SHAREHOLDER Update

starpharma

JANUARY 2020

VIVAGEL® BV

›› VivaGel® BV launched in the UK

Starpharma's breakthrough product for the management of bacterial vaginosis, VivaGel® BV, was launched in the UK in November 2019, under the brand Betafem® BV Gel. The UK launch followed the first European launches in June 2019, including in Germany and other countries. The UK product sits within the feminine care range under Mundipharma's Betadine® umbrella brand.

During the December quarter, Starpharma supplied product to Mundipharma to support the roll-out of VivaGel® BV in further European countries, including Central and Eastern Europe, where launches are planned in the coming months.

The first Asian regulatory approvals were received for VivaGel® BV in August 2019 and product has been delivered in Asia.

Advanced marketing activities are underway in preparation for the launch of BETADINE™ BV Gel in Asia and further regulatory submissions have been made in countries across Asia and other Mundipharma regions.

Asia represents an important market for VivaGel® BV, with an estimated 1.5 billion women in the region. Mundipharma have a leading position in feminine care in Asia with their successful international brand BETADINE.

"I am very delighted that we have our first regulatory approvals in Asia to introduce this true innovation in the management of bacterial vaginosis (BV). We are working closely with Starpharma to secure further approvals and look forward to launching BETADINE®BV Gel and to extending our line of feminine care products in Asia." **Raman Singh, Mundipharma CEO**

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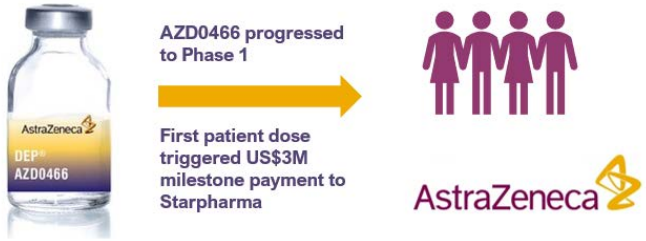
DEP® PORTFOLIO

›› AstraZeneca first DEP® product enters the clinic; triggers US$3M milestone

In December 2019, AstraZeneca commenced its first-in-human phase 1 clinical trial for AZD0466 in a range of cancers, to be conducted at 4-5 sites in the US. This follows the approval of an investigational new drug (IND) application by the US FDA.

AZD0466, which is a highly optimised nanomedicine formulation of AstraZeneca's novel dual Bcl2/xL inhibitor, utilises Starpharma's proprietary DEP® delivery technology. AstraZeneca describes AZD0466 as having the potential to be a 'best-in-class' agent in this field due to its ability to target both Bcl2 and Bcl/xL, with a broad opportunity in both solid and haematological tumours (blood cancers).



The development of AZD0466 is being progressed under a multi-product licence whereby Starpharma is eligible to receive development, launch and sales milestones of up to US$124 million, plus tiered royalties on net sales for the product. The first dose of AZD0466 administered in the phase 1 trial triggered a milestone payment to Starpharma of US$3 million. AstraZeneca also funds the development costs of DEP® AstraZeneca products (including AZD0466) under the licence.

›› DEP® cabazitaxel trial moves into phase 2 on positive results

The phase 1 component of the phase 1 / 2 trial for DEP® cabazitaxel was completed in December 2019. The trial met its objective of identifying a recommended Phase 2 Dose (RP2D) and has now transitioned seamlessly into phase 2.

In phase 1, encouraging efficacy signals were observed in 67% of patients assessed and included prolonged stable disease in multiple tumour types, including prostate cancer. Efficacy signals were observed in cancers not usually responsive to conventional cabazitaxel (Jevtana®), such as ovarian cancer, and at doses lower than used for Jevtana®.

