

Starpharma to present at Bell Potter Healthcare Conference

Melbourne, Australia; 8 November 2022: Starpharma (ASX: SPL, OTCQX: SPHRY) has been invited to present today at the <u>Bell Potter Healthcare Conference</u>, a virtual conference taking place on 8-10 November showcasing Australia's leading healthcare companies to institutional investors and Bell Potter's retail network.

Starpharma will present a brief overview of the business, with a focus on recent milestones, including clinical data for DEP® cabazitaxel in prostate cancer, which was recently presented at the European Society of Medical Oncology in Paris, France; and progress with partnered DEP® programs, including a second DEP® Research Agreement signed with MSD.

The Bell Potter Healthcare Conference presentation is attached.

This announcement is intended for investors and market participants only. VIRALEZE™ is not approved for use or supply in Australia.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for DEP® drug delivery, respiratory viruses and VivaGel®.

Starpharma's proprietary drug delivery platform technology, DEP®, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies.

DEP® partnerships include oncology programs with AstraZeneca, with MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE™ is not approved for use or supply in Australia. SPL7013 is also utilised in the following products - VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries and are registered in >45 countries, including the UK, Europe, Japan, Southeast Asia, South Africa, Australia and New Zealand.

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Starpharma Holdings Limited

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Disclosure

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.



Forward Looking Statements

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", or similar expressions, or by express or implied discussions regarding potential fillings 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 authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any 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 trial results, including additional analysis of existing data, and new 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 document 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 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.







8 November 2022

Dr Jackie Fairley, CEO











Important notice and disclaimer

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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.

This document is intended for investors and market participants only.

FLEURSTAT BVgel (VivaGel® BV) for the treatment of BV and relief of symptoms: ASK YOUR PHARMACIST ABOUT THIS PRODUCT. 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 of completing a course, or if you consider you may be at risk of a sexually transmitted infection (STI). See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).

VIRALEZE™: Not approved for sale or supply in Australia. ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE. This medical device is a regulated health product that bears, under this regulation, the CE marking in the EU. Do not use if you have a history of sensitivity to any ingredient in the formulation. Not for use in children under the age of 12 years. See a doctor If you are pregnant or breastfeeding. Always follow recommendations from health authorities, including vaccination and good hygiene practices, such as the use of masks, physical distancing, and regular handwashing to ensure the best possible protection against cold/respiratory viruses.

Starpharma's dendrimer platform delivers significant optionality with multiple potential revenue streams, valuable products & clinical-stage assets



Through innovative research and development, Starpharma is creating therapies which have the potential to improve patient health worldwide.

- Unique polymer (dendrimer) platform creating valuable patented healthcare products (>200 patents)
- Deep portfolio of high-value products onmarket and clinical stage assets, with current sales, near term potential commercial and clinical milestones
- Products address clear unmet medical need for large markets; established manufacturing and supply chain
- Successful partnerships with leading global companies
- Well funded (\$42.3M 30 Sept 2022); international share register made up of ~55% institutions, ~40% retail, ~5% staff & other



DEP® - A valuable proprietary nanoparticle drug delivery platform creating significant optionality, accelerates path to market and manages investment risk



VIRALEZE™ Nasal Spray -Registered in >30 countries worldwide; available in pharmacies, retail outlets and online in certain markets



VivaGel® BV - Registered in >45 countries; licensed in >160 countries, on-market in the UK, Europe, Asia, South Africa, Australia & NZ



VivaGel® condom -Approved in Japan, Europe, Australia & Canada

















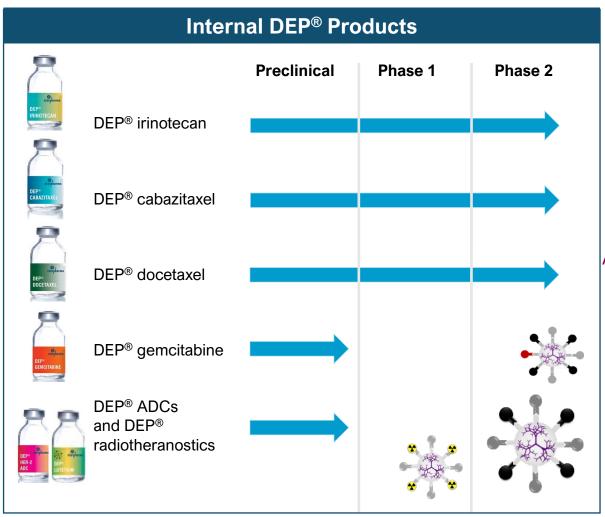






Starpharma's portfolio: High-value assets including multiple DEP® clinical-stage assets, VIRALEZE™ and VivaGel® products on market





Marketed Products



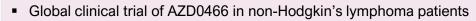
Partnered DEP® Products & Programs



Multiproduct DEP® licence, including the development of AZD0466

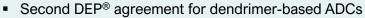


Global clinical trial of AZD0466 in leukemia patients





DEP® agreement for dendrimer-based ADCs





- DEP® partnership to develop DEP® nanoparticle formulations of an anti-infective drug
- DEP® program to develop and evaluate DEP® drug conjugates
- Second DEP® program to develop and evaluate additional DEP® drug conjugates



Financial Summary

Strong balance sheet with revenues from product sales and partnerships



Key Financial Data	FY22 A\$M	FY21 A\$M
Revenue	4.9	2.2
Other Income	0.3	1.3
Loss for the period	(16.2)	(19.7)
Net operating cash outflows	(13.2)	(14.8)
Net financing & investing cash inflows	2.4	46.1

FY22 Result

- Revenue up 128% to \$4.9M (FY21: \$2.2M) on the rollout of VIRALEZE™
- Lower Other Income with the completion of the MRFF grant for VIRALEZE[™] during the year, corresponding with lower VIRALEZE[™] development costs
- Reported Loss down 18% to \$16.2M (FY21: \$19.7M)
- Receipt of \$7.7M R&D tax incentive

Cash as at 30 Sept 2022: \$42.3M*

*Excludes anticipated R&D tax incentive of ~\$7M, expected to be received in the next 2-3 months.













