

Starpharma to present at Bell Potter Healthcare Conference

Melbourne, Australia; 14 November 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) has been invited to present today at the [Bell Potter Healthcare Conference](#), a virtual investor conference that showcases Australia's leading healthcare companies to institutional investors and Bell Potter's retail network.

Starpharma will present an overview of the business, with a focus on recent milestones, including the positive clinical data reported for DEP[®] cabazitaxel¹ and DEP[®] irinotecan² in multiple cancers, as well as the positive preclinical data from the DEP[®] radiotheranostics programs.

The Bell Potter Healthcare Conference presentation is appended.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ("DEP[®]") drug delivery technology, and marketed products, including VIRALEZE™ and VivaGel[®] BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP[®] drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP[®] programs, Starpharma has multiple DEP[®] partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP[®] platform, partnered DEP[®] programs have the potential to generate significant future milestones and royalties.

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 35 countries*, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel[®] BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on [LinkedIn](#).

¹ ASX Announcement dated 18 October 2023: [Positive DEP[®] Cabazitaxel Results in Multiple Cancers](#).

² ASX Announcement dated 13 September 2023: [Positive DEP[®] irinotecan clinical results to be presented at international oncology conference](#).



WE Communications
Hannah Howlett
WE-AUStarPharma@we-worldwide.com

Starpharma Holdings Limited
Dr Jackie Fairley, Chief Executive Officer
Justin Cahill, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com
4-6 Southampton Crescent
Abbotsford Vic 3067

Disclosure
This ASX Announcement was authorised for release by the Chair, 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", "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 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.



Starpharma Overview

Bell Potter Healthcare Conference

Dr Jackie Fairley, Chief Executive Officer

14 November 2023



Important notice and disclaimer

This document is intended for investors and market participants only. 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 commercialisation 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 materialise, 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 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 future performance of any Starpharma product. FLEURSTAT BVgel (VivaGel® BV) for the treatment and prevention of recurrent 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 use 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 is an innovative biopharmaceutical company and leader in dendrimer technology



Innovative drug delivery platform, DEP®

Proprietary nanoparticle platform; ability to create innovative therapies and enhance existing drugs; significant optionality; accelerates path to market; and manages investment risk.

Deep portfolio of high-value assets

Three promising internal clinical-stage assets are under development: improved, patented versions of widely used cancer medications, and a strong pipeline of preclinical-stage assets, including radiotheranostics.

Multiple products on market.

Multiple global pharma partnerships

DEP® partnerships with three of the world's top 10 pharmaceutical companies: MSD, Genentech and AstraZeneca. Starpharma generates returns via research fees, milestones & royalties. Funded by large pharma partners. DEP® platform offers the ability to partner widely without Starpharma funding programs.

Strong financial position

Cash balance of \$35.6M (30 September 2023), including \$6.6 M received from Mundipharma in August 2023; and excluding the \$7.2 M R&D tax incentive refund received in October 2023.

Strong international institutional share register

Institutions include Allianz, UIL/ICM, Allan Gray, M&G, and Fidelity.



Starpharma's portfolio: multiple clinical-stage assets, partnerships and products in market



DEP[®] pipeline

Products	Target indication	Preclinical	Phase 1	Phase 2
DEP [®] cabazitaxel	Prostate and other cancers	Phase 2 complete & results reported		
DEP [®] irinotecan	Colorectal and other cancers	Phase 2 recruitment complete		
DEP [®] docetaxel	Pancreatic and other cancers	Phase 2 recruitment complete		
DEP [®] gemcitabine	Solid cancers	[Progress bar]		
DEP [®] HER-2 ADC	Solid cancers	[Progress bar]		
DEP [®] HER-2 radiotherapy	Solid cancers	[Progress bar]		
DEP [®] HER-2 radiodiagnostic	Diagnostic	[Progress bar]		
Partnerships	Various			

Commercialised products

VIRALEZE™ Antiviral Nasal Spray



VivaGel[®] BV



VivaGel[®] Condom



Partnered DEP[®] programs

Two DEP[®] ADC Research Agreements with MSD (Merck & Co., Inc.)



Two DEP[®] Research Agreements with Genentech



DEP[®] anti-infective research partnership with Chase Sun



Multi-product DEP[®] license with AstraZeneca



Financial Summary

Strong balance sheet with revenues from product sales and partnerships



Q1 FY24 Result.

- Net cash inflow of \$0.4M for Q1 FY24.
- Strong cash position with \$35.6M at 30 September 2023.
 - Includes \$6.6M cash payment received from Mundipharma in relation to the settlement of VivaGel® BV rights.
 - Excludes the \$7.2M Research and Development Tax Incentive refund received in October 2023, and the R&D loan of \$4M repaid in October 2023.
- Cash outflows ending 30 September 2023, included R&D costs of \$3.4 million related to the completion of recruitment and treatment in multiple DEP® clinical programs; following completion of our clinical programs, Starpharma expects to see reductions in operating cash outflows in H2 FY24.

