SHAREHOLDER Update

starpharma

OCTOBER 2020

SPL7013 COVID-19 NASAL SPRAY

>> Starpharma is expediting the development of the SPL7013 COVID-19 nasal spray

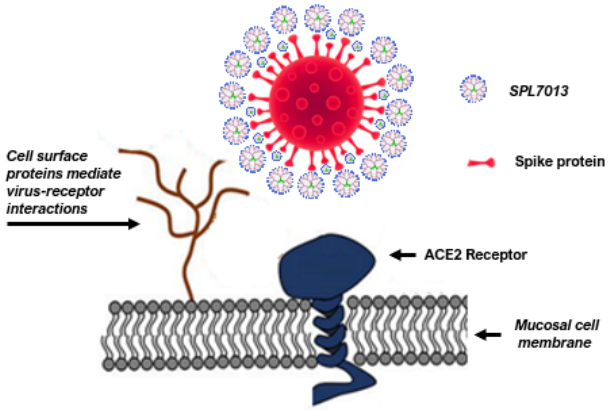
In September 2020, Starpharma announced it had completed additional antiviral testing for SPL7013 against SARS-CoV-2 in the laboratory of internationally recognised virology researcher, Professor Philippe Gallay, at the renowned Scripps Research Institute in the US.

Testing showed that SPL7013 COVID-19 nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2, and the potent antiviral activity of SPL7013 against SARS-CoV-2 was demonstrated in vitro when used either before or after infection, meaning that the nasal spray could potentially be used before or after exposure to the virus.

Above: indicative packaging for the SPL7013 COVID-19 nasal spray

Since establishing its potent antiviral activity, Starpharma has expedited the development of the SPL7013 nasal spray and has already completed reformulation, pilot product manufacture, selection of device and packaging components, and selection of a manufacturer. Compilation of regulatory documentation is also underway in preparation for submission. The company has also commenced commercial discussions across a range of distribution channels and customer groups and expects that the product will be ready for market in 1H CY2021.

Based on its previously established mechanism of action in multiple viruses, SPL7013 is thought to bind to the SARS-CoV-2 "spike" proteins, thereby blocking the ability of the virus to attach to, and infect, mucosal (human) cells.



INTERNAL DEP®

>> Rapid progress in the DEP® irinotecan phase 2 & preparations underway for clinical combinations

DEP® irinotecan phase 2 trial is recruiting patients rapidly, with 26 patients already dosed and a high level of interest in the study. Encouraging efficacy signals have been observed for a number of tumour types, including colorectal, ovarian and oesophageal cancer. The trial continues to recruit patients with cancers with a focus on colorectal as well as other cancer types, such as breast and pancreatic. Reponses to DEP® irinotecan include stable disease for more than 1 year in a patient with stage IV breast cancer with extensive liver metastases. This impressive result is despite the patient having been heavily pre-treated - with more than 100 cycles of 11 different breast cancer treatments previously.

Starpharma has commenced preparations for the addition of clinical combinations with DEP® irinotecan, based on investigator interest and preclinical studies, including in the area of immunotherapy.

>> DEP® irinotecan in combination with immuno-oncology showed superior performance in colon cancer models

In June 2020, Starpharma announced that DEP® irinotecan in combination with an immuno-oncology (IO) agent (anti PD-1 antibody) showed superior anti-tumour activity and significant survival benefit in two colorectal cancer (CRC) models when compared to the anti PD-1 antibody or irinotecan alone. Significant improvement in both survival and efficacy were seen, notably in the particularly aggressive CT-26 CRC model.

These results indicate that DEP® irinotecan in combination with an anti PD-1 antibody (like Merck's Keytruda®) could boost the efficacy over anti PD-1 antibody alone, or the combination of these immuno-oncology agents with standard chemotherapeutic agents. These results provide important data which inform the identification of value-adding clinical combinations and potential partnering opportunities.

"Anti PD-1 antibodies have been a major breakthrough in cancer treatment, but substantial unmet need remains, and non-responders make up more than 75% of all incident cancers, highlighting the need for more effective agents and combinations"[1]

IO agents like anti PD-1 antibodies are important treatments in several major cancers and the market for these agents is expected to exceed US$55 billion by 2025, and include Merck's Keytruda®, BMS' Yervoy® and AstraZeneca's Imfinzi®.