DEP® Platform





DEP[®] technology:

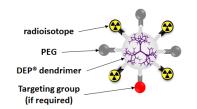
- Based on proprietary, branched polymers called dendrimers
- Represents a platform with significant optionality – applicable to many different drugs



DEP® dendrimer-drug conjugate



DEP® dendrimer antibody drug conjugate



Improved Safety / Reduced side effects

Control release kinetics of drug to reduce Cmax related toxicities



Improved Efficacy / Performance

DEP® achieves drug targeting, improved PK and controlled release



New IP / Extended Patent Life

DEP® creates new intellectual property and extends patent life



Tumour Targeting

DEP® delivers 40-70x more drug in tumour cf. the original drug



Improved PK & Half-Life

Tuning of drug release and plasma half life to improve performance



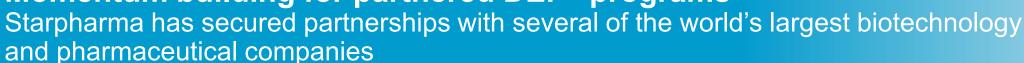
Improved Solubility

Highly water-soluble enabling the removal of toxic excipients

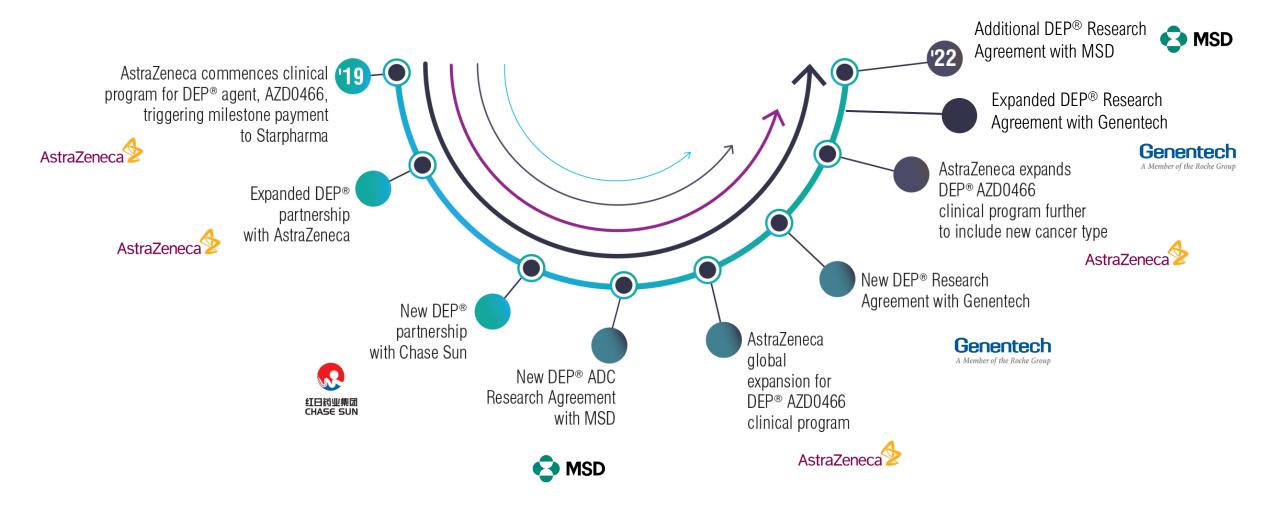
Broad applicability

Applicable to a wide range of therapeutic areas and treatment modalities (e.g., radiotheranostics, ADCs); DEP® is potentially applicable to ~70% of the top 200 pharmaceuticals (by sales)

Momentum building for partnered DEP® programs







DEP® partnering creates significant value and optionality





AstraZeneca's novel DEP® nanoparticle AZD0466

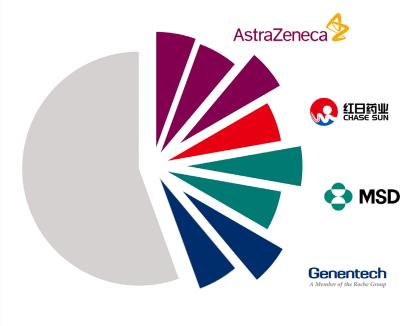
- Clinical program significantly expanded and advanced in 2021, to a multi-region, global Phase 1/2 clinical trial in advanced haematological malignancies
- Clinical program expanded further in 2022 to include an additional indication, non-Hodgkin's lymphoma
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AstraZeneca; US\$7M in milestones received to date

 Total AZD0466 deal up to US\$124M milestones + royalties (est. up to A\$2.4B revenue to SPL)



DEP® platform allows for multiple partnerships

Starpharma has multiple partnered DEP® programs, including with large pharma companies: AstraZeneca, MSD, and Chase Sun.