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VIVAGEL® BV

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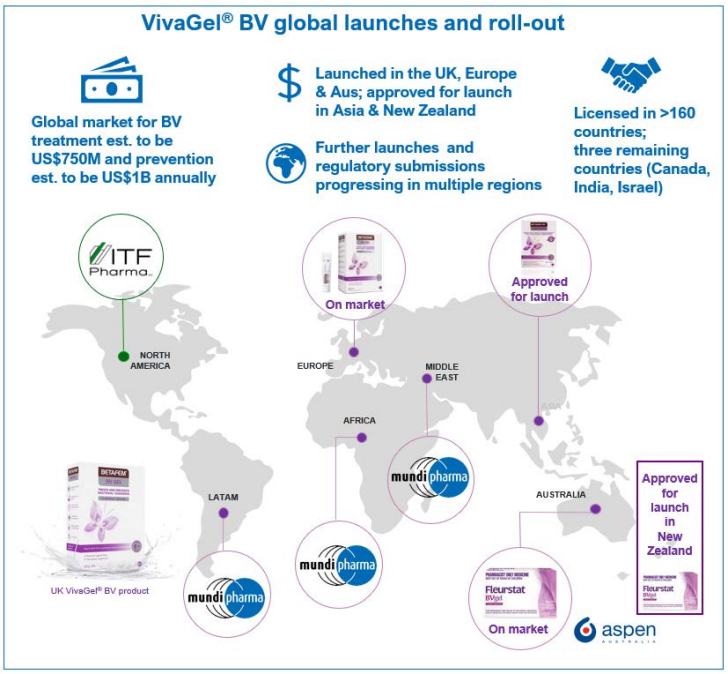
The Starpharma and Mundipharma marketing and regulatory teams continue to work collaboratively together on further launches of VivaGel® BV in Mundipharma's territories. Regulatory activities are underway for multiple countries across Mundipharma's regions.



›› Fleurstat BVgel marketing campaign; New Zealand launch planned

The Australian launch of Fleurstat BVgel has been described as one of Aspen's most positively received new product launches, with excellent feedback from healthcare professionals and patients.

More than 2,700 Australian pharmacies currently stock Fleurstat BVgel, which is now stocked in 100% of Chemist Warehouse, Priceline & Blooms pharmacies. Featured below is an example of the direct-to-consumer marketing activities undertaken by Aspen.

Aspen expect to launch Fleurstat BVgel in New Zealand in the coming months, and launch preparations are advancing well with sales training completed and product supply in place.

"We are very impressed with healthcare practitioner and consumer feedback on the product, and in the market uptake of Fleurstat BVgel at this early stage of a major launch. We see a great future ahead."

Rob Barnes, Head of Consumer OTC, Aspen

VIVAGEL® BV IN THE US

›› Dual strategy to achieve approval of the NDA in the US

Starpharma has thoroughly explored its options to achieve approval of VivaGel® BV in the US with ongoing support from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA). Following this, Starpharma initiated a dual strategy to achieve approval:

- Seeking formal review of some of the FDA's initial conclusions via an administrative review process; and
- Preparation for a possible BV treatment trial.

The FDA continues to acknowledge the potential benefits of a non-antibiotic BV therapy and VivaGel® BV's QIDP and Fast Track status remain on foot based on the potential for VivaGel® BV to address a significant unmet need in BV.

Should a BV treatment trial be required, Starpharma has already progressed significant activities, including protocol development, protocol review by the FDA, contingent CRO appointment and investigator/site selection. This preparation will enable the trial to commence rapidly and expedite completion, if required.

VIVAGEL® CONDOM

›› Okamoto joins forces with Japanese government for STI prevention campaign

Okamoto and the Japanese Ministry of Health, Labour & Welfare recently developed a joint STI prevention campaign using VivaGel® condoms.

Okamoto has an outstanding product portfolio and holds a strong condom market position in the Asian region. Okamoto has revenue of approximately US$1 billion with more than 2,600 employees and is Japan's leading marketer of condoms.

Pictured above: Ministry of Health STI campaign, featuring popular Japanese character, Sailor Moon.

›› VivaGel® condom receives regulatory approval in Europe

In November 2019, Starpharma was granted marketing approval for the VivaGel® condom in Europe. Starpharma's marketing partner in Europe, LifeStyles, will now undertake marketing preparations ahead of the launch of the VivaGel® condom under the brand name Absolute™ DUAL PROTECTION.

INTERNAL DEP®

>> DEP® cabazitaxel progresses to phase 2 on positive results

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DEP® cabazitaxel patients have also experienced significantly fewer side effects such as nausea and bone marrow toxicity (neutropenia, anaemia, thrombocytopenia) than are typically seen with conventional cabazitaxel (Jevtana®), and no anaphylaxis or hypersensitivity reactions have been observed.

