

SHAREHOLDER Update

MAY 2020

VIVAGEL® BV

>> VivaGel® BV launched in Asia

In February, VivaGel® BV was successfully launched in Asia under the brand name BETADINE™ BV Gel. The product has initially been launched in South East Asia, where it is now available over-the-counter (OTC), without the need to see a doctor. Asia is the third region to launch VivaGel® BV and is a significant market where Mundipharma has a leading position in feminine care with their successful international brand BETADINE.

Mundipharma is rolling out BETADINE™ BV Gel across Asia, as regulatory approvals are granted. Starpharma's and Mundipharma's marketing and regulatory teams continue to work actively together on further launches of VivaGel® BV in Mundipharma's territories. Regulatory activities are underway for multiple countries across Mundipharma's regions.



Pictured above: Images from Betadine® BV Gel video commercial

>> Fleurstat BVgel launched in NZ

Earlier this year, Aspen launched Fleurstat BVgel in New Zealand. Marketing activities have commenced, and the product is available in some pharmacies. Fleurstat BVgel will be progressively rolled-out in New Zealand.



INTERNAL DEP®

>> DEP® irinotecan phase 2 commences after positive phase 1 results



In May, the phase 1 part of the DEP® irinotecan phase 1 / 2 trial was successfully completed ahead of schedule, with phase 2 commencing immediately.

The phase 1 part of the trial enrolled 7 patients with colorectal cancer, pancreatic cancer and breast cancer, who were each dosed with up to 10 cycles of DEP® irinotecan. DEP® irinotecan was well-tolerated and patients generally experienced less severe side effects, including no cases of severe diarrhoea, which is particularly problematic (FDA black box warning) with the marketed form of irinotecan, Camptosar®.

Encouraging efficacy signals have been observed in 50% of evaluable patients to date, and in all three tumour types enrolled, despite the fact that enrolled patients were heavily pre-treated - some with up to 100+ cycles of prior treatment and the majority with more than 10 cycles.

The phase 2 part of the DEP® irinotecan trial is now underway at The Christie, The Royal Marsden and Newcastle Freeman Hospital. Additional trial sites, the Beatson and the Kinghorn Cancer Centre, Sydney, are expected to commence recruitment shortly.

SPL7013 AGAINST SARS-COV-2 (CORONAVIRUS)

The potent antiviral activity of SPL7013, the active in VivaGel®, has been consistently demonstrated in multiple studies against many viruses, including HIV, herpes simplex, hepatitis B, HPV, Zika and adenovirus.

Following the outbreak of coronavirus earlier this year, Starpharma instigated testing of SPL7013 against the new virus. The findings from the study showed significant antiviral activity of SPL7013 against the SARS-CoV-2 virus and several product opportunities are now being explored. Initially the plan is to focus on a nasal/inhaled preventative product which could augment other prevention strategies and/or reduce severity of disease. Specialist clinical feedback confirms a role for alternative prevention strategies to complement potential vaccines, particularly for high-risk populations such as frontline medical staff, people housed in crowded settings and elderly people.



VIVAGEL® BV

>> Fleurstat BVgel ranks as #1 topical BV treatment

Fleurstat BVgel has achieved ranking as the #1 topical BV treatment in Australia after ~12 months on the market. During the past few months, promotional activities for the product have continued across Australia, with strong support from physicians and pharmacists.

Where can I buy Fleurstat BVgel for bacterial vaginosis?

Fleurstat BVgel is an over the counter BV treatment and is available from most leading pharmacies without prescription. A pharmacist must decide whether Fleurstat BVgel is right for you before you can purchase it.

Your Location:

Search radius: 50 km

>> Okamoto adds 11 more Asian countries to licence

Following the Japanese launch of VivaGel® antiviral condom under Okamoto's highly successful Zero Zero Three (003) brand, Okamoto sought an expansion of its licence to additional countries in Asia. In March, Starpharma granted Okamoto marketing rights to a further 11 countries in Asia which include South Korea, Indonesia, Malaysia, Thailand, Singapore and the consumer non-government China market.