[1] (August 2019 IO presentation by Peter F Lebowitz (M.D. PhD), Global Therapeutic Area Head, Oncology, Janssen Oncology, with data sourced from Cancer Incidence from Globocan 2018)

VIVAGEL® BV

>> VivaGel® BV launched in Central & Eastern Europe and Nordic region

VivaGel® BV (Betadine® BV Gel) was launched in Central and Eastern European (CEE) region in June 2020. This followed European launches in Germany, UK and several other European countries. VivaGel® BV is available Over-The-Counter (OTC) in the CEE, without the need to see a doctor or obtain a prescription. More recently, VivaGel® BV (Betadine® BV Gel) was also launched in the Nordic region and preparations for further launches are underway.

"Betadine® BV Gel (VivaGel® BV) is fast-becoming a trusted brand, based on its quality and effectiveness as a treatment for BV. We are delighted to be able to deliver this product to women in eastern and central Europe through our extensive marketing and distribution network."

Raman Singh, Mundipharma CEO

>> VivaGel® BV regulatory update

Fleurstat BVgel gains expanded TGA approval to include prevention of recurrent Bacterial Vaginosis (BV) indication

In September 2020, the Australia Therapeutic Goods Administration (TGA) approved an expansion of the marketing authorisation for VivaGel® BV (Fleurstat BVgel) to include the indication of prevention of recurrent bacterial vaginosis. The expanded claims under the marketing authorisation bring the approved indications for VivaGel® BV (Fleurstat BVgel) in line with those in Europe and Asia.

This prevention of recurrent BV indication for VivaGel® BV approved by TGA includes prevention of unpleasant vaginal odour and discharge, and helping to maintain normal vaginal pH and vaginal flora balance.

VivaGel® BV has now been approved in 40 countries with further submissions underway

The Starpharma and Mundipharma teams continue to work together on additional regulatory submissions to support further launches of VivaGel® BV in Mundipharma's territories. A significant number of submissions have been progressed, and recent approvals have been received for countries in Africa and the Middle East.

In the US, Starpharma is receiving ongoing input from its team of expert FDA consultants (regulatory, statistical, clinical, legal - including senior ex-FDA staffers). The formal FDA review is ongoing, and COVID-19 has had an impact on timing.

FLEURSTAT BVGEL (VivaGel® BV) for the treatment of BV and relief of symptoms: Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. Do not use for more than 7 days unless a doctor has told you to. See your doctor if symptoms persist after 7 days or recur within 2 weeks, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).

SPL7013 COVID-19 NASAL SPRAY

Continued from page 1.

>> Starpharma awarded $1 million MRFF funding for COVID-19 nasal spray

In early September 2020, Starpharma was awarded $1 million in matched funding by the Australian Government's Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Program to expedite development and commercialisation of its SPL7013 COVID-19 antiviral nasal spray.

Starpharma's product was selected by an expert international industry panel as one of only five recipients for this COVID-19 specific MRFF funding which required projects to be capable of achieving *substantial and rapid impact in the global response to the COVID-19 pandemic within 12 months*. This is an important initiative aimed at accelerating Australian innovations to address the global COVID-19 pandemic.

"The selection of Starpharma's COVID-19 nasal spray recognises both its global relevance and near-term potential with differentiated features which are complementary to other preventative measures, like vaccines. We are proud of our contribution to the global biomedical industry response to combat COVID-19"

Dr Jackie Fairley, CEO Starpharma

CAPITAL RAISING

>> Starpharma completes oversubscribed A$45M placement, SPP underway

On 30 September 2020, Starpharma announced it had raised A$45 million via a placement to domestic and international institutional, sophisticated and professional investors ("Placement"). The Placement was oversubscribed with strong demand from existing institutional shareholders while also bringing new large domestic and international funds on to the register. The Placement was conducted at $1.50 per share, representing a 6.5% discount to the last closing price ($1.605 per share) prior to Starpharma's shares going into a Trading Halt on 28 September 2020.

A Share Purchase Plan (SPP) is open until 27 October 2020 for eligible shareholders to participate, at the same Placement price of A$1.50 per share without incurring brokerage costs, up to a maximum of A$30,000.