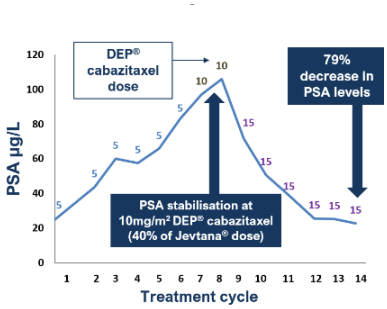
Recruitment into the phase 2 part of the trial is now underway with two new trial sites being added, Imperial College London and Velindre Cancer Centre in Cardiff, in addition to Guy's & St Thomas' Hospital and University College London.

DEP® CABAZITAXEL CASE STUDY: 70-year old man with stage III prostate cancer

- heavily pre-treated; cancer progressed on four other anti-cancer therapies
- was unable to tolerate standard docetaxel due to toxicity (neutropenia)
- received 14 cycles of DEP® cabazitaxel with no neutropenia
- response to DEP® cabazitaxel began at 40% of the typical dose

Response to DEP® cabazitaxel

- Prolonged stable disease >47 weeks
- 79% decrease in PSA levels



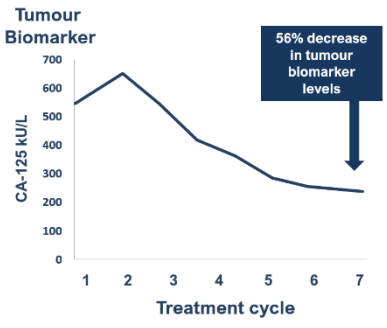
Graph (right): PSA level following DEP® cabazitaxel

DEP® CABAZITAXEL CASE STUDY: 73-year old woman with stage IV (metastatic) ovarian cancer

- heavily pre-treated - with 33 cycles of five different anti-cancer therapy regimens (including several combinations). Patient's cancer progressed on all of these and she was unable to tolerate standard docetaxel due to toxicity (neutropenia)

Response to DEP® cabazitaxel

- received 7 cycles of DEP® cabazitaxel (well tolerated)
- achieved a 56% decrease in tumour biomarker levels
- tumour response commenced at 60% of the currently recommended Jevtana® dose



Graph (above right): Tumour biomarker level following DEP® cabazitaxel

INTERNAL DEP®

DEP® DOCETAXEL CASE STUDY: 46 year old man with stage IV lung cancer (NSCLC)

- genetic profile limited treatment options (having not qualified for 1st line immunotherapy)
- cancer had progressed after seven cycles of platinum-based chemotherapy + immunotherapy & an investigational enzyme inhibitor
- received two cycles of DEP® docetaxel + nintedanib

Response to DEP® docetaxel + nintedanib

- reduction in size of tumour lesions of up to 45%
- stable disease >9 weeks
- improvement in tumour-related pain

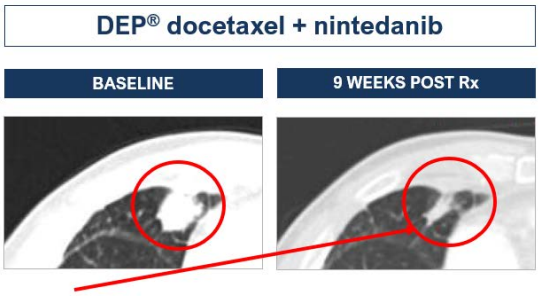


Image (above): CT scans of lung (right middle lobe) showing 41% reduction in size of tumour lesion following DEP® docetaxel + nintedanib

>> DEP® irinotecan phase 1/2 trial

In August 2019, Starpharma commenced its phase 1/2 clinical trial for DEP® irinotecan. The objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP® irinotecan to define a recommended phase 2 dose (RP2D), and to determine preliminary anti-tumour efficacy of the product in select tumour types. DEP® irinotecan is the third DEP® product to enter the clinic from Starpharma's internal portfolio.

The DEP® irinotecan trial is initially being conducted at multiple leading UK cancer centres including The Christie, The Royal Marsden and Newcastle Freeman Hospital. Recruitment is progressing well in the escalation phase, with some patients having received seven cycles of treatment and efficacy signals observed. Additional sites in the UK and Australia will open and commence recruitment as the trial progresses and for the phase 2 part of the trial.

Approximately 40-45 patients with advanced solid tumours, including colorectal cancer (CRC), will be enrolled across the combined phase 1/2 trial. CRC is one of the most common cancers in the world, affecting more than 1 million individuals annually, and is the fourth-leading cause of cancer-related death.