DEP® platform offers optionality, enabling multiple licences to run in parallel



Starpharma has a research partnership with Chase Sun to develop several DEP® nanoparticle formulations for an anti-infective drug

Starpharma



AstraZeneca's novel DEP® nanoparticle AZD0466



- AZD0466 is a highly optimised DEP® nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor (AZD4320)
- Dual Bcl-2/xL inhibition with AZD0466 has potential for broader activity than the marketed Bcl-2 inhibitor, venetoclax (Venclexta®). In 2021, Venclexta® had sales of ~US\$1.82 billion
- Clinical program significantly expanded and advanced in 2021, to a multi-region Phase 1/2 clinical trial in advanced haematological malignancies; AstraZeneca is now recruiting at sites in South Korea, Italy, Germany, Australia and USA
- This Phase 1/2 leukaemias trial is aimed at seamless transition to Phase 2, to facilitate expedited marketing approval
- A new multi-centre trial for AZD0466 in patients with non-Hodgkin's lymphoma, announced by AstraZeneca, is recruiting at sites in the USA and South Korea, with further planned recruitment at sites in Italy, France, Spain, Portugal, Canada, and Australia
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AZ; US\$7M in milestones received to date
- Total AZD0466 deal up to US\$124M milestones + royalties (est. up to A\$2.4B revenue to SPL)
- AZD0466 studies in a human mesothelioma model were recently <u>published in Nature</u>
 <u>Biotechnology</u>





Clinical program for AZD0466	Status
Global Phase 1/2 study in advanced haematological malignancies (AML & ALL)	Recruiting & opening new sites
Global Phase 1/2 study in non-Hodgkin lymphoma	Recruiting & opening new sites
Additional indication planned	Details TBA



AstraZeneca presented AZD0466 posters at 2021 Annual Society of Hematology (ASH) Meeting

Poster 1: 2353 NIMBLE: A Phase I/II Study of AZD0466

https://ash.confex.com/ash/2021/webprogram/Paper147482.html

<u>Poster 2</u>: 1867 Combination Therapy of Bcl-2/XL dual Inhibitor AZD0466 with Acalabrutinib to Overcome Therapeutic Resistance in Aggressive R/R Mantle Cell Lymphoma https://ash.confex.com/ash/2021/webprogram/Paper151609.html



DEP[®] internal oncology programs Multiple clinical-stage assets with high commercial value potential



Phase 2





DEP® DOCETAXEL: Enhanced version of docetaxel (Taxotere®) widely used for breast, lung & prostate cancer

Docetaxel (Taxotere®) was a blockbuster cancer drug with peak global sales >US\$3B despite having multiple US FDA "Black Box" warnings

Advantages of DEP® docetaxel**:

Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; tumour-targeting (~70x more); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).

Phase 2

CABAZITAXE



DEP® CABAZITAXEL: Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana®)

JEVTANA (cabazitaxel)

Cabazitaxel (Jevtana®) - global sales of ~US\$600M for 2020 despite having multiple US FDA "Black Box" warnings

Advantages of DEP® cabazitaxel**:

Improved toxicity profile; detergent-free formulation; no steroid pre-treatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).

Phase 2





DEP® IRINOTECAN: Improved version of irinotecan (Camptosar®) predominantly used for colorectal cancer

Camptosar® had peak global sales of US\$1.1B despite having multiple US FDA "Black Box" warnings.

Advantages of DEP® irinotecan#*: Irinotecan is a pro-drug that is converted to the more active metabolite, SN38; DEP® solubilises SN38 and allows direct dosing, avoiding the need for liver conversion and patient variability; improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



Starpharma's deep preclinical pipeline includes DEP® candidates including:

- DEP® gemcitabine
- DEP® radiotherapeutic candidates
- DEP® antibody drug conjugate (ADC) candidates
- Other therapeutic areas

COMMERCIAI **OBJECTIVE**



Create value through clinical proof-ofconcept (Phase 2)



License following Phase 2 clinical data; platform validation



Clinical data adds value to partnered programs



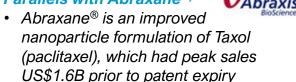
Utilise accelerated development/reg. pathways (i.e. 505b2) for optimal ROI

DEP[®] cabazitaxel: Advantages over Jevtana[®] Many commercial parallels with Abraxane[®] (paclitaxel)



	Jevtana® 2020 sales ~US\$500M	DEP® cabazitaxel (Patented, improved nanoparticle formulation)	
FDA Black box	Neutropenic Deaths (febrile neutropenia)	Not observed	
warning	Severe hypersensitivity (polysorbate-80 detergent)	Not observed; detergent-free formulation	
Premedication	 Antihistamine (required) Corticosteroid (required) H2 antagonist (required) Antiemetic prophylaxis (recommended) 	Not required; polysorbate- 80/detergent-free formulation	
Primary G-CSF prophylaxis (bone marrow protection)	Prophylactic G-CSF recommended for older/high-risk patients (to prevent severe myelosuppression)	 Not required Significantly less bone marrow toxicity and severe neutropenia 	
Patent	EU – expiredUS – 2031	 EU – 2039 US – 2039 (potential for 5-year extension) 	

Abraxane® Case study (DEP® cabazitaxel has many Parallels with Abraxane®)



- Abraxane® approved in 2005 by the FDA initially for the treatment of breast cancer with further indications added
- Celgene acquired Abraxis¹ in 2010 for ~\$2.9B; Abraxane⁸ sales were US\$314M in 2009
- Abraxane[®] sales in 2020 US\$1.24B (Celgene now part of BMS)
- Abraxane® now accounts for ~97% of paclitaxel sales (\$)

