starpharma

SHAREHOLDER Update

FEBRUARY 2018

INTERNAL DRUG DELIVERY

›› New sites open for the DEP® docetaxel phase 2 trial

A number of patients have already received multiple cycles of DEP® docetaxel in the phase 2 trial which commenced in major UK hospitals, including Guy's Hospital London, in 2017.

University College London Hospital Cancer Clinical Trials Unit was recently initiated in the phase 2 DEP® docetaxel trial and is expected to commence recruitment shortly. Two further sites in the UK are also in the process of being initiated.

The phase 2 trial is an open-label, two-stage design, with the objective of establishing anti-tumour activity (efficacy) and safety of DEP® docetaxel at the Recommended Phase 2 Dose.

As part of the trial, Starpharma is also investigating the benefits of combining DEP® docetaxel with another anti-cancer agent, nintedanib (Vargatef®) in lung cancer.

Consistent with the phase 1 study, patients have not required steroid pre-treatment and have not experienced neutropenia (low white blood cell levels) or hair loss following treatment with DEP® docetaxel, typical with standard docetaxel.

DEP® docetaxel positive phase 1 trial results

- ✔ No neutropenia
- ✔ Only one case of mild hair loss (1/27)
- ✔ No reports of other adverse events typical with standard docetaxel such as anaphylaxis, fluid retention, diarrhoea and nail disorders
- ✔ Encouraging efficacy signals (13/27)

(continued on page 2)

INTERNAL DRUG DELIVERY

›› DEP® cabazitaxel phase 1 / 2 trial commences

Starpharma recently commenced its phase 1 / 2 clinical trial for DEP® cabazitaxel, having received regulatory and ethics approvals.

The trial will be conducted at multiple sites, with Guy's Hospital London and University College London Hospital in the UK being the first sites to open for recruitment.

Further sites will open and commence recruitment as dose escalation progresses and the phase 2 part of the trial gets underway.

The objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP® cabazitaxel, to define a Recommended Phase 2 Dose, and then to determine anti-tumour efficacy of the product in select tumour types.

DEP® cabazitaxel is the second product from Starpharma's DEP® platform to enter the clinic, and follows DEP® docetaxel (see left column), which delivered positive phase 1 clinical results in 2017.

Excellent preclinical results – Improved efficacy, safety & survival

DEP® cabazitaxel significantly outperformed leading cancer drug, Jevtana®, in a human breast cancer model with respect to both level and duration of anti-cancer activity and survival, and with superior safety.

(continued on page 2)

VIVAGEL®

›› VivaGel® BV NDA submission lodged under Fast Track program

FDA SUBMISSION

QIDP FDA FAST TRACK GRANTED

Starpharma has already submitted a substantial portion of its US New Drug Application (NDA) for VivaGel® BV through a rolling submission process to the FDA, with remaining sections to be submitted in the near future.

In 2017, VivaGel® BV was granted Fast Track status and Qualified Infectious Disease Product (QIDP) designation by the FDA, which are designed to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs. Based on experience with other products granted Fast Track status, NDA review time is expected to be approximately 6-8 months.

The NDA includes data from the phase 3 trials for the prevention of recurrent BV reported in August 2017, as well as earlier trial data on BV treatment.

›› VivaGel® BV approved by TGA

VivaGel® BV recently received Australian marketing approval from the Therapeutic Goods Administration (TGA).

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INTERNAL DRUG DELIVERY

New sites open for the DEP® docetaxel phase 2 trial

(continued from page 1)

DEP® docetaxel phase 2 trial

- Open-label, two-stage design
- Objectives are to establish anti-tumour activity (efficacy) and safety of DEP® docetaxel (at the Recommended Phase 2 Dose (RP2D) of 60mg/m^2)
- First stage to enrol ~20 patients with either lung or prostate cancer (the key approved indications for standard docetaxel (e.g. Taxotere®))
- Second stage to enrol a further 20 patients (tumour types based on results from the first stage)
- Also investigating the potential benefits of combining DEP® docetaxel with another anti-cancer agent, nintedanib (Vargatef®)

About DEP® docetaxel

Starpharma's DEP® docetaxel is an enhanced version of anti-cancer drug docetaxel. DEP® docetaxel has been designed to reduce side effects such as neutropenia and other adverse side-effects, while enhancing efficacy.

Docetaxel is one of the most widely used cancer drugs for treatment of a wide range of solid tumours including breast, lung and prostate.

There are a number of conventional docetaxel formulations, such as Taxotere®. Taxotere® is marketed by Sanofi Aventis and generated peak global sales in excess of US$3 billion despite having multiple US FDA "Black Box" warnings including for anaphylaxis and neutropenia.