Key Financials

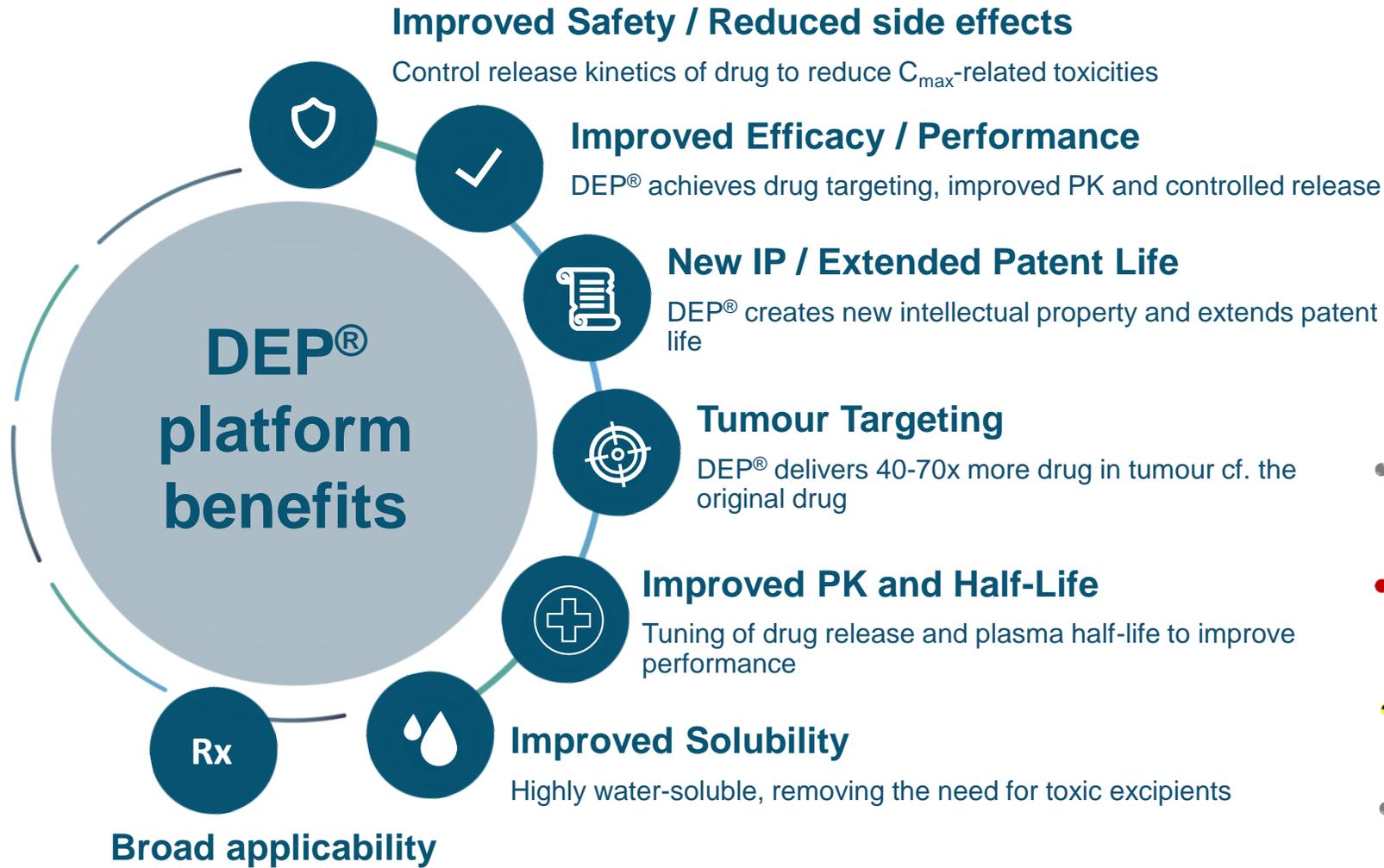
	FY23 \$M	FY22 \$M	FY21 \$M
Revenue	4.2	4.9	2.2
Other Income	0.1	0.3	1.3
Loss for the period	(15.6)	(16.2)	(19.7)
Net operating cash outflows	(13.5)	(13.2)	(14.8)

Cash at 30 September 2023: \$35.6 M*

*Excludes the \$7.2 M Research and Development Tax Incentive refund received in October 2023; and excludes the \$4M R&D loan repaid in October 2023.

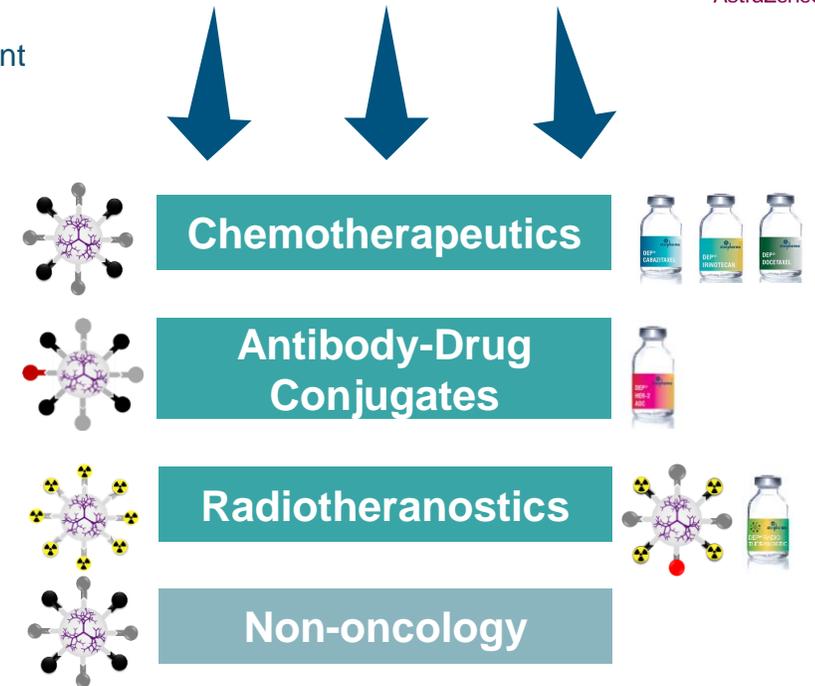


Starpharma's DEP[®] platform: highly versatile, enhancing the commercial and therapeutic value of a wide range of drugs



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)

Multiple DEP[®] therapeutic areas across partnered and internal programs



DEP[®] partnering creates significant value and optionality

Starpharma's DEP[®] platform enhances the commercial and therapeutic value of a wide range of drugs, creating multiple potential revenue streams and significant IP leverage



DEP[®] platform offers significant optionality, enabling multiple licenses to run in parallel without Starpharma funding programs

DEP[®] partnering process

- **Research Phase** - typically involves Starpharma making multiple DEP[®] candidates followed by testing by Partner; funded by Partner.
- **Commercial Phase** – typically a license with milestones and royalties payable to Starpharma.
- Development costs funded by Partners.