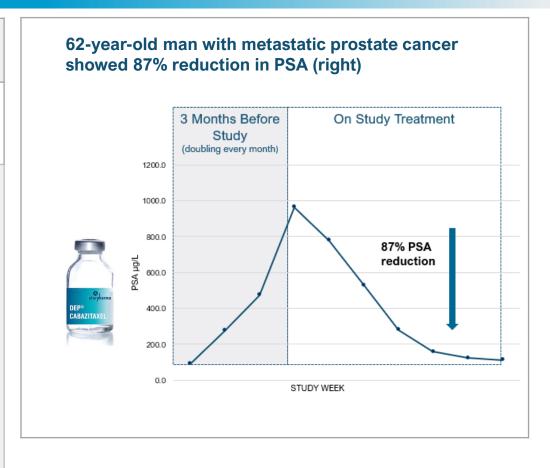




DEP® cabazitaxel: Phase 2 trial ongoing, encouraging efficacy signals Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana®)



Prostate, ovarian, gastro-oesophageal, cholangiocarcinoma, head & neck, lung, thymic and other cancers
 Encouraging efficacy signals have been observed, including radiological responses, significant target tumour shrinkage and substantial tumour biomarker reductions (e.g., Prostate Specific Antigen (PSA)), in cancers including prostate, ovarian, lung, gastro-oesophageal, head and neck and other cancers.
 These impressive tumour responses were observed in heavily pre-treated patients and include significant tumour shrinkage including in prostate and ovarian cancer, in patients who have failed multiple other lines of cancer treatment.
• Significantly fewer and less severe side effects, particularly bone marrow toxicity, than is usually associated with Jevtana®.



Sites:



Imperial College Healthcare







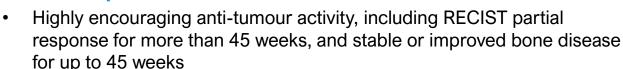
DEP® cabazitaxel Phase 2 Trial – Positive Interim Results in Prostate Cancer Cohort Presented at ESMO 2022



DEP[®] cabazitaxel - Phase 2 prostate cancer cohort

- 25 heavily pre-treated patients with Stage (IV) hormone-refractory prostate cancer
- DEP® cabazitaxel patients (56%) had received at least two prior chemotherapy regimens, whereas only 16%[^] of patients in published Jevtana® data had received this level of prior treatment
 - Average of 4 prior anti-cancer treatments and >70 months/cycles
 - >95% had received prior taxanes, including docetaxel and cabazitaxel (Jevtana[®])
- No need for prophylactic steroids or antihistamines as polysorbate 80-free aqueous formulation
- No primary G-CSF² prophylaxis required, despite age and low neutrophil counts

DEP® cabazitaxel - Phase 2 interim results in prostate cancer



- Median PFS of 3.9 months, which is more than 30% longer than published PFS data for standard cabazitaxel (2.9 months[^])
- 100% of evaluable patients¹ achieved a response in ≥1 measure of efficacy
- 52% of patients evaluable for PSA achieved PSA reduction ≥50% from baseline
- 83% of patients evaluable for bone disease experienced an improvement or no progression
- 68% of patients evaluable for 2 or 3 efficacy measures achieved a response for all evaluable measures (soft tissue disease, PSA, and bone disease)
- No patients required routine steroid pre-medication or daily oral steroid
- DEP® cabazitaxel was generally well-tolerated, with AEs similar in character to those observed with standard cabazitaxel



^{1:} Evaluable patients are those who received ≥1 dose DEP® cabazitaxel and had an applicable efficacy assessment conducted post treatment. 3 patients were not evaluable for efficacy.

^{2:} G-CSF: granulocyte-colony stimulating factor, is used as a therapy for myelosuppression

^{^:} Eisenberger, M, et al. J Clin Oncol, 2017;35(28):3198-206

DEP® cabazitaxel: Key interim efficacy and safety findings in Phase 2 Prostate cohort vs. published Jevtana® results



Key Efficacy Measures

Efficacy Measure	DEP [®] cabazitaxel (20 mg/m²)	Jevtana ^{®1} (20 mg/m²)
PSA Reduction ≥50%	52.4%	29.5%
Partial Response#	18.2%	18.5%
Improved/stable Bone Disease	83.3%	Not reported

Longer Progression Free Survival (PFS) (median)

DEP [®] cabazitaxel (20 mg/m²) (N=25)	Jevtana ^{® 1} (20 mg/m²) (N=598*)	Jevtana ^{® 1} 25 mg/m²) (N=602*)	Jevtana ^{® 2} (25 mg/m²) (N=378*)
3.9 months	2.9 months	3.5 months	2.8 months

PFS = Composite endpoint from date of randomization to date of first tumour progression, PSA progression, or death. Note that the Jevtana studies^{2,3} also included pain progression





Key Safety Measures

<u>DEP® cabazitaxel had significantly fewer</u> Grade 3/4 Treatment Related Adverse Events vs. Jevtana®

DEP [®] cabazitaxel	Jevtana ^{® 1}	Jevtana ^{®1}
(20 mg/m²)	(20 mg/m²)	(25 mg/m²)
(N=25)	(N=580†)	(N=595 [†])
7.5%	39.7%	54.5%

Safety Outcomes	DEP [®] cabazitaxel (20 mg/m²) (N=25)	Jevtana ^{®2} (20 mg/m²) (N=580†)
Neutropenia ≥ grade 3	16.0%	41.8%
Febrile neutropenia ≥ grade 3	0%	2.1%
Thrombocytopenia ≥ grade 3	0%	2.6%
Neutropenic infection / sepsis	0%	2.1%

- 1 Eisenberger, M., et al., PROSELICA. J Clin Oncol, 2017, 35(28):3198-206.
- 2 Heidenreich, A, et al. *Eur J Cancer*, 2014,50:1090-9
- # Partial Response: ≥30% reduction in measurable target Tumour size
- † Safety populations (received at least 1 dose)