The funds being raised will allow the company to fund advancement across all areas of the business including:

- Expediting the commercialisation, and launch following regulatory approval, of the COVID-19 SPL7013 nasal spray and exploring other presentations (e.g. COVID-19 eye drops) for SPL7013
- Expediting and advancing DEP® clinical programs to support licensing, including undertaking additional DEP® clinical trial combinations and advancing additional DEP® candidates to the clinic
- DEP® pipeline development to develop new DEP® candidates to advance into clinical trials (e.g. antiviral, oncology &/or radiotherapeutic)
- Provide working capital to enhance balance sheet to support activities across the business

INTERNAL DEP®

›› DEP® docetaxel

The phase 2 DEP® docetaxel trial continues to progress well, with further observations of encouraging efficacy signals, including prolonged stable disease and tumour shrinkage such as in patients with pancreatic, oesophageal and gastric cancer.

Based on compelling DEP® preclinical data and investigator interest, a combination DEP® docetaxel with gemcitabine trial commenced in July 2020. This combination study will recruit an initial cohort of approximately 10-12 patients and will run in parallel with the phase 2 DEP® docetaxel trial.

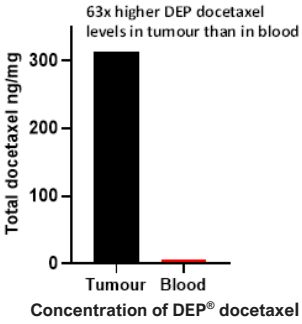
Patient biopsies demonstrate tumour targeting of DEP® docetaxel

During the phase 2 DEP® docetaxel trial, multiple patient tumour biopsies have demonstrated that the same tumour targeting observed with DEP® in animal studies has also been replicated in patients treated with DEP® docetaxel, delivering substantially higher levels of drug than in blood. This accumulation of DEP® drug in tumour tissue is an important benefit of DEP® which has been demonstrated in multiple preclinical studies.

PATIENT CASE STUDY: 72 year old woman with extensive intrahepatic cholangiocarcinoma, an often fatal cancer that affects the bile ducts

Cholangiocarcinoma is a rare but aggressive form of cancer. The 5-year survival rate for intrahepatic cholangiocarcinome is very low (8%).

- Patient was heavily pre-treated having progressed following 8 cycles of prior anti-cancer therapy
- Patient received 4 cycles of DEP® docetaxel and achieved >16 weeks stable disease
- A tumour biopsy following dosing with DEP® docetaxel and showed 63 fold more DEP® docetaxel in the tumour tissue than in blood (i.e. a tumour to blood ratio of ~63x)



DEP® PRODUCTS FEATURED AT AACR

›› Multiple DEP® products showcased at AACR 2020 Annual Meeting

Five posters featuring DEP® products were presented at the 2020 AACR (American Association for Cancer Research) Annual Meeting in June. The annual AACR Annual Meeting is one of the most widely attended cancer research meetings and brings together leading cancer research from institutions all over the world.

The posters highlight the reproduceable improvements in both efficacy and therapeutic index enabled by the DEP® technology which are platform benefits that have been observed in both internal products and partner programs. Three of the five poster presentations feature AstraZeneca's novel oncology DEP® product, AZD0466. The AZD0466 posters highlight the significant improvement in therapeutic index delivered by the DEP® technology, which enabled the progression of AZD0466 into the clinic, and the impressive efficacy across multiple tumour models and patient samples.

INTERNAL DEP®

›› DEP® cabazitaxel

The phase 2 DEP® cabazitaxel trial continues to progress with encouraging efficacy signals, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA), in cancers including prostate, ovarian, lung, gastro-oesophageal and others.

In August 2020, a new trial site was opened at the Kinghorn Cancer Centre in Sydney. The DEP® cabazitaxel trial is also continuing at multiple leading cancer centres in the UK.

PATIENT CASE STUDY: 65-year old man with late-stage (metastatic) gastro-oesophageal cancer

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Heavily pre-treated patient with >15 cycles of three different kinds of anti-cancer treatment and cancer progressed
- Patient received 6 cycles of DEP® cabazitaxel

Response to DEP® cabazitaxel: Achieved a 50% reduction in target tumours and maintained this for >27 weeks.

PARTNERED DEP®

›› New DEP® partnership signed with Chase Sun for anti-infective program

In August 2020, Starpharma signed a new DEP® partnership with Chase Sun to develop several DEP® nanoparticle formulations for an anti-infective drug with the view of enhancing its performance and expanding its therapeutic utility.

Chase Sun is a leading listed Chinese pharmaceutical company focussed on R&D and commercialisation of healthcare products, with more than 6,000 employees. Chase Sun's market capitalisation exceeds A$3 billion (stock code 300026) and its 2019 sales were in excess of A$1 billion.