Two DEP[®] ADC Research Agreements with MSD

Genentech

A Member of the Roche Group

Two DEP[®] Research Agreements with Genentech



红日药业集团
CHASE SUN

DEP[®] anti-infective research partnership with Chase Sun

AstraZeneca

Multiproduct DEP[®] license & option agreement with AstraZeneca

Starpharma's internal DEP[®] oncology portfolio

Multiple clinical-stage assets with high commercial value potential



DEP [®] Program	Original Drug Formulation	Advantages of DEP [®] Product ^{#*}
DEP[®] cabazitaxel (Phase 2)  Dendrimer version of leading prostate cancer drug cabazitaxel (Jevtana [®]) 	Cabazitaxel (Jevtana [®]) – global sales of ~US\$500M for 2021 despite having multiple US FDA “Black Box” warnings.	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).
DEP[®] docetaxel (Phase 2)  Dendrimer 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.	Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; tumour-targeting (~70x more drug in tumour); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).
DEP[®] irinotecan (Phase 2)  Dendrimer 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.	Tumour-targeting; irinotecan is a pro-drug converted to the 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).



#Clinical studies have demonstrated reduction in important side effects with DEP[®] such as bone marrow toxicity, anaphylaxis, severe diarrhoea and hair-loss

*Multiple preclinical studies have established improved efficacy, survival and safety with DEP[®] with many different drugs

DEP[®] cabazitaxel Phase 2 trial – Positive Results

Positive results across multiple tumour types enhancing market potential



DEP[®] cabazitaxel

- Phase 2 trial (N=75) – complete and results reported

Summary of Key Efficacy Results

- Heavily pre-treated, **advanced prostate cancer patients (mCRPC)** treated with DEP[®] cabazitaxel achieved a median progression-free survival (PFS) that was more than 50% longer and a median overall survival (OS) that was 10% longer than published data for Jevtana[®] at the same dose².
- In **advanced, platinum-resistant ovarian cancer patients**, who were heavily pre-treated with an average of 4 prior lines of chemotherapy, DEP[®] cabazitaxel achieved a disease control rate (DCR) of 66.7% and an objective response rate (ORR) of 17.6%, which compares favourably to standard-of-care therapies that report ORRs ranging from ~9 to 16%^{4,5,6}.
- In **advanced gastro-oesophageal cancer patients**, DEP[®] cabazitaxel achieved a median progression-free survival (PFS) and median overall survival (OS) that were 53.1% and 28.5% longer, respectively, than similar patient cohorts treated with standard-of-care paclitaxel⁷.

Trial Sites



Results reported in Starpharma's ASX Announcement dated 18 October 2023

2 Eisenberger, M., et al., PROSELICA. *J Clin Oncol*, 2017, 35(28):3198-206

4 Taxol[®] (paclitaxel) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf.

5 Mutch, DG, et al., *J Clin Oncol*, 2007;25(19):2811-2818.

6 Pujade-Lauraine, E, et al., *J Clin Oncol*, 2014;32(13):1302-1308.

7 Stockton, S, et al., *The Oncologist*, 2023;28(9):827-e822.

Jevtana[®]

2021 sales
~US\$500M



FDA “Black Box” warnings:

- Neutropenic deaths (febrile neutropenia)
- Severe hypersensitivity (polysorbate-80 detergent)

Extensive premedication:

- Antihistamine (required)
- Corticosteroid (required)
- H2 antagonist (required)
- Antiemetic prophylaxis (recommended)

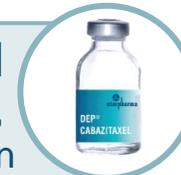
Prophylactic G-CSF recommended for older/high-risk patients (to prevent severe myelosuppression)

Short-Term Patents

- EU – expired
- US – 2031

DEP[®] cabazitaxel

Starpharma's patented, nanoparticle formulation



Detergent-free formulation; no neutropenic deaths or severe hypersensitivity observed; therefore, would not expect “black box” warnings

Premedication not required; polysorbate-80/detergent-free formulation

Prophylactic G-CSF not required; significantly less myelosuppression in high-risk patients: e.g., patients with low neutrophil count and ≥75yrs

New / extended IP

- EU – 2039
- US – 2039 (potential for 5-year extension)

Key results for DEP[®] cabazitaxel in prostate cancer



Clinically meaningful efficacy outcomes were achieved with DEP[®] cabazitaxel despite these advanced mCRPC patients being significantly more heavily pre-treated prior to trial entry vs. patients in published trials of Jevtana[®].

Heavily pre-treated patient cohort.

- Median of 4 lines and 70 cycles of prior anti-cancer therapy.
- 60% of DEP[®] cabazitaxel treated patients had received \geq two prior chemotherapy regimens, compared to 16%² of Jevtana[®] patients in published trial data.

Highly encouraging efficacy results.

- DEP[®] cabazitaxel achieved a disease control rate (DCR) of 70.6% and an objective response rate (ORR) of 16.7%.

Longer progression-free survival and overall survival

Key Efficacy Measures	DEP [®] cabazitaxel (20 mg/m ²) (N=25 [†])	Jevtana [®] (20 mg/m ²) (N=598 [†]) ²
Median PFS	4.4 months	2.9 months
Median overall survival (OS)	14.7 months	13.4 months
PSA Reduction \geq 50%	52.4%	29.5%

Results reported in Starpharma's ASX Announcement dated 18 October 2023. All efficacy response data are for evaluable patients.

[†] Intent to treat (ITT) populations; PFS = composite endpoint from date of randomisation to date of first tumour progression, PSA progression, or death. (Jevtana[®] studies also included pain progression)

¹ Prostate cancer: Statistcs <https://www.cancer.net/cancer-types/prostate-cancer/statistics>.