Okamoto has an outstanding product portfolio and leading market positions within the Asian region with a number 1 or 2 ranking in multiple relevant Asian countries. Okamoto has revenue of approximately US\$1 billion with more than 2,600 employees and is Japan's leading marketer of condoms.

Under this licence Starpharma will be eligible to receive royalties on sales of the VivaGel® condom and will also receive revenue on supply of SPL7013 active. Okamoto will be responsible for regulatory submissions, marketing and other related costs. The licence also incorporates launch obligations for Okamoto.

>> US regulatory update

As part of its strategy for FDA approval of VivaGel® BV, Starpharma continues to progress the FDA review process with input from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA). This review of some of the FDA's initial conclusions via an administrative review process is ongoing, and with some delay anticipated due to COVID-19.

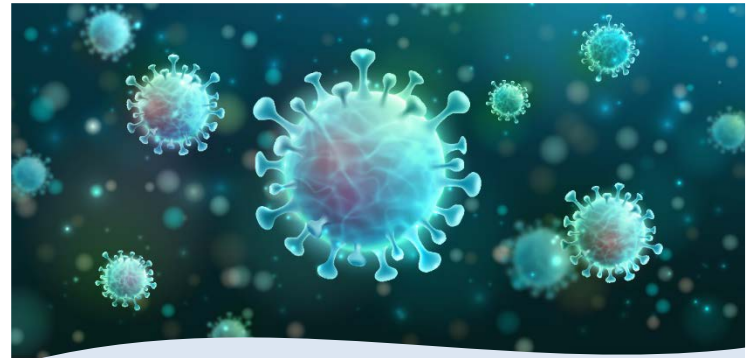


In view of the COVID-19 pandemic, and in particular, the disruption to the US healthcare system, the Company has paused activities relating to a potential BV treatment trial in the US, and Starpharma will continue to monitor the situation.

SPL7013 AGAINST SARS-COV-2 (CORONAVIRUS)

Continued from page 1.

SPL7013 is approved and marketed in products in Europe, Australia, and parts of Asia. The Company already has a great deal of regulatory and manufacturing data on hand and will be seeking to leverage this to fast-track product development and approvals. Starpharma is already in discussion with regulators regarding the regulatory path, and ways to expedite approvals.



"We're pleased to be in a position to contribute to the global effort against the COVID-19 pandemic, and aside from this critical health imperative, we anticipate that such a product could also generate a significant commercial opportunity".

Dr Jackie Fairley, CEO Starpharma

COVID-19 UPDATE

>> Starpharma's operations continue with minimal disruption

Starpharma has implemented a business continuity plan to mitigate the impacts of COVID-19 and a comprehensive program of measures to protect the health and safety of staff and trial patients. Operations - laboratory and in-house GMP manufacturing facilities - are currently in full operation.



Preclinical programs, other research and clinical trial support continue to progress with minimal disruption.

The design of the DEP® clinical programs is such that COVID-19 is not expected to adversely affect the integrity of trial results but may impact overall timing. Enrolled patients are continuing their DEP® treatment, and recruitment of new patients has slowed but is now recommencing at some sites/hospitals as the peak demand for COVID-19 patient care passes.

At present, there is little disruption to supply chain activities for VivaGel® BV and inventory levels are adequate. The Company is well positioned to withstand impacts of COVID-19 with a strong balance sheet, including significant available cash of \$36.1 million, as at 31 March 2020.

INTERNAL DEP®

>> DEP® docetaxel

The phase 2 DEP® docetaxel trial is progressing well, with further observations of encouraging efficacy signals in very heavily pre-treated patients. These include prolonged stable disease and substantial target tumour shrinkage in patients with cancers including lung, prostate, pancreatic, gastric and oesophageal cancer.

A total of 46 patients across two arms of the phase 2 study (monotherapy and combination) have undergone or are undergoing treatment with DEP® docetaxel at six sites in the UK.

