SHAREHOLDER Update

starpharma

JULY 2019

VIVAGEL® BV

›› VivaGel® BV launched in Europe

Starpharma's breakthrough product for bacterial vaginosis, VivaGel® BV, was launched in Europe in June under the brand name Betadine BV™. The product was launched in several countries in Europe, including Germany, with further roll-out in additional European countries expected during the year. Europe is the second region to launch VivaGel® BV and represents a large commercial opportunity with access to more than 260 million women.

Betadine BV™ will be available over-the-counter (OTC) for the treatment and prevention of BV, without the need to see a doctor or obtain a prescription. The product is being marketed by Mundipharma, a global pharmaceutical company with a leading position in feminine care.

The launch of Betadine BV™ in Europe triggers a milestone payment of US$0.5M (A$0.7M) to Starpharma. Starpharma is eligible to earn total milestones up to US$24.7M, plus revenue share, for all territories under Mundipharma's licence.

Starpharma is working closely with Mundipharma on further regulatory submissions in several Mundipharma regions, such as Asia.

VivaGel® BV has been licensed for over 160+ countries, through Starpharma's partners Mundipharma, ITF Pharma and Aspen Pharmacare. Discussions are ongoing for the licensing of VivaGel® BV in Canada, India and Israel.

DEP® PORTFOLIO

›› Starpharma signs second commercial oncology agreement with AstraZeneca

Whilst at the ASCO meeting in early June, Starpharma signed a new commercial deal with AstraZeneca – a Development and Option Agreement to progress development of a DEP® version of one of AstraZeneca's major marketed oncology medicines.

Following completion of agreed preclinical studies by Starpharma, AstraZeneca has the option to licence the DEP® oncology drug candidate for an option exercise fee of US$5M, plus industry standard development and commercialisation milestones and escalating royalties on sales. Further details would be disclosed at the time of option exercise.

AstraZeneca

US$5M OPTION EXERCISE FEE + INDUSTRY STANDARD MILESTONES + ESCALATING ROYALTIES

If exercised by AstraZeneca

In the event that AstraZeneca does not exercise the option to license the drug candidate, Starpharma has the option to license full rights to develop and commercialise the DEP® improved drug candidate itself or through a sub-licensee with milestones and royalties payable to AstraZeneca upon commercialisation of the product.

This second commercial oncology agreement follows an existing multiproduct licence for use of Starpharma's DEP® drug delivery platform in the development and commercialisation of several AstraZeneca oncology drug candidates, including AZD0466 (featured on page 3).

IN THIS ISSUE

VIVAGEL® BV

›› Fleurstat BVgel launched in Australia – first launch globally of VivaGel® BV

In April, VivaGel® BV was officially launched in Australia by Aspen Pharmacare (Aspen) as Fleurstat BVgel. The product has undergone distribution and is now available in Australian pharmacies.

With the launch of Fleurstat BVgel, this is the first time Australian women have been able to purchase a BV product over-the-counter in pharmacies - previously, women have only been able to access antibiotic-based treatments for BV, which are available by prescription from a GP or specialist.

The launch of Fleurstat BVgel attracted media from several outlets, including Channel Nine News (above).

The product was also featured on the cover of the May edition of the Australian Journal of Pharmacy (AJP) which has a circulation of around 21,500 pharmacists.

VIVAGEL® CONDOM

›› VivaGel® condom launched in Japan by Okamoto

In June 2019, Okamoto launched the VivaGel® condom in Japan under its leading and highly successful 003 brand. This is the first condom with an antiviral coating in Japan and will also carry the VivaGel® brand. The 003 refers to the thinness of the condom and is recognised as a 'super thin' standard of latex.

Okamoto is Japan's leading marketer of condoms with a majority share of the Japanese condom market – and a strong record in the successful commercialisation of new products. In addition to its dominant position in the Japanese condom market, Okamoto also holds strong market positions in several other Asian markets, including Korea, Taiwan, Thailand, Singapore and China.

Starpharma is eligible to receive royalties based on sales of the VivaGel® condom and also revenue on supply of SPL7013 active. Starpharma received first receipts from Okamoto in April.

Photo above: Mr Toshio Tamura, President & CEO of Okamoto Industries, presenting at Okamoto's launch of the 003 VivaGel® condom. The launch was attended by media outlets and featured on Japan's mainstream evening news, WBS (World Business Satellite) on the "TV-Tokyo" channel.

›› US regulatory progress – VivaGel® BV

As previously announced, Starpharma recently received formal feedback from the US FDA regarding approval of two related BV indications - BV treatment and the prevention of recurrent BV.