INTERNAL DRUG DELIVERY

DEP® cabazitaxel phase 1 / 2 trial commences

(continued from page 1)

DEP® cabazitaxel phase 1 / 2 trial

- Open-label, two-part study (Phase 1 sequential dose escalation, phase 2 dose expansion)
- Objectives are to define the maximum tolerated dose (MTD) to establish safety and explore anti-tumour activity (efficacy) of DEP® cabazitaxel
- Planning to enrol approximately 35 patients across the phase 1 / 2 trial, with the trial being conducted at multiple sites including Guy's Hospital London and University College London Hospital

The adaptive phase 1 / 2 trial design for DEP® cabazitaxel enables Starpharma to move seamlessly from phase 1 to phase 2 and to explore efficacy as early as possible. As the trial progresses, decisions will be made as to which tumour types to focus on and any additional patients required to further characterise efficacy in specific tumour types.

About DEP® cabazitaxel

Starpharma's DEP® cabazitaxel is a detergent-free version of cancer drug Jevtana®. Jevtana® is a leading oncology agent used to treat advanced prostate cancer and is also under development for other cancers including breast cancer, bladder cancer and head and neck cancer. Sales of Jevtana® are estimated to reach US$500M this year.

Jevtana® has FDA-mandated 'Black Box' warnings in relation to neutropenia, which is a major dose limiting side effect, and severe hypersensitivity (e.g. anaphylaxis) resulting from the polysorbate 80 detergent used in its formulation.

PARTNERED DRUG DELIVERY

AstraZeneca-Starpharma collaboration

AstraZeneca

Liz Chatwin, Country President, AstraZeneca, Australia and New Zealand, recently visited Starpharma's head office to meet with key members of the Starpharma team. Ms Chatwin toured the Company's in-house scale-up facility, where Starpharma has recently manufactured one of several DEP® products being developed by AstraZeneca under its multiproduct licence with Starpharma.

The most advanced drug under this licence is AZD0466 – a highly optimised dendrimer formulation of a novel dual Bcl2/xL inhibitor, which has the potential to be a best-in-class cancer drug with a broad combination opportunity in solid and haematological tumours.

AZD0466 is an oncology drug in the same class as Venetoclax (a first generation Bcl2 inhibitor approved by the FDA in 2016).

Development of AZD0466 is funded by AstraZeneca and clinical trials are expected to commence in 2018. Starpharma and AstraZeneca also have an additional DEP® program, separate to the multiproduct DEP® licence, underway.

During the visit, Ms Chatwin and Dr Fairley were interviewed by *The Australian* about Starpharma's highly successful partnership with AstraZeneca. Ms Chatwin commented that Starpharma was chosen as a partner after a global search because its DEP® drug delivery technology had the ability to enhance AstraZeneca's oncology medicines.

Liz Chatwin, AstraZeneca (left) and Jackie Fairley, Starpharma

THE AUSTRALIAN

"We have looked for collaborations around the world to find partners with a similar approach who we can work with to help us bring new medicines to patients. There was evidence that when using Starpharma's technology with anti-cancer molecules, it could actually improve both the effectiveness and the safety of those molecules and provide them with a broader application". *Liz Chatwin, Country President, AstraZeneca Australia & New Zealand*

DEP® irinotecan progressing towards the clinic

Starpharma also has a DEP® version of major cancer drug, irinotecan (marketed by Pfizer under the brand name Camptosar®). DEP® irinotecan has demonstrated significantly better anti tumour activity and increased survival compared with standard irinotecan in a variety of human colon cancer models.

Irinotecan is primarily used to treat colorectal cancer, where there is a significant unmet need and an attractive market. Starpharma is expediting its development and scaling up the drug for further preclinical studies prior to clinical trials. The Company also has a number of other DEP® candidates under assessment.

VIVAGEL®

›› VivaGel® BV approved by TGA

(continued from page 1)

VivaGel® BV will be marketed in Australia by Aspen Pharmacare as Fleurstat™ BV gel, whilst also carrying the VivaGel® brand. Aspen is responsible for all marketing, promotion and local distribution of the product.

Starpharma will supply Aspen with the VivaGel® BV product and will also receive royalties on net sales.

