

## VIRALEZE™

### >> SPL7013 in VIRALEZE™ virucidal against influenza A and B

Starpharma recently reported new virucidal data for SPL7013, the antiviral agent in VIRALEZE™ nasal spray. SPL7013 achieved 95% and 99.7% reduction in viral infectivity\* within 5 minutes against influenza A and B, respectively. In this experiment, the findings also showed that the virucidal activity of SPL7013 was superior to two antiviral agents used in currently marketed nasal sprays - hydroxypropyl methyl cellulose (HPMC) and iota-carrageenan. In contrast to the potent and rapid effect of SPL7013, HPMC and iota-carrageenan did not exhibit virucidal effect in this experiment at 30 minutes. See Figure 1 below for comparison of SPL7013 with HPMC.

**Figure 1. Infectivity of influenza A virus (log<sub>10</sub> PFU/mL) following incubation with SPL7013 or HPMC (mg/mL)**

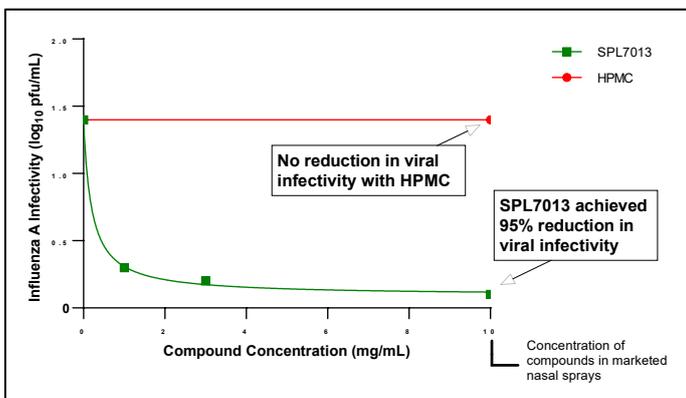


Figure 1 shows influenza A infectivity (plaque forming units (PFU)) following 30 mins' incubation of virus with SPL7013 (0, 1, 3 or 10 mg/mL) or HPMC (0 or 10 mg/mL).

\*Noting the maximal possible reduction of virus infectivity in these assays was 96% for influenza A and 99.8% for influenza B.

### >> VIRALEZE™ to relaunch in the UK



In April, Starpharma was pleased to announce that VIRALEZE™ nasal spray will relaunch in the UK shortly, following the successful resolution of issues raised by the MHRA. This positive outcome follows the provision of extensive technical information on SPL7013 and VIRALEZE™ by Starpharma. The company is now working closely with LloydsPharmacy for the relaunch of VIRALEZE™ in the UK, with product expected to be available to UK consumers this month.

*"Together with LloydsPharmacy, we are excited to make VIRALEZE™ available to UK consumers again very soon."*

– Dr Jackie Fairley, Starpharma CEO

## DEP® PARTNERING

### >> AstraZeneca expands the clinical program for their DEP® agent, AZD0466



In February, AstraZeneca advised of a further expansion of their AZD0466 clinical program to include a new indication - non-Hodgkin's lymphoma, one of the 10 most commonly occurring cancers worldwide.

AZD0466 is a highly optimised DEP® nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor that is being developed with high priority by AstraZeneca under Starpharma's multiproduct licence agreement. AstraZeneca's AZD0466 trial in patients with non-Hodgkin's lymphoma has commenced with recruitment underway.

This expanded lymphoma clinical program will run in parallel with the ongoing global phase 1/2 trial in patients with acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL). The leukemia trial replaces the first-in-human study in solid cancers, following AstraZeneca's decision to focus initial development activities on haematological cancers to expedite AZD0466's development.

In addition to these two trials, AstraZeneca recently informed Starpharma that it plans to expand the AZD0466 clinical program to include an additional cancer type. Starpharma welcomes these positive developments for AZD0466 and its further expanded market potential.