² Eisenberger, M., et al., PROSELICA. *J Clin Oncol*, 2017, 35(28):3198-206

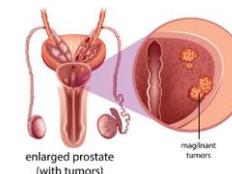
- DEP[®] cabazitaxel had significantly fewer Grade 3/4 Treatment-Related Adverse Events (TRAEs) vs. Jevtana[®] in advanced prostate cancer patients.

Comparative bone marrow toxicity in prostate cancer patients treated with DEP[®] cabazitaxel vs published data on Jevtana[®]

Safety Outcomes	DEP [®] cabazitaxel (20 mg/m ²) (N=25 [^])	Jevtana [®] (20 mg/m ²) ² (N=580 [^])
Neutropenia* \geq grade 3	16.0%	41.8%
Febrile neutropenia \geq grade 3	0%	2.1%
Thrombocytopenia* \geq grade 3	0%	2.6%
Neutropenic infection / sepsis	0%	2.1%

*Lab detected neutropenia or thrombocytopenia, regardless of whether the event was reported as an adverse event; Safety population[^] (received at least 1 dose)

Prostate cancer is the fourth most commonly diagnosed cancer in the world. It is the second leading cause of cancer death in men in the United States¹.



Key results for DEP[®] cabazitaxel in ovarian cancer



Highly encouraging durable efficacy responses (DCR, ORR) in heavily pre-treated advanced, platinum-resistant ovarian cancer patients.

Cancer Type	Platinum-resistant Ovarian
Patients' Prior Anti-Cancer Therapy (Median)	4 lines, 25 cycles
Disease Control Rate (DCR)	66.7%
Objective Response Rate (ORR)	17.6%
Median PFS	3.1 months

Heavily pre-treated patient cohort.

- 100% of patients had received at least one prior taxane.
- 45% of patients received 2 or more lines of taxane treatment.

Highly encouraging efficacy results.

- Tumour shrinkage of up to 40% and response durations of up to 34 weeks.
- Objective response rate (ORR) of 17.6% in evaluable patients. Compares favourably to standard-of-care single-agent therapies that report ORRs ranging from ~9 to 16% (paclitaxel [Taxol[®]], topotecan [Hycamtin[®]], gemcitabine [Gemzar[®]] or pegylated liposomal doxorubicin [Caelyx[®]])^{2,3,4}.
- 75% of the evaluable ovarian cancer patients achieved reductions of up to 95% in ovarian cancer biomarkers, CA125, or CEA.



Platinum-resistant ovarian cancer represents a significant unmet clinical need with:

- a median survival of 9-12 months and
- fewer than 15% of patients respond to subsequent chemotherapy⁵.

Results reported in Starpharma's ASX Announcement dated 18 October 2023. All efficacy response data are for evaluable patients.

<https://ocrahope.org/get-the-facts/staging>

² Taxol[®] (paclitaxel) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf.

³ Mutch, DG, et al., J Clin Oncol, 2007;25(19):2811-2818.

⁴ Pujade-Lauraine, E, et al., J Clin Oncol, 2014;32(13):1302-1308.

⁵ <https://erc.bioscientifica.com/view/journals/erc/25/5/ERC-17-0336.xml#:~:text=Platinum%2Dresistant%20ovarian%20cancer%20has,2014.>

Key results for DEP[®] cabazitaxel in gastro-oesophageal cancers

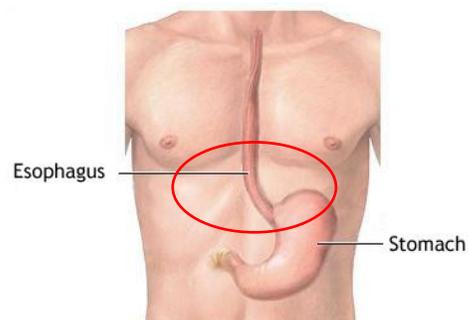


DEP[®] cabazitaxel achieved excellent efficacy responses in advanced gastro-oesophageal cancers, which represent a significant unmet medical need.

Cancer Type	Gastro-oesophageal
Patients' Prior Anti-Cancer Therapy (Median)	1 line, 6 cycles
Disease Control Rate (DCR)	80%
Objective Response Rate (ORR)	30%
Median PFS	4.0 months
Median overall survival (OS)	8.6 months

Highly encouraging efficacy results.

- DEP[®] cabazitaxel results compare favourably to standard-of-care paclitaxel treatment in patients with oesophageal or gastro-oesophageal junction cancers.
- DEP[®] cabazitaxel achieved a more than 50% longer median progression-free survival (PFS) and a 30% longer median overall survival (OS) than paclitaxel administered weekly as a second-line treatment¹.
- The majority of these patients were refractory to first-line therapy. Despite this, DEP[®] cabazitaxel achieved a disease control rate (DCR) of 80%, and an ORR of 30% in evaluable gastro-oesophageal cancer patients. Responses included stable disease (SD) for up to 27 weeks and partial responses (PR) for up to 17 weeks.



Advanced gastro-oesophageal cancers are a significant unmet medical need with limited treatment options. These cancers progress rapidly and have a very poor one-year survival rate of only 20%².

Results reported in Starpharma's ASX Announcement dated 18 October 2023. All efficacy response data are for evaluable patients.

¹ Stockton, S, et al., The Oncologist, 2023;28(9):827–e822.