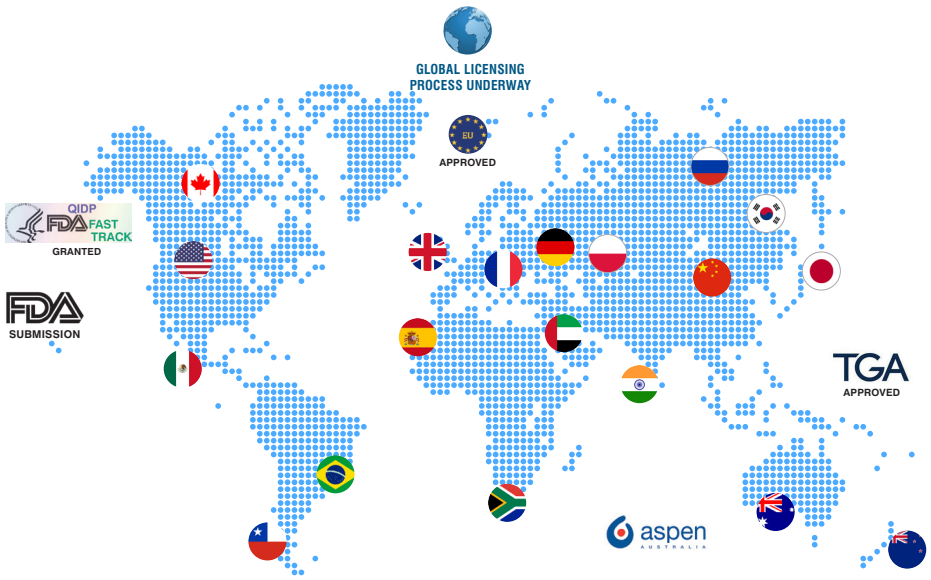
Launch plans for VivaGel® BV are well advanced and the product is expected to be available in pharmacies shortly.

"Australian clinicians and pharmacists will soon be able to recommend this novel non-antibiotic treatment for this common and problematic condition".

Dr Jackie Fairley, CEO Starpharma

›› Extensive global licensing negotiations for VivaGel® BV

Licence negotiations in multiple territories are occurring in parallel and continue to progress well. A number of term sheets and licence contracts are currently under negotiation with parties, including major global and regional companies as well as companies specialising in women's health.



VivaGel® BV licence strategy and negotiations positively impacted by:

- ✔ Fast Track status and QIDP
- ✔ Revised, favourable FDA BV guidance
- ✔ Successful phase 3 VivaGel® BV prevention of recurrent BV results
- ✔ NDA lodgement under rolling submission with Fast Track status
- ✔ TGA and EU approval, relevant for other markets

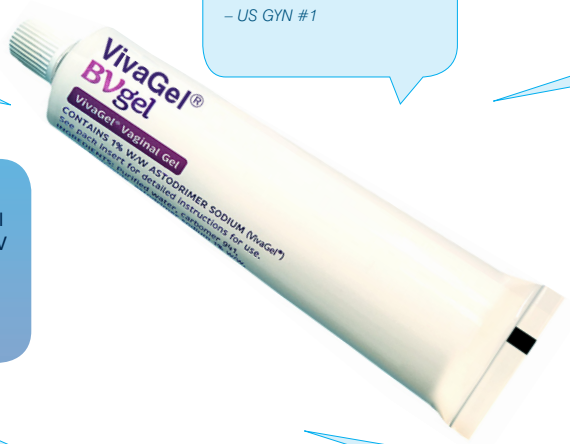
›› Positive market research findings for VivaGel® BV – from US physicians and payers alike

Starpharma recently completed comprehensive independent market research for VivaGel® BV in the US to inform marketing plans and its licensing discussions for the product. The market research involved a qualitative component via detailed interviews with 11 obstetrician-gynaecologists and seven payers, and a quantitative component via surveys with 70 obstetrician-gynaecologists and 30 primary care physicians. See below some verbatims from the research:

*"I think part of the reason why we are seeing **more recurrence** is that there has got to be some kind of **resistance being built up to the antibiotics**."*
– US GYN #5

*"I would love to try it [VivaGel® BV] because **it is not an antibiotic**."*
– US GYN #1

*"The good news is **not having an antibiotic** hanging around the environment **is good**. The more antibiotics you have out there, the more potential for resistance."*
– US Payer #3



Following VivaGel® BV launch, physicians estimate that twice as many physicians will prescribe a preventative therapy to their BV patients (currently only off-label regimens available) and 75% more patients will be prescribed a preventative therapy.