Clinical program for AZD0466	Status
Global phase 1/2 study in advanced haematological malignancies (AML & ALL)	Recruiting & opening new sites
Multi-centre phase 1/2 study in non-Hodgkin's lymphoma	NEW Sites open & recruitment underway
Additional indication planned	NEW Details TBA

### >> Business development and conferences

This month, Executives from Starpharma are participating in major industry conferences *American Society of Clinical Oncology (ASCO)* and *BIO International Convention* in the US as part of the company's business development and clinical strategy. In addition to partnering activities at these conferences, Starpharma will hold meetings at major R&D sites of two DEP® partners in the US, including Merck. Starpharma will also be meeting with new potential partners while in the US in relation to existing DEP® assets and to expand the company's partnered DEP® programs.



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## INTERNAL DEP®

### >> DEP® cabazitaxel clinical program



Starpharma's phase 2 clinical trial of DEP® cabazitaxel has recruited 62 patients, with encouraging efficacy signals observed in multiple cancer types including prostate, ovarian and gastro oesophageal.

Starpharma announced positive interim findings for the prostate cancer cohort of the DEP® cabazitaxel trial, showing 100% of patients assessed for efficacy experienced one or more efficacy signals following treatment with DEP® cabazitaxel. The DEP® cabazitaxel trial is continuing to recruit additional patients with ovarian and gastro oesophageal cancers, following observation of promising efficacy signals in these additional tumour types.

### >> DEP® irinotecan clinical program

Starpharma's phase 2 clinical program for DEP® irinotecan has recruited 78 patients, with encouraging efficacy signals observed in a range of important tumour types, including colorectal, breast, ovarian, pancreatic, lung, and oesophageal. These responses include impressive and prolonged tumour shrinkage, in some cases up to 72 weeks, and reductions in tumour markers.



### >> DEP® irinotecan combination arm to commence

Starpharma is progressing a DEP® irinotecan combination arm, which will run in parallel to the phase 2 monotherapy investigations for DEP® irinotecan.

DEP® irinotecan will be used in combination with 5-FU + Leucovorin (FOLFIRI), which is a commonly used treatment regimen in colorectal cancer. Enrolment of patients in this combination arm is expected to commence shortly, pending finalisation of the recommended combination dose.

### >> DEP® docetaxel clinical program



Starpharma's DEP® docetaxel clinical program has recruited 71 patients across the monotherapy and combination arms. Encouraging efficacy signals have been observed in patients with lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers. These efficacy signals include prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients.

### >> DEP® clinical case studies

#### 55-year-old Woman with Stage IV Colorectal Cancer



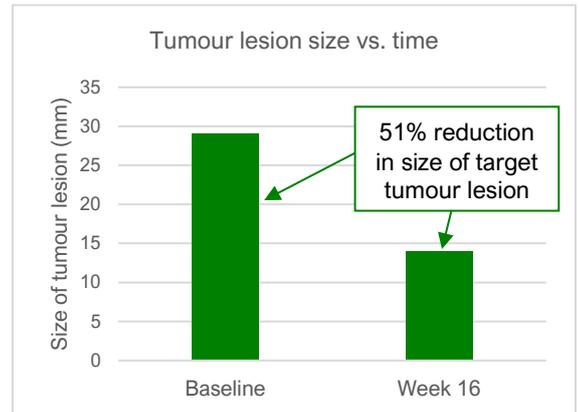
- The patient had extensive metastases in their liver and lung and was heavily pre-treated, having received 19 cycles of 3 previous treatment regimens
- Response to treatment with DEP® irinotecan after 6 treatment cycles:
  - 73% reduction in tumour marker (CEA<sup>†</sup>) levels
  - 20% reduction in target lesions

<sup>†</sup>Carcinoembryonic antigen

#### 60-year-old Woman with Stage IV Uterine Sarcoma



- Patient's cancer had progressed following 3 different previous anti-cancer treatment regimens
- Response to treatment with DEP® docetaxel in combination with gemcitabine after 5 treatment cycles:
  - 51% reduction in size of target tumour lesion



### >> DEP® gemcitabine clinical study to commence shortly

Starpharma is progressing a phase 1/2 clinical trial of DEP® gemcitabine, following encouraging preclinical results and significant clinician interest. The company is completing final preclinical activities, including product manufacture, prior to commencing the first in-human study for this DEP® product.