^{*} Intent-to-treat populations

DEP® cabazitaxel: clinical case study in oesophageal cancer



Oesophageal cancer

- Oesophageal cancer is the sixth leading cause of cancerrelated mortality worldwide.¹
- The diagnosis typically occurs in patients with locally advanced unresectable or metastatic disease, when palliative chemotherapy is the primary treatment option.
- The 5-year survival rates can be as low as 5%.²

1.Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin*. 2021;71(3):209-249. doi:10.3322/caac.21660

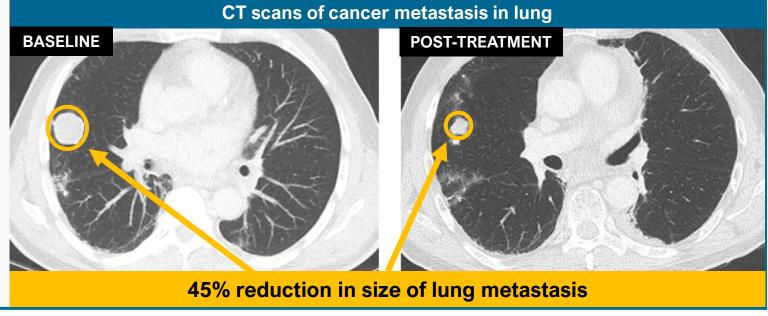
2.Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin*. 2021;71(1):7-33. doi:10.3322/caac.21654

73-year-old man with stage IV oesophageal cancer



- Cancer progressed following extensive radiation therapy and chemotherapy
- Achieved partial response (significant tumour shrinkage) following 5 cycles of DEP® cabazitaxel:
 - 42% overall decrease in tumour burden
 - 45% reduction in size of lung metastasis





DEP® irinotecan: Phase 2 trial underway, encouraging efficacy signals



Enhanced version of irinotecan (Camptosar®) - predominantly used for colorectal cancer

Trial status:	Phase 2, ongoing, 83 patients recruited			
Efficacy signals seen in:	Breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer			
Interim observations:	Encouraging efficacy signals observed include prolonged stable disease, impressive tumour shrinkage and reductions in tumour marker levels for a number of tumour types, including breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer			
Combinations:	Combinations, based on investigator interest and preclinical studies, being explored with partners to create value			
Sites:	The ROYAL MARSDEN NHS Foundation Trust Guy's and St Thomas' NHS Foundation Trust The Christie The Christie The Christie The Christie The Spundation Trust Supplementation Trust The Newcastle Upon Tyne Hospitals NHS Foundation Trust NHS Foundation Trust The Spundation Trust The Spundation Trust The Spundation Trust The Newcastle Upon Tyne Hospitals NHS Foundation Trust The Newcastle Upon Tyne Hospitals The Spundation Trust The Newcastle Upon Tyne Hospitals The Spundation Trust The Spundation Trust The Newcastle Upon Tyne Hospitals The Spundation Trust The Newcastle Upon Tyne Hospitals The Spundation Trust The Newcastle Upon Tyne Hospitals The Newcastle U			



DEP[®] irinotecan incorporates the irinotecan active moiety (SN38) and is an improved version of Camptosar[®]

DEP® irinotecan:

- Provides the ability to solubilise the active metabolite, SN38
- Removes the need for liver metabolism
- Showed improved efficacy and survival benefit in preclinical models
- Patented formulation

Results from DEP® irinotecan Phase 1 trial:

- Encouraging efficacy signals observed in 50% of evaluable patients, all of whom were heavily pretreated
- Efficacy signals observed included prolonged stable disease and substantial tumour shrinkage in tumour types including CRC, pancreatic and breast cancer
- No cases of the severe high-grade diarrhoea with DEP® irinotecan – this side effect is experienced by 20-40% of patients with conventional irinotecan, and often requires hospitalisation
- Patients treated with DEP® irinotecan generally experienced less severe side effects than typically associated with Camptosar®; AEs observed included nausea, vomiting, alopecia and neutropenia

Phase 1/2 Combination arm

DEP® irinotecan in combination with 5-FU+ Leucovorin ('FOLFIRI') – a commonly used combination treatment, particularly first-line, in colorectal cancer has commenced

DEP® irinotecan: clinical case study in ovarian cancer



55-year-old woman with heavily pre-treated stage IV ovarian cancer

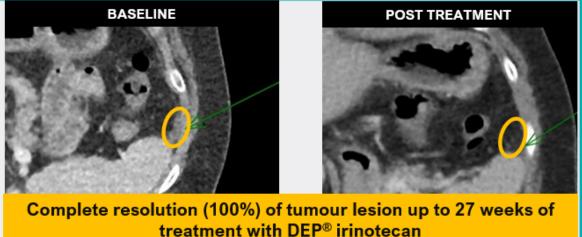


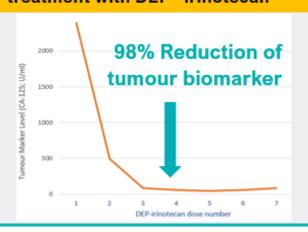


Ovarian cancer has the lowest survival rate of women's cancer* with a 5-year survival of ~17% for Stage IV

- Patient was heavily pre-treated with > 60 treatment
 cycles of 6 different kinds of anti-cancer therapy
- Platinum and PARP-resistant ovarian cancer
- Received 10 cycles of DEP® irinotecan
- Response to DEP® irinotecan:
 - Complete resolution of target tumour lesion after 3 cycles of treatment;
 - Partial Response maintained for up to 27 weeks
 - 98% reduction in tumour biomarkers