The FDA feedback highlighted there are several potential options and Starpharma is currently working through these with the FDA, recognising that an approval for one indication would have a positive impact on approval for the other indication.

Starpharma's focus is to pursue the most expeditious and efficient path to approval. As part of its evaluation of options, Starpharma is seeking expert regulatory/legal advice on the avenues available for review of some of the conclusions reached by FDA. Other options include generating confirmatory clinical data through an additional BV treatment trial. Should it be determined that a new clinical trial is the best strategy, Starpharma would be in a position to commence a BV treatment trial quickly.

Starpharma continues to liaise with the FDA and work closely with its team of expert FDA consultants, statisticians and legal advisors in relation to the US approvals.

INTERNAL DEP®

>> Clinical trials for internal DEP® products progressing well

DEP® docetaxel: The monotherapy arm of the trial continues to show encouraging efficacy signals and a notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including hair-loss, anaphylaxis and oedema.

Based on investigator interest and anti-cancer activity observed, other tumour types including pancreatic cancer are also being explored as well as additional potential combinations where synergy has already been observed in preclinical studies.

The combination arm of the trial was expanded based on positive interim results for DEP® docetaxel + nintedanib (no protocol-defined DLTs, efficacy signals, lack of bone marrow toxicity). Encouraging efficacy signals continue to be observed.

DEP® cabazitaxel:

The dose escalation phase for DEP® cabazitaxel phase 1 / 2 trial is underway at Guy's Hospital London and University College London Hospital, with patient recruitment continuing at the 6th dose escalation level. Several patients have been dosed with multiple cycles of DEP® cabazitaxel.

Encouraging efficacy signals have been observed in multiple patients in prostate cancer, for which cabazitaxel is approved and other tumour types. These responses have also occurred at doses several fold lower than typically used for cabazitaxel (due to the dose-escalation phase). No DLTs or other significant toxicities associated with DEP® cabazitaxel have been observed.

>> 3rd DEP® drug to enter the clinic; DEP® irinotecan combination data

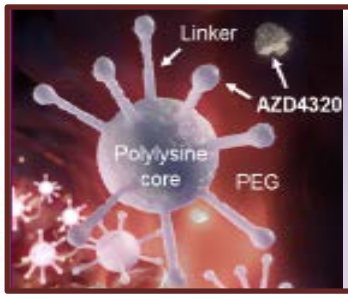
Starpharma is currently completing final trial preparations for the DEP® irinotecan phase 1 / 2 trial which is expected to start shortly. This is the 3rd DEP® product to enter the clinic from Starpharma's internal portfolio. The clinical trial will be conducted in multiple sites, commencing with three UK hospitals: Guy's Hospital London, The Christie and The Royal Marsden.

Further preclinical data was announced in May, whereby DEP® irinotecan showed significant efficacy and safety benefits over leading colorectal cancer drugs irinotecan (Camptosar®) and cetuximab (Erbitux®), in the irinotecan-refractory HT-29 human colon cancer model. These impressive results were despite the fact that these standard colorectal cancer (CRC) treatments, Camptosar® and/or Erbitux®, showed limited activity in this preclinical model. This study builds on previously announced promising efficacy data for DEP® irinotecan in human colon and pancreatic cancer models.

PARTNERED DEP®

>> AstraZeneca highlights AZD0466 at 2019 ASCO meeting & upcoming US FDA IND

AstraZeneca highlighted AZD0466 during its presentation by Dr Susan Galbraith, Head of Oncology IMED at the recent ASCO (American Society of Clinical Oncology) meeting.



...Next wave of innovation

"AZD0466 (Bcl2/xL): nanomedicine to improve therapeutic margin".

Image, left, extracted from the ASCO presentation by Dr Susan Galbraith, Head of Oncology, IMED - AstraZeneca

AZD0466 is a DEP® Bcl2/xL inhibitor conjugate, with broad combination potential being evaluated in both solid and haematological tumours (blood cancers), due to its potential to target both Bcl2 and Bcl/xL pathways.

AZD0466 is being developed under AstraZeneca's multiproduct DEP® licence with Starpharma and has now completed preclinical development. A US FDA investigational new drug application (IND) is planned for AZD0466 in the near future with the product expected to enter the clinic later this year.

*"AZD0466 – which is a dual Bcl2/xL inhibitor which we are developing in a **nanomedicine formulation in collaboration with Starpharma** – as a dendrimer formulation - and **due to go into the clinic later this year.**"*

Quote above from Dr Susan Galbraith's 2019 ASCO presentation

>> Patent published for AstraZeneca Bcl2/xL DEP® conjugates

The first patent for DEP® Bcl2/xL inhibitor conjugates, developed in collaboration with AstraZeneca under the multiproduct licence, was granted by the US Patent and Trademark Office in June. These patented DEP® Bcl2/xL inhibitor conjugates (including AZD0466) combine Starpharma's innovative DEP® technology with AstraZeneca's novel Bcl2/xL inhibitors, which are being investigated for treating various cancers, including leukemias.