>> New candidate - DEP® gemcitabine

Starpharma has advanced a new internal DEP® candidate, DEP® gemcitabine, into development. DEP® gemcitabine demonstrated significantly enhanced anti-tumour activity compared with Gemzar® (gemcitabine), both alone and in combination with Nab-paclitaxel (Abraxane®), in a human pancreatic cancer model.

DEP® gemcitabine is a DEP® version of Lilly's Gemzar® (gemcitabine) - a well-established anti-cancer drug, which had peak sales of US$1.7 billion. A patent has been filed for Starpharma's proprietary DEP® gemcitabine, providing coverage to 2040.

DEP® PIPELINE

>> GMP DEP® facility licence

Starpharma has been granted a licence from the TGA to manufacture API (Active Pharmaceutical Ingredient). This licence enables Starpharma to prepare API for a range of DEP® products for the conduct of human clinical trials, including late-stage phase 3 trials. Having a TGA licence and in-house capabilities allows Starpharma to accelerate the development of DEP® products for internal and partnered programs through rapid manufacture and development of DEP® materials. It provides for greater flexibility and cost efficiencies in sourcing clinical materials than with third-party manufacturers for internal programs, and enables Starpharma to facilitate partnered programs whilst generating additional revenues.

>> DEP® combinations add further value

Combination therapies are important treatment options in oncology, as they provide enhanced therapeutic outcomes, including the potential to reduce drug resistance.

Starpharma has undertaken a broad range of DEP® combination studies, which have delivered impressive preclinical results, as set out in the table below. The synergistic anti-cancer effects seen in these studies have shown significant benefits with DEP® products in combination with other marketed anti-cancer drugs. The enhanced effects are thought to be due to the improved pharmacokinetics and increased drug-tissue levels (tissue targeting) achieved with dendrimer delivery. Combination data informs clinical development and identifies value-adding DEP® combinations to progress. Combination studies of DEP® products with immuno-oncology products are also now underway.

DEP® COMBINATION	CANCER TYPE (human xenograft)	IMPROVED EFFICACY (compared to current standard of care)
DEP® docetaxel + gemcitabine (Gemzar®)	Pancreatic	✓
DEP® cabazitaxel + gemcitabine (Gemzar®)	Pancreatic	✓
DEP® irinotecan + Erbitux®	Colon	✓
DEP® irinotecan + Lynparza®	Colon	✓
DEP® Bcl2/xL + Rituximab	Lymphoma	✓
DEP® gemcitabine + Abraxane®	Pancreatic	✓

OUTLOOK

>> VivaGel® portfolio

- Launch VivaGel® BV in Asia and NZ
- Commercial roll-out of VivaGel® BV in Europe, Asia, NZ & other markets
- Dual strategy to achieve FDA approval
- 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 Europe & China
- Further development / co-development of SPL7013 ophthalmic drops

>> DEP® portfolio

- Progress DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan clinical trials
- AZD0466 clinical progress and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and deals for further compounds
- Progress partnered DEP® deals & program developments, including DEP® ADCs
- Explore value-adding DEP® combinations including commencement of DEP® docetaxel + gemcitabine combination in the clinic
- Advance other DEP® products, including DEP® gemcitabine, DEP® radiopharmaceuticals, DEP® ADCs

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NEWS & EVENTS

>> J.P. Morgan conference

In early January, Dr Jackie Fairley, CEO and Dr Tony Eglezos, VP Business Development, attended the annual J.P. Morgan Healthcare Conference. Based in San Francisco, this is one of the largest annual healthcare conferences in the US, which attracts executives from major pharmaceutical companies around the world. During the event, Starpharma met with new and existing partners focussing primarily on Starpharma's DEP® opportunities.

J.P.Morgan

38th Annual J.P. Morgan Healthcare Conference

>> $4.9M R&D tax incentive received

The $4.9M R&D tax incentive was received in December 2019. The cash balance as at 31 December 2019 was $35.9M not including the US$3M milestone payment from AstraZeneca triggered in late December 2019.

>> AGM webcast

Starpharma held its Annual General Meeting on 21 November 2019.
A webcast of the meeting is available at www.boardroom.media.

>> Starpharma featured in *The Australian*

The Australian recently interviewed Dr Jackie Fairley and discussed the power of Starpharma's DEP® platform and how it improves cancer drugs, helps patients and provides commercial optionality when partnering with big pharmaceutical companies. The article was featured on the business section front page on 11 November 2019.

THE AUSTRALIAN

Disclosure

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