* https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts-_2019_-FINAL.pdf





DEP® docetaxel: Phase 2 trial ongoing, encouraging efficacy signals

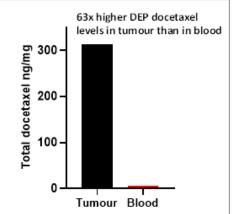
Enhanced version of docetaxel (Taxotere®) – widely used for breast, lung & prostate cancer



Trial status:	Phase 2 trial ongoing, 74 patients recruited [^]		
Efficacy signals seen in:	Lung, pancreatic, oesophageal, cholangiocarcinoma, gastric cancers (and others)		
Combinations:	+ gemcitabine (Gemzar®), targeting pancreatic cancer		
	+ nintedanib (Vargatef®), targeting lung cancer		
Interim observations:	• Encouraging efficacy signals observed, including prolonged stable disease and significant tumour shrinkage in patients with pancreatic, oesophageal, cholangiocarcinoma, and gastric cancer. These impressive tumour responses include stable disease for up to 40 weeks and significant tumour shrinkage in a heavily pre-treated late-stage oesophageal cancer patient.		
	Notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects incl. hair-loss, mouth ulcers, anaphylaxis and oedema.		
	Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and 9 different anti-cancer regimens previously).		
Sites:	Guy's and St Thomas' NHS Foundation Trust The Christie The Leeds		



The same tumour targeting observed with DEP® in animal studies has been replicated in patients treated with DEP® docetaxel. delivering substantially higher levels of drug to the tumour (> 63x) than in blood



DEP® docetaxel clinical combination studies

DEP® docetaxel + gemcitabine (Gemzar®)

Based on compelling DEP® preclinical data & investigator interest, combination DEP® docetaxel with gemcitabine trial commenced, targeting pancreatic cancer

DEP® docetaxel + nintedanib (Vargatef®)

- Encouraging efficacy signals observed
 - Prolonged stable disease & tumour shrinkage in nonsmall cell lung cancer; heavily pre-treated patients
 - Notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects, including mouth ulcers, anaphylaxis and oedema

DEP® docetaxel clinical case studies: monotherapy and in combination

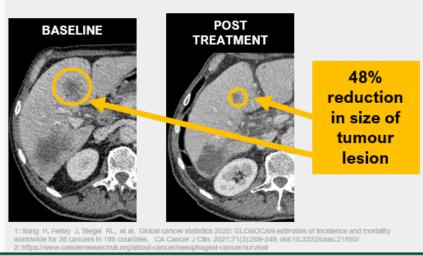


66-year-old man: stage IV oesophageal cancer with liver metastases (monotherapy)



Oesophageal cancer is the sixth leading cause of cancer-related mortality worldwide¹; 5-year survival rates can be as low as 5%²

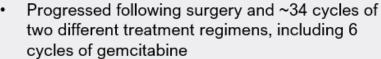
- Patient had progressive disease after radiotherapy and 9 cycles of two different treatment regimens
- Response to DEP® docetaxel:
 - Reduction in size of tumour lesions of up to 48%; maintained for >16 weeks



74-year-old man with stage IV pancreatic cancer (in combination with gemcitabine)

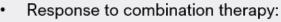


Pancreatic cancer is the 12th most common cancer worldwide.³ The 5-year survival rate is only 10.7%.⁴



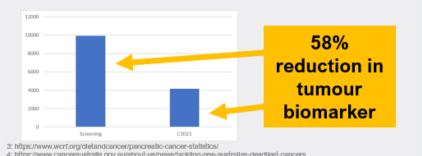


Received 5 cycles of DEP® docetaxel + gemcitabine



- 58% reduction in tumour biomarker CA19-9 after 13 weeks
- Stable disease for >19 weeks





Starpharma's DEP® platform - broad applicability and exceptional optionality





Multiple DEP® products and therapeutic areas - partnered and internal programs



Chemotherapeutics	Radiotheranostics	Antibody Drug Conjugates (ADCs)	Non-oncology
 Franchise extension Generic differentiation New Chemical Entities Combinations including immuno-oncology AstraZeneca	 Radiotheranostic applications – growth area Can use variety of isotopes and targeting 	 Flexible technology Increased drug antibody ratio Targeting group agnostic Site selective payload attachment 	Antiviral Anti-infective Endocrinology 红日药业集团 CHASE SUN

DEP® - a valuable platform for ADCs (antibody drug conjugates) already supporting partnerships with leading companies



Starpharma's DEP® technology represents a valuable partnering platform which has the potential to generate revenue through royalties and milestones



Starpharma has two DEP® research agreements with MSD for dendrimer-based ADCs using DEP® technology.