Top VivaGel® BV attributes to patients

1. Speed of odour resolution
2. Efficacy
3. Speed of discharge resolution
4. Mode of action (non-antibiotic)
5. Route of administration (vaginal gel)

*"It [VivaGel® BV] is certainly simple enough and **the side effect profile is minimal**."*
– US GYN #6

*"The biggest unmet need is to be able to prescribe a treatment that has **minimal side effects**, does not interfere with the patient's lifestyle and **resolves symptoms quickly**."*
– US PCP #1

*"I like the molecule [VivaGel® BV] **there is nothing really that treats that recurrent patient**".*
– US Payer #2

*"It seems like **it [VivaGel® BV] would replace current [off label] prophylactic regimens** that I recommend".*
– US NP #1

Source: Independent US VivaGel® BV Market Research 2017

CORPORATE NEWS

›› Q2 Cashflow Report at 31 December

Starpharma reported that its cash balance as at 31 December 2017 was $49.9 million.

The cash outflows for the quarter included $3.2 million (US$2.4 million) paid to the FDA on the submission of the New Drug Application (NDA) for VivaGel® BV in November. Subsequent to the NDA submission, Starpharma received a Small Business Waiver from the FDA for the NDA submission fee. The full amount was refunded in January, increasing the Company's cash balance since 31 December 2017.

Starpharma's cash balance places the Company in a very strong position to continue to accelerate its multiple DEP® candidates, such as DEP® docetaxel and DEP® cabazitaxel, through clinical development, advance partnered programs and secure valuable commercial licences for VivaGel® BV ahead of launch in a number of key markets.

In addition to the NDA refund, Starpharma's R&D tax incentive refund of $3.7 million is also anticipated in the March quarter.

An Australian Government Initiative AusIndustry

R&D Tax Incentive

›› OTCQX market recognition

Starpharma was recently named as one of the top performing companies on the OTCQX market in 2017.

BEST 50 OTCQX 2018

The Company ranked number 25 in the OTCQX Best 50, which is an annual ranking of the top 50 US and international companies traded on the OTCQX market based on their performance (total return and volume growth).

CORPORATE NEWS

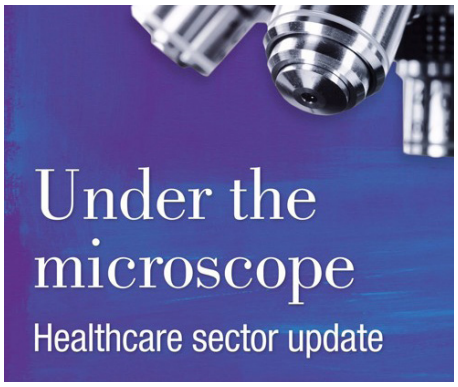
›› Starpharma News & Events

›› In January 2017, Starpharma attended the annual J.P. Morgan Healthcare Conference. Based in San Francisco, this is one of the largest annual healthcare conferences in the US. Investor meetings and partnering discussions with international pharmaceutical companies were held whilst attending the conference.

J.P.Morgan

January 8 - 11, 2018
36TH ANNUAL HEALTHCARE CONFERENCE
San Francisco, California

›› Morgans Under the Microscope series featured Dr Jackie Fairley discussing a number of key milestones that are approaching and the licensing arrangements entered into with AstraZeneca. http://www.starpharma.com/news/in_the_media



›› Online financial news portal Finance News Network reported Starpharma received TGA marketing approval for VivaGel® BV, which is expected to be available in pharmacies under the Fleurstat™ brand. http://www.starpharma.com/news/in_the_media

FINANCE NEWS NETWORK

OUTLOOK

Starpharma anticipates a number of important milestones across its VivaGel® and DEP® portfolios, including those highlighted below.

›› VivaGel® portfolio

- FDA — Finalise and submit NDA for VivaGel® BV
- Launch of VivaGel® BV in Australia (under Fleurstat™ brand), Europe, US and elsewhere
- Sign licence agreement(s) for VivaGel® BV (multiple territories/licences)
- Further regulatory approvals for VivaGel® BV
- Launch of VivaGel® condom in additional regions, such as Europe, Japan and China
- FDA — FDA approval of VivaGel® BV

›› DEP® portfolio

- Progress with DEP® docetaxel and DEP® cabazitaxel trials
- AstraZeneca — AstraZeneca program developments, including progressing AZD0466 to the clinic and associated milestones
- Additional DEP® candidates developed and advanced to the clinic (e.g. DEP® irinotecan)
- AstraZeneca — Further AstraZeneca compounds advanced and expanded licenses
- Targeted DEP® program developments and licences
- Other partnered DEP® deals anticipated

Starpharma Holdings Limited
(ASX:SPL; OTCQX:SPHRY)
ABN 20 078 532 180
4-6 Southampton Crescent
Abbotsford
Vic 3067
+61 3 8532 2700

www.starpharma.com

Company
Nigel Baade
CFO/Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com

Media Relations
Rebecca Wilson
WEBuchan
Mob: +61 417 382 397
rwilson@buchanwe.com.au