² <https://www.cancerresearchuk.org/about-cancer/stomach-cancer/survival>

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DEP[®] cabazitaxel: patient case study



69-year-old woman with stage IV platinum-resistant ovarian cancer

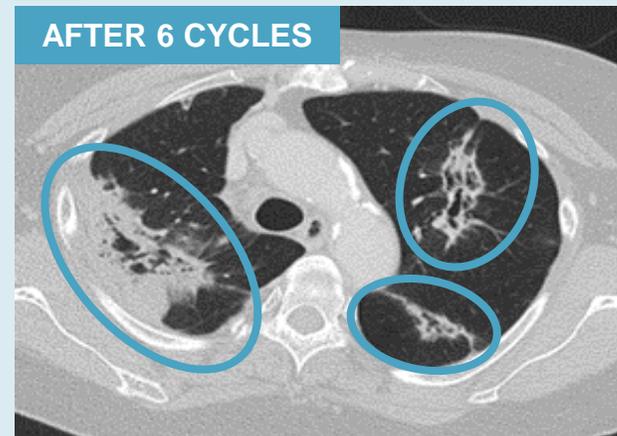
Patient's cancer had progressed prior to entering the DEP[®] cabazitaxel study, following:

- 12 cycles of two different platinum treatment regimens
- Extensive surgery and radiation therapy
- Extensive lung metastases with long-standing cough and related findings on chest examination

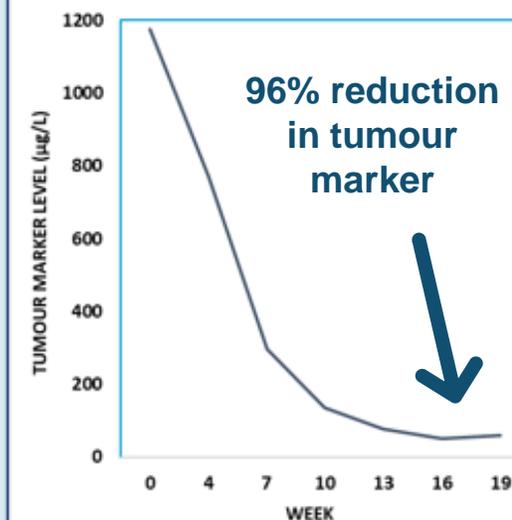
Following treatment with DEP[®] cabazitaxel (6 cycles), the patient achieved:

- Partial response (significant tumour shrinkage);
- Up to 43% reduction in size of individual lung metastasis
- Anticancer response maintained for 34 weeks
- 96% reduction in CEA tumour marker
- Cough and chest exam abnormalities resolved after cycle 3

CT scans of lung metastases



Reduction in Tumour Marker on DEP[®] cabazitaxel treatment



Key Opinion Leaders (KOLs) comments on DEP[®] cabazitaxel Phase 2 results



*“In our cancer early phase trials unit at Guy’s Hospital, we conduct many studies of novel oncology therapeutics. **The results with DEP[®] cabazitaxel clearly demonstrate promising and durable anti-cancer activity in very hard-to-treat cancer patients, not only in prostate cancer patients but also platinum-resistant ovarian cancer, and advanced gastro-oesophageal cancers. These advanced patients have few treatment options and we have had many patients who benefited from DEP[®] cabazitaxel therapy. It was also pleasing to see the limited impact on bone marrow function of this agent given these advanced patients are often at risk of complications of chemotherapy-induced bone marrow toxicity, especially low neutrophil counts.**”*



Guy’s and St Thomas’
NHS Foundation Trust

Professor James Spicer, FRCP, MBBS, PhD, Professor of Experimental Cancer Medicine at King’s College London and Consultant in Medical Oncology and the Principal Investigator for the trial at Guy’s Hospital in London.

“I am impressed with the data on Starpharma’s novel dendrimer formulation of cabazitaxel, not only in prostate cancer patients, but in patients with other difficult-to-treat diseases such as advanced platinum-resistant ovarian and gastro-oesophageal cancers. DEP[®] cabazitaxel showed very encouraging efficacy signals in these heavily pre-treated patients who have few options remaining.”

“For example, in elderly patients with prostate cancer who typically would not tolerate standard cabazitaxel due to low neutrophil counts and other adverse effects, treatment with DEP[®] cabazitaxel was possible due to its lack of significant effects on the bone marrow and its generally well-tolerated safety profile, and achieved some excellent outcomes for these patients.

“Based on the data and my experience with DEP[®] cabazitaxel, it represents a well-tolerated and promising treatment alternative, not only to standard cabazitaxel for prostate cancer patients, but also for ovarian, gastro-oesophageal and potentially other cancers for which standard cabazitaxel is not indicated.”

Imperial College
London

Dr David Pinato, MD, MRCP (UK), MRes, PhD, Clinical Reader and Consultant Medical Oncologist, Director of Developmental Cancer Therapeutics, and Investigator for the trial at Imperial College London.

Commercial Opportunity for DEP[®] cabazitaxel



The global prostate cancer drugs market was valued at more than **US\$12 billion** in 2022 and is forecast to expand at a compound annual growth rate (CAGR) of 8.4% from 2023 to 2030. Globally, prostate cancer cases reached more than 1.4 million diagnosed in 2020.



The global ovarian cancer drugs market was valued at an estimated **US\$3.4 billion** in 2022 and is anticipated to grow at a CAGR of 6.6% from 2023 to 2030. In 2020, a total of 313,959 new cases of ovarian cancer were recorded globally.



The global gastro-oesophageal cancer drugs market was valued at approximately **US\$4.6 billion** in 2021 and is expected to expand at a CAGR of 4.58% from 2022 to 2030. The number of cases globally is expected to grow from almost 1.7 million in 2020 to approximately 2.5 million by 2035.

These positive efficacy results in prostate, ovarian, and gastro-oesophageal cancers demonstrate the significant market value and growth potential for DEP[®] cabazitaxel, not only in the approved prostate cancer indication of Jevtana[®] but also in other cancers that have a high unmet medical need.

<https://www.grandviewresearch.com/industry-analysis/prostate-cancer-therapeutics-market>.

Wang, L, et. al., *Front. Public Health*, 2022;10:811044.

<https://www.grandviewresearch.com/industry-analysis/ovarian-cancer-drugs-market>.

Huang, J, et. al., *Cancers*, 2022;14(9):2230.