DEP® gemcitabine is a DEP® version of Lilly's Gemzar® (gemcitabine), which is a widely used anti-cancer drug that achieved peak sales of US\$1.7 billion. Gemzar® is one of the leading chemotherapeutic drugs used to treat pancreatic cancer and can be administered as a monotherapy or in combination with other therapies such as Abraxane®.

In Starpharma's preclinical studies, DEP® gemcitabine demonstrated significantly improved anti-tumour activity compared to Gemzar® in human pancreatic cancer xenograft models. When used in combination with Abraxane®, DEP® gemcitabine also significantly outperformed a combination of Gemzar® and Abraxane®. DEP® gemcitabine will be the company's fourth internal DEP® product to enter the clinic.

### >> DEP® radiotheranostics, DEP® Antibody Drug Conjugates & other DEP® candidates

Starpharma continues to develop and advance additional DEP® candidates towards the clinic, including in exciting and innovative research areas, such as radiotheranostics and antibody drug conjugates.



## DEP® PARTNERING

### >> Partnered DEP® programs

Starpharma now has partnered DEP® programs with several leading pharmaceutical companies around the world and has an active business development program to build this further. These partnerships include the multi-product license with AstraZeneca that encompasses the AZD0466 clinical development program, a DEP® ADCs program with Merck & Co., Inc., a DEP® anti-infective program with Chase Sun, and a DEP® program with a major US biopharmaceutical company.



While Starpharma continues working on these existing DEP® programs, further DEP® partnerships are at an advanced stage of negotiation with leading pharmaceutical companies, including in the innovative research areas of DEP® radiotheranostics and DEP® ADCs.

### >> Business development and conferences

*Continued from page 1.*

In April, Starpharma presented at the *Novel Format Conjugates Summit*, an industry conference focusing on next generation Non-Traditional Antibody Drug Conjugates (ADCs) for oncology and beyond. There is an increasing interest in novel approaches to the development of ADCs, and Starpharma's presentation was extremely well received. This conference brought together international thought leaders to share cutting-edge scientific advances from the world of alternative format conjugates. The industry event was held in Boston in the US and hosted speakers and attendees from international companies including AstraZeneca, Merck, Lilly, Sanofi, Takeda, Regeneron and Avidity. The abridged presentation is available on Starpharma's website at [www.starpharma.com](http://www.starpharma.com).

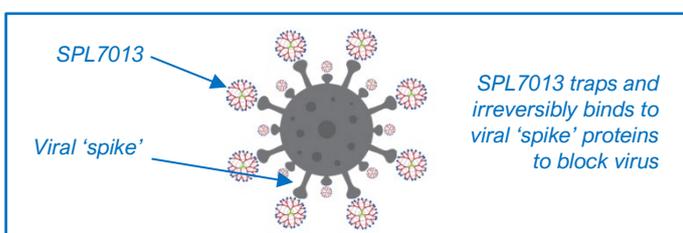


## VIRALEZE™

### >> SPL7013 (VIRALEZE™) highly active against Omicron and outperforms other antiviral agents

Starpharma completed further antiviral testing of SPL7013, the agent in VIRALEZE™ nasal spray, against the highly contagious Omicron variant of SARS-CoV-2. The antiviral testing was conducted by Professor Philippe Gallay at The Scripps Research Institute in the US.

SPL7013 achieved the maximal possible reduction for the Omicron variant of >99.5% of virus infectivity, in this study, and also outperformed other antiviral agents used in marketed nasal sprays, including iota-carrageenan. SPL7013 was ~30 times more potent than iota-carrageenan against the Omicron variant, which is currently marketed in multiple nasal sprays, and 70 times more potent than heparin, which has been reported as a potential antiviral nasal spray.



### >> International rollout of VIRALEZE™

VIRALEZE™ is now registered in more than 30 countries worldwide. VIRALEZE™ has been well received by both consumers (online and instore) and healthcare professionals in markets where the product has been launched.



Starpharma is also actively progressing registration and commercialisation for VIRALEZE™ in new markets to expand the product's availability globally.

### >> Regulatory progress in Australia

Starpharma continues to engage with the TGA in Australia. The TGA recently confirmed the nasal spray product meets the definition of a medical device. This confirmation follows thorough review by senior personnel of the extensive mechanistic data on the product and aligns the regulatory classification with the product's classification in more than 30 other countries, including the UK.