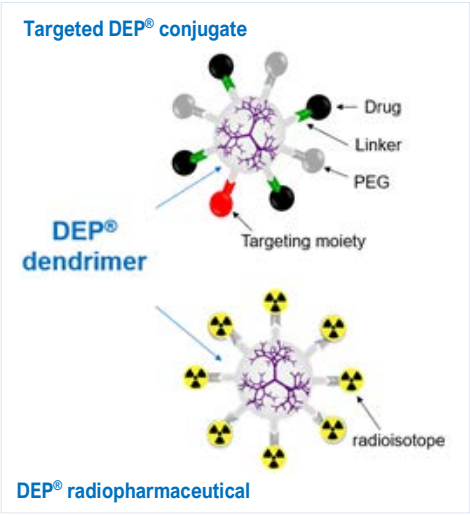
This patent provides US exclusivity until 2038, with the potential for up to 5 years' extension. The granted patent shows promising data on DEP® Bcl2/xL inhibitor conjugates in various preclinical human tumour models, both alone and synergy in combination with other leading current anti-cancer treatments (data announced to the ASX on 31 August 2018).

PIPELINE

>>DEP® Radiopharmaceuticals

The versatility of the DEP® platform means it can be used with a wide range of therapies (e.g. small molecules, peptides, antibodies, radioisotopes).

This includes its use to generate DEP® radiopharmaceutical candidates. Starpharma is currently undertaking further testing of DEP® radiopharmaceutical candidates in a variety of preclinical models.



In keeping with other DEP® candidates, DEP® radiopharmaceutical conjugates have the potential to reduce off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches. They also provide commercial opportunities for co-development of therapeutic and diagnostic products.

Radiopharmaceuticals represents a growing area of cancer treatments, with recent deals including Novartis' US$3.9B acquisition of Advanced Accelerator Applications and its acquisition of Endocyte for US$2.1B, and the acquisition of Australian company Sirtex for ~A$1.9B in 2018 by a consortium including CDH Genetech.

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OUTLOOK

>> VivaGel® portfolio

Roll-out of VivaGel® BV in Europe & other markets

Working with FDA and expert advisers to address requirements for US approval

Further VivaGel® BV licences for India, Canada & Israel

Further regulatory approvals for VivaGel® BV

Revenue from VivaGel® BV milestones & sales/royalties

VivaGel® condom approvals / launch in additional regions, such as Europe & China

Further development / co-development of SPL7013 ophthalmic drops

>> DEP® portfolio

Progress with DEP® docetaxel & DEP® cabazitaxel clinical trials; explore value-adding combinations

DEP® irinotecan trial commencement; explore value-adding combinations

Other DEP® program developments, including new DEP® candidates, DEP® radiopharmaceuticals

AstraZeneca program developments including: AZD0466 IND filing, trial start & revenue from milestones; Exercise of Option Agreement; deals for further compounds

Other partnered DEP® deals & program developments, which includes Antibody Drug Conjugates (ADCs)

NEWS & EVENTS

>> Bell Potter names Starpharma in 'Top Picks'

Starpharma was named in Bell Potter's healthcare 'Top Picks' List for FY20.

>> Starpharma at ASCO

Senior executives from Starpharma attended the 2019 ASCO (American Society of Clinical Oncology) meeting and met with AstraZeneca and signed a 2nd commercial agreement (see page 1). Meetings were also held with other partners, and also with clinical investigators from each trial site for all three DEP® clinical studies. The feedback from observations was very encouraging and future planning was discussed.

>> Investor conferences

Dr Jackie Fairley was invited to present at the Macquarie Australia Conference in May which attracts more than 800 investors from around the world. Dr Fairley also made presentations to the Goldman Sachs Emerging Companies and UBS Healthcare Conferences.

>> Treasurer announces new $250M SME fund at Starpharma's labs

On 7 June, Starpharma hosted The Hon. Tim Pallas, Treasurer of Victoria, during his announcement of the State Government's new $250 million Victorian Business Growth Fund for SMEs. This initiative will facilitate investment by superannuation funds into small-to-medium sized innovative businesses with compelling potential for growth and jobs creation.

Above: left to right: Dr Jackie Fairley, CEO Starpharma; Rosemary Kelly, Director First State Super; The Hon. Tim Pallas, State Treasurer; and Michael Dundon, CEO Vic Super.