<https://www.grandviewresearch.com/industry-analysis/gastrointestinal-diagnostics-market-report>.

Global Cancer Observatory, GLOBOCAN 2020, International Agency for Research on Cancer 2023.

DEP[®] irinotecan Phase 2 trial: Recruitment complete

Encouraging efficacy signals across multiple tumour types enhancing market potential



DEP[®] irinotecan

- Phase 2 trial complete; positive interim results
- Recruitment now complete (N=107); monotherapy and 5-FU combination

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 **colorectal** and hard-to-treat tumours such as **ovarian** (including **platinum-resistant**), **gastroesophageal**, and pancreatic cancers.
- No cases of severe diarrhoea with DEP[®] irinotecan – this side effect is experienced by 20-40% of patients with conventional irinotecan and often requires hospitalisation[^].
- Less severe side effects than typically associated with Camptosar[®]; AEs observed included nausea, vomiting, hair loss and neutropenia.

Combination arm

DEP[®] irinotecan + 5-FU + Leucovorin ('FOLFIRI')

Trial Sites



[^] H. Bleiberg, & E. Cvitkovic. (1996) Characterisation and Clinical Management of CPT-11 (Irinotecan)-induced Adverse Events. *European Journal of Cancer*, Volume 32 Supplement 3.

Camptosar[®]

Peak sales - US\$1.1B



FDA "Black Box" warnings:

1. Severe, life-threatening diarrhoea
2. Myelosuppression

Formulation requires conversion to SN38 (active component of irinotecan) in the body

Other AEs include early diarrhoea which may be accompanied by cholinergic symptoms (*salivation, diarrhoea, blurry vision, sweating, incontinence*)

Indication:

- Colorectal, in combination with 5-fluorouracil (5-FU) and leucovorin
- Colorectal (single agent)

Expired Patents

- EU – expired
- US – expired

DEP[®] irinotecan

(SN38 nanoparticle formulation)



- No severe diarrhoea observed;
- Less myelosuppression / neutropenia

DEP[®] conjugate of SN38 does not require hepatic conversion – less interpatient variability, reduced toxicity

No cases of severe diarrhoea and no cholinergic symptoms observed

Indication:

- Colorectal
- Additional potential indications include ovarian, gastro-oesophageal, and pancreatic

New/extended IP

- EU – 2039
- US – 2039 (potential for 5-year extension)

DEP[®] irinotecan: Phase 2 trial

Positive interim results in advanced colorectal cancer



Monotherapy arm

Heavily pre-treated advanced colorectal (colon) cancer patients treated with DEP[®] irinotecan monotherapy



Heavily pre-treated patient cohort

- Average of 4 treatment regimens prior to trial entry.
- Average of 31 treatment cycles prior to trial entry.
- >97% of patients had progressed after prior treatment with conventional irinotecan.

Positive interim results (N=38)

- Despite this heavy pre-treatment, DEP[®] irinotecan monotherapy achieved durable efficacy responses for up to 72 weeks with a disease control rate (DCR) of 48% in evaluable patients.
- No severe diarrhoea or cholinergic syndrome.
- Significantly fewer severe treatment-related adverse events.

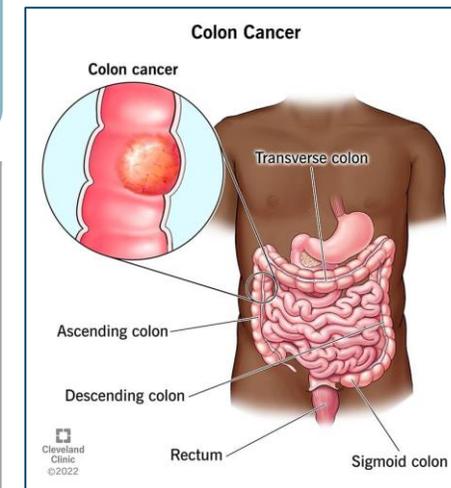
Combination arm

DEP[®] irinotecan in combination with 5-fluorouracil (5-FU) and leucovorin (LV)



Positive interim results (N=5)

- DCR is 100% and ORR of 20% (cf. published data in advanced CRC patients for conventional irinotecan plus 5-FU/LV (FOLFIRI) as second-line therapy (i.e., in patients less heavily pre-treated than in the current study) reported an ORR of 4%.
- Clinicians reported significant clinical benefit in these heavily pre-treated patients, including durable responses for up to 35 weeks (SD and partial response [PR]) with very good tolerability.



“The results of the DEP[®] irinotecan trial to date have been very promising for patients with advanced colorectal cancer who have exhausted standard treatment options, with prolonged responses and excellent tolerance of the product, including in patients who could not previously tolerate standard irinotecan or had failed prior therapy. Our experience in treating more than 20 patients on the trial to date have shown promisingly low rates of severe gastrointestinal adverse events and absence of cholinergic toxicity, which are both common and problematic side effects of standard irinotecan therapy. I am also getting consistent feedback from several patients in the trial that they far prefer DEP[®] irinotecan plus 5-FU/LV compared to the standard FOLFIRI regimen, which uses conventional irinotecan. In this heavily pre-treated group of CRC patients, prolonged disease control seen with DEP[®] irinotecan is an excellent outcome and a significant clinical benefit and warrants ongoing development.”

- Dr Jenny Liu, MD, PhD, FRACP, Medical Oncologist and Principal Investigator at the Kinghorn Cancer Centre, St Vincent’s Hospital in Sydney.

All efficacy response data reported are for evaluable patients. Evaluable patients are those that received ≥ 1 dose cycle of DEP[®] irinotecan and had a CT scan to assess response to treatment at ≥ 8 weeks after commencement of treatment with DEP[®] irinotecan.

DCR comprises stable disease (SD), partial responses (PR) and complete responses (CR).
ORR comprises PR and CR.

Tournigand et al., FOLFIRI Followed by FOLFOX6 or the Reverse Sequence in Advanced Colorectal Cancer: A Randomized GERCOR Study, *Clinical Oncology*, 2023;41(19):3469-3477.