*VIRALEZE™ is not approved for sale or supply in Australia.*

## VIVAGEL®

### >> New peer-reviewed publication of VivaGel® BV in Archives of Gynecology & Obstetrics

VivaGel® BV was featured in a recent article published in the highly regarded peer-reviewed European journal, *Archives of Gynecology & Obstetrics*. The article highlights the significant unmet need for new treatment and prevention options in bacterial vaginosis (BV), and the role that Starpharma's VivaGel® BV can play in addressing this need. VivaGel® BV is currently registered in more than 45 countries and this publication will support marketing activities and inclusion of the product in clinical treatment guidelines for BV.

### >> Okamoto launches new VivaGel® condom brand in Japan

Starpharma's VivaGel® condom partner in Japan, Okamoto, launched an additional VivaGel® condom range under the brand name *Pure marguerite*, targeting younger demographics. The range is being distributed through major national retail chains in Japan.



*Archives of Gynecology & Obstetrics*



*Okamoto's new Pure marguerite condom brand*

## CORPORATE

### >> Quarterly Cashflow: 3Q FY22

Starpharma released its latest Quarterly Cashflow and Activities Report for the March quarter. Starpharma's cash balance as at 31 March 2022 was \$54.8 million, an increase of \$3.6 million from 31 December 2021. Receipts for the quarter of \$9.6 million, comprised of receipts from customers of \$1.8 million, including sales of VIRALEZE™, and the \$7.7 million R&D tax incentive refund. Net operating cash inflows were positive \$3.0 million for the quarter.



### >> Our People

Starpharma welcomed highly experienced industry executive, Dr Jeff Davies, to its Board of Directors as a non-executive Director on 1 April 2022. Dr Davies is a former executive, with over 35 years of biopharmaceutical industry experience, holding senior technical and commercial executive roles at CSL, including Executive Vice President & General Manager at CSL for the Asia-Pacific Region, and Global Head of Plasma Product Research and Development at CSL-Behring, Switzerland.



After 15 years at Starpharma, Dr David Owen has made the decision to return to his home-state of Queensland and has accepted a Professorship at The University of Queensland. We congratulate David on his new role and thank him for his significant contribution to Starpharma. For more than five years, Starpharma's discovery and manufacturing chemistry teams have been led by two experienced senior research managers, Dr Richard Hufton and Dr Brian Kelly, who between them have more than 40 years of industry experience, including more than 20 years at Starpharma, and following David's departure, have taken on additional responsibilities. Richard and Brian have deep knowledge of the DEP® platform, pharmaceutical research and development and have played key roles in our internal and partnered DEP® programs. Under their leadership, Starpharma's highly experienced chemistry and development teams will continue to expand and develop our DEP® pipeline, including our growing portfolio of industry partnerships.

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## KEY VALUE DRIVERS & OUTLOOK

### >> DEP®

- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan clinical programs; progress value-adding combination studies
- AZD0466 clinical progress, expansion of indications, trial sites recruitment & receipts of milestones
- AstraZeneca: Exercise of Option Agreement &/or deals for further compounds
- Progress existing partnered DEP® programs, including with Merck & Co., Inc., Chase Sun, and other partners
- Execute/expand new DEP® partnerships/agreements
- Advance DEP® radiotheranostics, DEP® ADCs & other DEP® candidates
- Advance value-adding DEP® combinations in clinic & other DEP® products



### >> VIRALEZE™

- Further roll-out of VIRALEZE™ nasal spray in registered countries
- Further VIRALEZE™ registrations
- Further VIRALEZE™ launches
- Further distribution & marketing arrangements with commercial partners
- Continued testing of SPL7013 against SARS-CoV-2 variants & other respiratory viruses



### >> VIVAGEL®

- Continued commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Further regulatory approvals & launches for VivaGel® BV, building revenues, milestones & sales/royalties
- VivaGel® BV - FDA review process
- VivaGel® condom approvals/launch in additional countries
- Further development/co-development of SPL7013



*This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", "outlook", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected. Starpharma is providing this information as of the date of this presentation and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events, or developments or otherwise. Clinical case studies/data: Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document, nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.*