>> DEP® cabazitaxel

In the DEP® cabazitaxel phase 2 trial - encouraging efficacy signals have been observed, including prolonged stable disease (>47 weeks), significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA), in cancers including prostate, ovarian, lung, gastroesophageal and others.

Nine patients have been treated with up to 5 cycles of treatment, across four sites in the UK with further sites to be added.

>> DEP® irinotecan

Continued from page 1.

The phase 2 trial objective is to establish anti-tumour activity (efficacy) and safety of DEP® irinotecan at the RP2D. The first stage will enrol approximately 20-30 patients with colorectal cancer and other cancers.

The study will further explore efficacy in selected tumour types and recruitment numbers may be adjusted based on results in certain patient cohorts.

DEP® PATIENT CASE STUDY

CANCER:



Breast cancer is the most common cancer affecting women. Breast cancer is the second leading cause of cancer-related death in Australian women, accounting for 14.9 per cent of all cancer deaths.

PATIENT:

Stage IV breast cancer patient with extensive liver metastases

- 45-year old woman with stage IV breast cancer
- extensive metastases including in the liver
- heavily pre-treated - more than 100 cycles of 11 different treatment regimens
- received 10 cycles of DEP® irinotecan to date

RESPONSE TO DEP® IRINOTECAN:

- response seen after 3 cycles of treatment
- prolonged stable disease >27 weeks
- well tolerated



DEP® PATIENT CASE STUDY

CANCER:



Ovarian cancer has the lowest survival rate of women's cancers and is the eighth most commonly occurring tumour in women.

PATIENT:



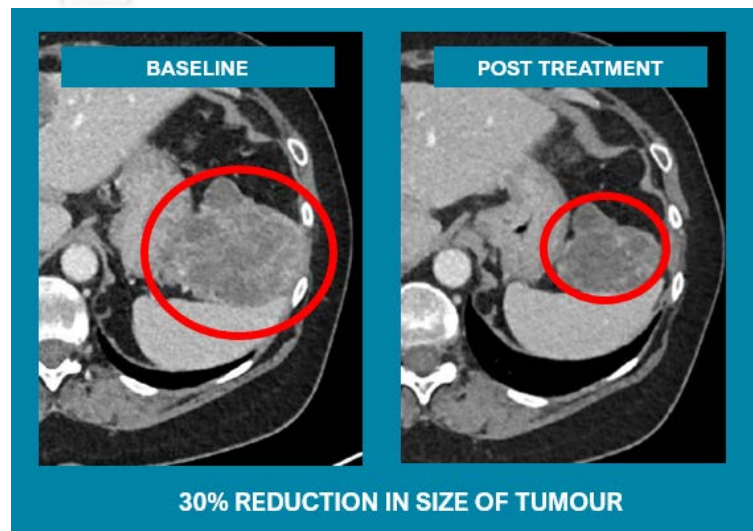
Advanced ovarian cancer patient with extensive metastases

- 60 year old woman with advanced (metastatic) ovarian cancer
- heavily pre-treated; her cancer progressed on 3 other anti-cancer therapies including paclitaxel (another taxane)
- previously had 14 cycles of treatment and multiple surgeries
- received 3 cycles of DEP® cabazitaxel to date

RESPONSE TO DEP® CABAZITAXEL:



- response seen after 3 cycles of DEP® cabazitaxel treatment; well tolerated
- 30% reduction in some tumours, 26% overall reduction across all target tumour lesions



PARTNERED DEP®

>> AstraZeneca's DEP® trial ongoing in the US & US\$3 million milestone payment received



In February, Starpharma received the US\$3 million milestone payment from AstraZeneca for the successful dosing of the first patient in the phase 1 DEP® clinical trial for AZD0466. AstraZeneca recently indicated this trial is continuing, and they are progressing activities in preparation for opening additional sites in the US.