<https://doi.org/10.1200/jco.22.02774>

DEP[®] irinotecan: Phase 2 trial

Positive interim results in platinum-resistant/refractory ovarian cancer



Advanced metastatic ovarian cancer patients treated with DEP[®] irinotecan monotherapy



Heavily pre-treated patient cohort

- Average of 6 treatment regimens and 30 treatment cycles prior to trial entry.
- 100% of patients' cancer was resistant or refractory to platinum-based therapies (standard-of-care).
- 100% of patients had exhausted available standard-of-care treatment options.

Positive interim results (N=23)

- DEP[®] irinotecan monotherapy achieved a **DCR of 100%**, and an **ORR of 43%** in ovarian cancer patients dosed every 2 weeks (Q2W) (cf. **standard-of-care single-agent therapies** for platinum-resistant ovarian cancer, including paclitaxel, topotecan, gemcitabine or pegylated liposomal doxorubicin, which report ORRs ranging from **~9 to 16%**).
- The DCR achieved in all ovarian cancer patients (Q2W and Q3W) is 72%, with several patients continuing to receive treatment and experiencing clinical benefit.
- Tumour shrinkage of up to 60%.
- **Response durations of up to 45 weeks.**
- **Tumour biomarker reductions of up to 98% in more than 75% of patients.**
- Clinical benefits reported by investigators in the study included complete resolution of a patient's debilitating tumour-related ascites and pleural effusion.

This cohort of patients with platinum-resistant/refractory ovarian cancer represents a significant unmet medical need and a potential expansion of the current market for irinotecan, given that **conventional irinotecan is not approved for the treatment of ovarian cancer, either alone or in combination.**



"I am impressed with the data on Starpharma's novel dendrimer formulation of the irinotecan active metabolite, SN38. In our patients, DEP[®] irinotecan has shown excellent tolerability and very encouraging efficacy. Compared to conventional irinotecan, tolerability for DEP[®] irinotecan is much improved. Based on the trial data, I believe DEP[®] irinotecan represents a well-tolerated and promising treatment alternative for patients with colorectal cancer, and potentially others, including platinum-resistant ovarian cancer."

- Dr Natalie Cook, MBChB, MRCP, PhD, the Principal Investigator of the study, a Medical Oncologist and Clinical Lead for the Manchester Experimental Cancer Medicine Centre at the Christie Hospital and University of Manchester in the UK.

Taxo[®] (paclitaxel) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf

Mutch et al., Randomized Phase III Trial of Gemcitabine Compared with Pegylated Liposomal Doxorubicin in Patients with Platinum-resistant Ovarian Cancer, *J Clin Oncol*, 2007;25(19):2811-2818. <https://doi.org/10.1200/jco.2006.09.6735>

Pujade-Lauraine et al., Bevacizumab Combined with Chemotherapy for Platinum-Resistant Recurrent Ovarian Cancer: The AURELIA Open-Label Randomized Phase III Trial, *J Clin Oncol*, 2014;32(13):1302-1308. <https://doi.org/10.1200/jco.2013.51.4489>

DEP[®] irinotecan: improved safety profile



DEP[®] irinotecan - improved tolerability profile c.f. published data on Camptosar^{®†}

Gastro-intestinal toxicity much improved with DEP[®] irinotecan treatment:

- ~20-40% of Camptosar[®] treated patients suffer from severe diarrhoea (≥ 7 stools per day), often require hospitalisation.
- **DEP[®] irinotecan patients experienced no severe diarrhoea.**

No cholinergic syndrome:

- ~47% colorectal cancer patients treated with Camptosar[®] experienced cholinergic syndrome.
- **No DEP[®] irinotecan patients experienced cholinergic syndrome.**

Severe diarrhoea

- **Grade 3:** ≥ 7 stools per day over baseline; hospitalisation indicated.
- **Grade 4:** life-threatening consequences, and urgent intervention is required.

Cholinergic syndrome

Symptoms include sweats, flushing, diarrhoea, abdominal cramping, salivation, visual disturbances, miosis and lacrimation.

Safety Outcome	DEP [®] irinotecan*	Camptosar ^{®†^}
GASTROINTESTINAL		
Diarrhoea \geq grade 3	0	~20-40%
Nausea \geq grade 3	2.2%	~10%
Vomiting \geq grade 3	1.1%	~10%
NERVOUS SYSTEM		
Cholinergic Syndrome	0%	~47%

^(350 mg/m²)
Q3W | N=765

*(8 - 15 mg/m² SN38)
Q3W | N=90

[†]H. Bleiberg, & E. Cvitkovic. (1996) Characterisation and Clinical Management of CPT-11 (Irinotecan)-induced Adverse Events. *European Journal of Cancer*, Volume 32 Supplement 3. https://www.medicines.org.uk/emc/product/6506-UK_SmPC April 2022

DEP[®] irinotecan: patient case study

71-year-old woman with heavily pre-treated, advanced, platinum-resistant ovarian cancer

The patient's cancer had progressed before enrolment in the DEP[®] irinotecan study, following extensive surgery and 39 treatment cycles with five different anti-cancer therapies.

The patient's cancer was resistant to platinum therapy with multiple metastases, including in the liver.

Following treatment with DEP[®] irinotecan, the patient achieved the following responses:

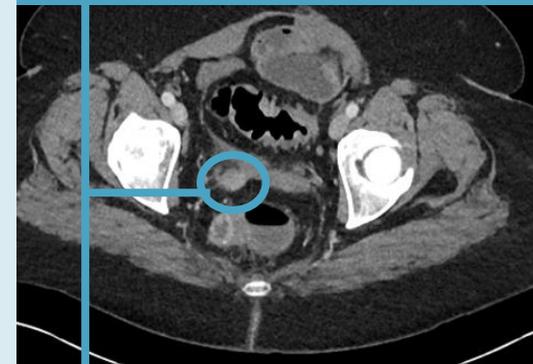
- ~60% reduction (partial response) in combined size of all tumour lesions after eight cycles of treatment.
- Up to 52% reduction in tumour biomarkers.