Chase Sun will fund all development costs associated with any DEP® product resulting from the program. In the event that Chase Sun wishes to commercialise any of the resultant DEP® products, a DEP® licence agreement will be entered into with Starpharma.

›› AstraZeneca's AZD0466 trial opens at MD Anderson Cancer Center

In July 2020, MD Anderson Cancer Center, the internationally renowned cancer center in Houston (Texas), opened as a further trial site for AZD0466. The phase 1 trial is currently underway at multiple sites in the US.

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

DEP® PIPELINE

›› Starpharma creates slow release soluble DEP® remdesivir

In recent months Starpharma has applied its novel DEP® drug delivery technology to create a long-acting, water soluble version of Gilead's antiviral drug, remdesivir (Veklury®). Remdesivir is being utilised for the treatment of COVID-19 under emergency use authorisation from the US Food and Drug Administration for patients with severe disease.

Current remdesivir formulations are administered intravenously, with each infusion taking up to 2 hours and requiring daily administration for 5 -10 days. In contrast, Starpharma's DEP® remdesivir is a water-soluble nanoparticle formulation of remdesivir, providing a controlled release (long acting) of remdesivir. In addition, the improved solubility means that DEP® remdesivir could be administered subcutaneously in ~2-3mls instead of by intravenous infusion, thereby potentially expanding its usage to non-hospital settings and improving patient access and convenience.

›› DEP® partnering, including Antibody Drug Conjugates

Starpharma has a number of DEP® Antibody Drug Conjugate (ADC) programs already underway with partners and has recently commenced discussions with multiple new pharmaceutical companies for DEP® programs in ADCs, and other therapeutic areas. ADCs continue to generate significant interest in oncology and have been the subject of recent deals, including Gilead's acquisition of Immunomedics for US$21 billion (Sep 2020).

›› DEP® lutetium; impressive efficacy in human prostate cancer model

In June 2020, Starpharma reported that its first DEP® radiotherapy candidate, DEP® lutetium, showed highly statistically significant anticancer activity, tumour regression and 100% survival (to >66 days) in a human prostate cancer model (DU-145). Starpharma has developed multiple novel radiotherapeutic and radiodiagnostic candidates.

Radiopharmaceuticals is a rapidly developing area of cancer treatment and diagnosis, and has recently generated several high-value deals and sales in this category are estimated to grow to $12–15 billion by 2030. (*Nuclear medicine world market report & directory, MEDraysintell, 2016*).

OUTLOOK

›› SPL7013 & Coronavirus

Expedite development and launch of SPL7013 antiviral nasal spray

›› VivaGel® portfolio

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

›› DEP® portfolio

- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan phase 2 trials; value-adding combination studies;
- AZD0466 clinical progress, and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and/or deals for further compounds
- Partnered DEP® deals & program developments, including DEP® ADCs
- Advance DEP® radiopharmaceuticals, DEP® ADCs and DEP® antivirals e.g. DEP® remdesivir
- Advance value-adding DEP® combinations in clinic and other DEP® products

NEWS & EVENTS

›› Annual Report & ESG Report

Starpharma's Annual Report and inaugural Environment, Social & Governance (ESG) Report were released in August 2020. The ESG Report shows how Starpharma contributes to the broader community, and outlines its responsible business practices. Both reports are available at www.starpharma.com.

›› Upcoming AGM

Starpharma's 2020 Annual General Meeting will be held online on Friday, 20th November 2020 at 11am (Melbourne time). In light of the current circumstances and Victorian COVID-19 restrictions this year, the AGM will be held as a virtual meeting. There will not be a physical venue for Shareholders to attend. For further details, including the Notice of AGM, click here.

›› ABC's 7.30 report featured Starpharma

The ABC's 7:30 report interviewed Starpharma CEO Dr Jackie Fairley to discuss the importance of creating COVID-19 preventative products while the world waits for a vaccine to be developed. Watch the full interview here.

›› Starpharma featured on Health Kick Podcast

Stockhead's Tim Boreham interviewed Dr Jackie Fairley for the Health Kick Podcast. Dr Boreham reported that Starpharma has gone from strength to strength with progress on its COVID-19 nasal spray. To hear an overview of the company, and update on current development programs and plans for the year ahead, listen to the full episode here.

Disclosure

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

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