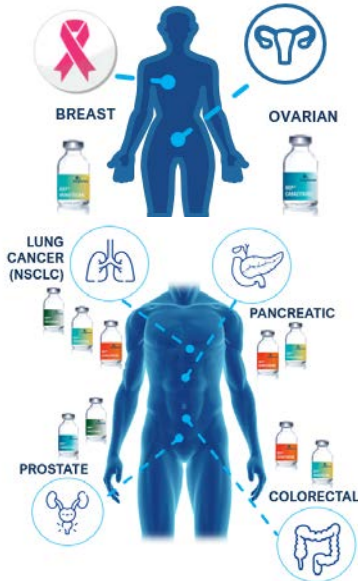
>> New DEP® ADC programs

Starpharma is currently finalising arrangements with potential partners prior to commencement of new Targeted (ADC) and non-ADC DEP® programs.

DEP® PIPELINE

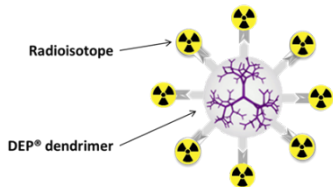
>> DEP® pipeline targets multiple high-value areas

Starpharma's DEP® pipeline targets significant needs and opportunities in oncology, including ovarian, breast, lung, pancreatic, prostate, colorectal cancer and various hard to treat tumours (for example cholangiocarcinoma, upper GI (oesophageal) and bladder cancer).



>> Other DEP® programs

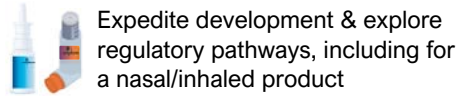
As part of Starpharma's DEP® pipeline development strategy, the Company continues to explore opportunities including radiotherapeutics and areas outside oncology, including antivirals. This activity pre-dated COVID-19 but with the increased focus on this category the Company has initiated a number of antiviral programs. Starpharma's DEP® technology is ideally suited to deliver clinically relevant benefits in the area.



Starpharma is also advancing its radiotherapeutics program with The University of Queensland and studies to date of radiolabelled dendrimers have already achieved an impressive level of tumour targeting compared to other delivery technologies. Efficacy studies are ongoing and patent filings are planned as part of this program.

OUTLOOK

>> SPL7013 & Coronavirus



Expedite development & explore regulatory pathways, including for a nasal/inhaled product

>> VivaGel® portfolio



- Commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Ongoing formal FDA review process
- Further VivaGel® BV licences for India, Canada & Israel
- Further regulatory approvals and launches for VivaGel® BV
- Revenue from VivaGel® BV - milestones and sales/royalties
- VivaGel® condom approvals/launch in additional regions, such as China/Europe
- Further development / co-development of SPL7013 antiviral ophthalmic drops

>> DEP® portfolio



- Progress DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan clinical trials & additional combination studies, e.g. DEP® docetaxel + gemcitabine; presentations/posters for DEP®
- AZD0466 clinical progress, posters / presentations & receipts from milestones
- AstraZeneca: Exercise of Option Agreement and deals for further compounds
- Progress other partnered DEP® deals & program developments, including DEP® ADCs
- Explore value-adding DEP® combinations & advance other DEP® products, including DEP® gemcitabine, DEP® radiopharmaceuticals, DEP® ADCs
- Continue to explore other DEP® programs including oncology and antivirals

NEWS & EVENTS

>> Quarterly cashflow - cash balance \$36.1 million at 31 March

Starpharma's ended the March quarter in a strong position with \$36.1 million.

Starpharma's strong cash reserves and clean balance sheet places the Company in a strong position to continue to progress its commercial and R&D activities in the current uncertain global environment of the COVID-19 pandemic.

>> Investor conference



Dr Jackie Fairley was invited to present at the Macquarie Australia Conference in May which attracted more than 1,000

investors from around the world. The presentation used for the event was an abridged version of the Company's corporate presentation and is available at www.starpharma.com.

>> ausbiz interview with CEO

Finance and market news website ausbiz co-founders Kylie Merritt and David Koch interviewed Starpharma CEO Dr Jackie Fairley to discuss DEP® irinotecan moving into phase 2 and how Starpharma is investigating product concepts for SPL7013 in the fight against COVID-19. To watch the full interview [click here](#).



Disclosure

This ASX Announcement was authorised for release by the Company Secretary.

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