide from degradation (Accelerated Testing at 54°C)**



**FINANCIALS**

**>> Full Year 2014 annual financial results**

Starpharma ended the 2014 financial year with important progress made across all three of its programs: VivaGel®, drug delivery and agrochemicals.

The company's cash position at the end of FY2014 was A\$24 million, while net cash burn for the period was A\$9.8 million. Starpharma posted a net loss of A\$14.6 million, up from the previous corresponding period. The loss increase was primarily due to VivaGel® and DEP™ docetaxel clinical programs in progress, and lower R&D tax incentive compared to FY2013. Financial year 2013 included A\$4.1 million of additional R&D tax incentive relating to FY2012 expenditure.

Key Financial Data	FY 2014 AUD \$M
Total revenue and income	1.3
R&D Tax incentive	4.2
Net loss after tax	(14.6)
Cash outflow from operations	(9.8)
Cash at 30 June	24.0

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**Forward Looking Statements**

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.