Significant commercial momentum in ADCs

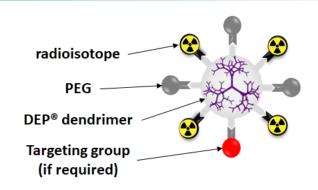


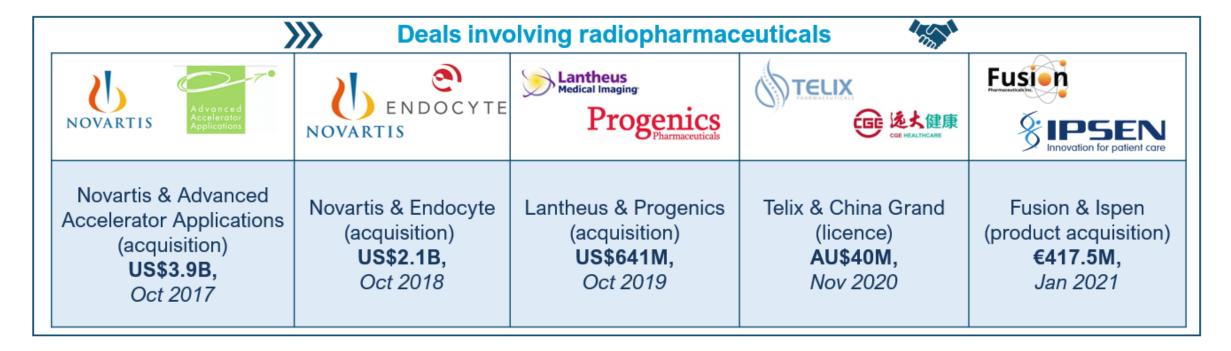
MSD VELOSBIO	Boehringer Ingelheim NBE therapeutics	Bristol-Myers Squibb	Synaffix Mersana THERAPEUTICS	immun•gen. Lilly	KELUN-BIOTECH 科伦博泰 MSD
Merck & VelosBio, US\$2.75B, Nov 2020	Boehringer Ingelheim & NBE Therapeutics, €1.2B, Dec 2020	BMS & Eisai, US\$3.1B, <i>June 2021</i>	Synaffix & Mersana, US\$1.0B, Nov 2021	ImmunoGen & Lilly, US\$1.7B, Feb 2022	Kelun-Biotech & MSD, US\$936M July 2022

DEP® - a valuable platform with application to multiple radiotheranostics



- Radiotheranostics is a rapidly developing area of cancer treatment and diagnosis with sales estimated to grow to \$12–15 billion by 2030[^]
- Significant corporate activity in recent years
- Starpharma's DEP® platform has yielded multiple radiotheranostic DEP® products
- Starpharma continues discussions with potential partners regarding access to Starpharma's DEP® platform and licensing DEP® radiotheranostic/radiopharmaceutical candidates





VIRALEZE™ antiviral nasal spray



VIRALEZE™ features

- Broad-spectrum antiviral nasal spray
- Contains a novel dendrimer molecule, SPL7013, which traps and blocks multiple cold/respiratory viruses including influenza, RSV, coronaviruses
- Blocks virus replication in lab studies both before and after exposure of cells to virus
- Well-tolerated; acts locally in the nasal cavity & is not absorbed into the bloodstream
- Provides a protective moisture barrier to help keep nasal tissue hydrated
- Convenient for use for travel, work, events /crowded settings
- Room temperature storage



VIRALEZE™ market & regulatory activity

- VIRALEZE™ antiviral nasal spray is registered in more than 30 countries worldwide*
- Available in pharmacies, retail outlets and online in a number of markets
- Partnered with:
 - LloydsPharmacy in the UK;
 - ADMENTA Italia Group in Italy;
 - HealthCo/TBL & Nam Thanh Medical in Vietnam;
 - E&N in countries in the Middle East;
 - Hengan International Group in Hong Kong and Macau
- Other VIRALEZE™ regulatory submissions are in progress and commercial discussions for multiple regions/countries underway















How VIRALEZE™ works

Antiviral effect of SPL7013 compares favorably with other marketed antiviral nasal sprays



- Viruses infect human cells by using viral surface proteins, or "spikes", to attach to receptor proteins on the surface of human cells
- Antiviral agent in VIRALEZETM, SPL7013, physically traps and blocks viral spike proteins thus preventing infection of cells

PL7013



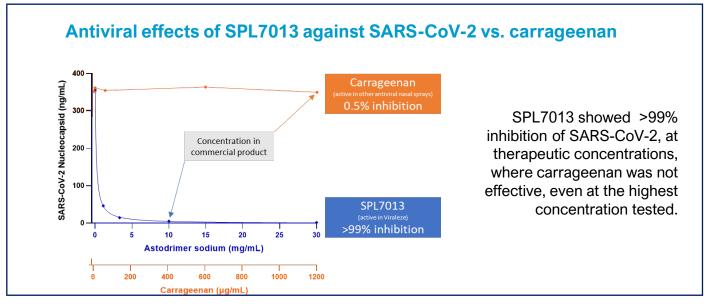


VIRALEZE™ acts as a barrier between the viral 'spike' proteins and the cell membrane, irreversibly trapping viral particles – blocking virus from entering the human cells

Spike protein

- Extensive research has been conducted at The Scripps Research Institute in the US and is published in the peer reviewed journal, Antiviral Research
- A 1% w/w concentration of SPL7013 (the concentration found in VIRALEZETM) has been shown to trap and block >99.9% of SARS-CoV-2 within 30 seconds; maintains its antiviral effects when applied either before or after exposure to virus
- SPL7013 has been shown to trap and block influenza viruses and RSV as well as other respiratory viruses that have caused pandemics SARS, MERS, and Swine Flu (H1N1)





VIRALEZE™ antiviral nasal spray registered in >30 countries, with a growing sales and distribution network



ADMENTA Italia

VIRALEZE™ partnered with **ADMENTA Italia Group for the** sales and distribution of VIRALEZE™ in Italian pharmacies

LloydsPharmacy

VIRALEZE™ partnered with LloydsPharmacy in the UK

Starpharma is also in advanced discussions with potential commercial partners in other regions

VIRALEZE™ Webstore www.Viraleze.co (outside Australia)



EUROPE



MIDDLE EAST





VIETNAM



VIRALEZE™ is registered in >30 countries worldwide. Registration of VIRALEZE™ is also being sought in multiple regions worldwide

VIRALEZE™ partnered with HealthCo/TBL for supply and distribution in Vietnam



Etqan & Nazahah Company



VIRALEZE™ partnered with **E&N** for sales and distribution in countries in the Middle East

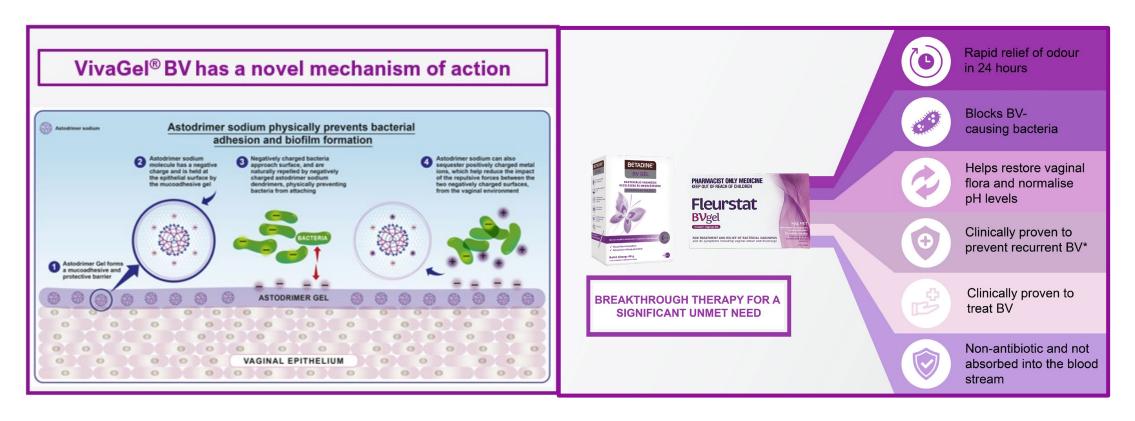
VIRALEZE™ partnered with **Hengan International Group for** sales and distribution Hong **Kong and Macau**



VivaGel® BV - a breakthrough product for the treatment of BV and prevention of recurrent BV



- Bacterial vaginosis or BV is the most common vaginal infection worldwide, affecting 1 in 3 women
- BV is caused by an imbalance of naturally occurring normal bacterial vaginal flora and can lead to a range of medical issues
- BV treatment has typically involved antibiotics (e.g., metronidazole). Antibiotic resistance is a problem and antibiotics have unpleasant side effects and there is demand for alternative approaches. Other current BV therapies do not prevent BV recurring



VivaGel® BV is licensed in >160 countries around the world and approved in >45 countries with multiple other submissions underway



Ongoing Active Marketing Campaigns by Partners for Brand Awareness and Sales

- Digital marketing campaigns, including social media
- √ In-store point of sales campaigns
- ✓ Brand catalogues for healthcare professionals e.g., pharmacists
- ✓ Peer-reviewed journal articles



Launched in the UK, Europe, Asia, South Africa, Australia & NZ



Further launches and regulatory submissions progressing in multiple regions







*In the US, a formal dispute resolution process is ongoing with the FDA as part of the regulatory process for VivaGel® BV. VivaGel® BV's Fast Track status & QIDP (qualified infectious disease status) remain on foot based on potential for VivaGel® BV to address a serious infection and significant unmet need in BV

VivaGel® Condom



- The VivaGel® condom incorporates SPL7013 antiviral, which has demonstrated activity in HIV, HSV-2, HPV
- Starpharma continues to support its marketing partners to progress registration and commercialisation of the VivaGel[®] condom
- Starpharma continues to progress regulatory activities in other regions





Okamoto launched an additional VivaGel® condom range in Japan, under the brand name *Pure Marguerite*, targeting youth segments of the market.

Key value drivers and outlook



DEP® Drug Delivery



Internal DEP® Clinical-stage Assets

- Progress and complete Phase 2 trials
- · Progress value-adding combination studies
- Licences for DEP® assets



Partnered DEP® Programs

- Progress existing partnerships with AstraZeneca, Merck & Co., Inc., Chase Sun, and Genentech
- Execute new and/or expand existing DEP® partnerships



AZD0466 Clinical Program

- · Clinical progress, including expansion of trial sites and recruitment
- Further milestones



Preclinical DEP® Programs

 Advance DEP® radiotheranostics, DEP® ADCs and other DEP® candidates



SPL7013 Products



VIRALEZE™ Nasal Spray

- Further commercial rollout and product launches
- Further registrations in other regions
- Further distribution and marketing arrangements with commercial partners
- Continued testing to support commercialisation



VivaGel® BV

- · Commercial rollout in other markets
- Further regulatory approvals and launches; milestones, product sales/royalties
- FDA review process





VivaGel® Condom

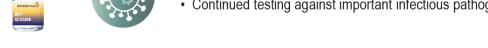
· Approvals/launches in additional countries





SPL7013

- Further development/co-development of other products
- · Continued testing against important infectious pathogens



Starpharma's Commitment to Environment, Social and Governance (ESG)



ENVIRONMENT

Appropriate systems in place 🙈 to comply with relevant Federal, State, and Local environment regulations

Starpharma has adopted documented procedures and processes to ensure all waste products are disposed of strictly in accordance with relevant



Starpharma is committed to conducting its operations in an environmentally responsible manner

View our Climate Change Position Statement online

GOVERNANCE

Compliance with





No breaches of:

- Code of Conduct

- Anti-bribery

- Whistleblowing

DIRECTOR **INDEPENDENCE**



BOARD 83% COMMITTEES

Starpharma is committed to the principles underpinning best practice in corporate governance, with a commitment to the highest standards of legislative compliance and financial and ethical behaviour.

SOCIAL



Starpharma's supplier code includes a wide range of business practices to provide suppliers with clear expectations regarding their conduct

Small, diverse workforce represented by 18 countries



'Having a diverse workforce drives better outcomes for our business and provides the company with greater breadth of experience and ideas'.



Download Report

The very nature of Starpharma's products affords the opportunity of changing lives for the better



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