Ovarian cancer is a common cancer with a low five-year survival rate of only ~17% for advanced cases.

BASELINE



POST TREATMENT



55% reduction in size of tumour lesion following treatment with DEP[®] irinotecan



DEP[®] docetaxel

Encouraging efficacy signals across multiple tumour types



DEP[®] docetaxel

- Phase 2 trial
- Recruitment now complete (N=80); monotherapy and combination

Interim observations

- Encouraging efficacy signals observed, including prolonged stable disease and significant tumour shrinkage in patients with a focus on **pancreatic, gastro-oesophageal, and cholangiocarcinoma**. Includes heavily pre-treated patients who have failed multiple other lines of treatment.
- These impressive tumour responses with DEP[®] docetaxel include stable disease for up to 40 weeks and significant tumour shrinkage in late-stage oesophageal cancer.
- Final patient recruitment is focused on hard-to-treat cancers, in parallel with the combination arm of DEP[®] docetaxel + gemcitabine.
- No anaphylaxis, notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects including hair-loss, mouth ulcers and oedema.

Combination arms

- DEP[®] docetaxel + gemcitabine (Gemzar[®])
- DEP[®] docetaxel + nintedanib (Vargatef[®])

Trial Sites



Taxotere[®]

Peak sales
~US\$3.1B



FDA “Black Box” warnings:

1. Neutropenia
2. Severe hypersensitivity (polysorbate-80 detergent)

Premedication required:

Oral corticosteroids

Expired Patents

- EU – expired
- US – expired

DEP[®] docetaxel

Starpharma's patented, nanoparticle formulation



No neutropenic deaths or severe hypersensitivity observed; detergent-free formulation; therefore, would not expect “black box” warnings

Premedication not required; polysorbate-80/detergent-free formulation

New/extended IP

- EU – 2032
- US – 2032 (potential for 5-year extension)

60-year-old woman with stage IV uterine cancer



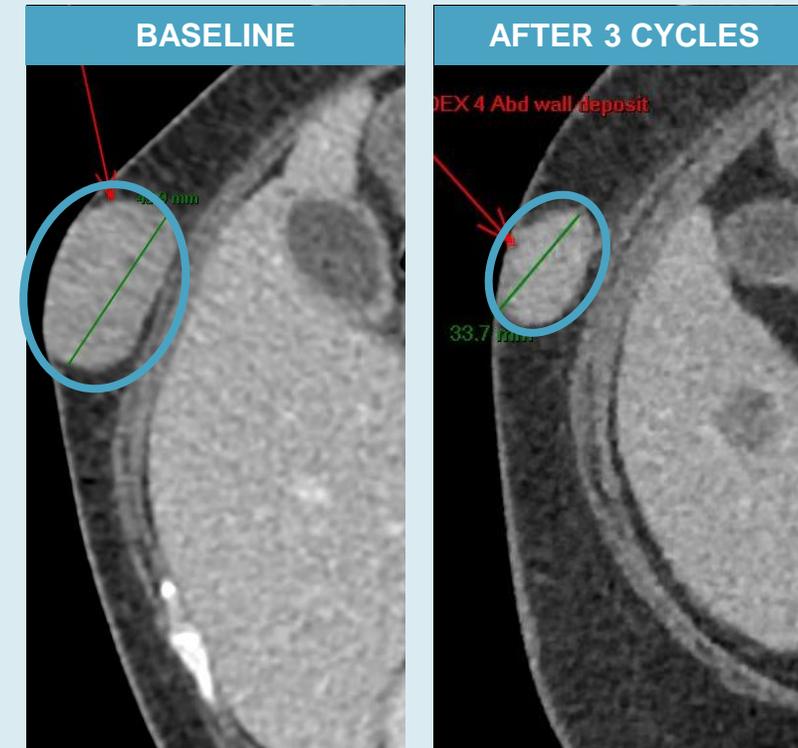
Patient heavily pre-treated prior to entering the study:

- >11 treatment cycles of 3 different kinds of anti-cancer therapies

Following treatment with DEP[®] docetaxel in combination with gemcitabine, the patient achieved:

- Stable disease response maintained for >23 weeks
- Tumour lesion reductions of up to 52% observed

32% reduction in tumour lesion



DEP[®] - a versatile platform with flexible applicability to a range of radiopharmaceuticals



- **Radiotheranostics is a rapidly developing area of cancer treatment and diagnosis** - the global radiopharmaceutical market is projected to reach US\$35 billion by 2031[^]
- **Significant corporate activity in recent years** - over US\$17 billion invested in M&A transactions between 2014 and June 2022* in the radiopharmaceutical market
- **Starpharma's DEP[®] platform has yielded multiple radiotheranostic DEP[®] candidates** and Starpharma continues to evaluate licensing opportunities for its internal radiotheranostic candidates and engages in discussions with potential partners exploring access to Starpharma's DEP[®] platform

DEP[®] radiopharmaceutical benefits include:

- Flexibility in size and structure of nanoparticle (allowing different targeting groups and pharmacokinetics)
- Enhanced tumour accumulation due to the enhanced permeability and retention (EPR) effect (10x nanobody alone)
- Enhanced tissue targeting and retention due to specific receptor binding (and internalisation)
 - Enhanced entry and specific accumulation allows for enhanced PET visualisation (diagnostic)
 - Enhanced accumulation and cellular internalisation in tumours delivers enhanced efficacy and less off-target toxicity
 - Potential to use DEP[®] in diagnostic and therapeutic approaches



[^]MEDDraysintell Nuclear medicine report Edition 2022

*https://www.medraysintell.com/_files/ugd/1beeab_6bc27b0bbe664527aca68f41bf7de2bc.pdf

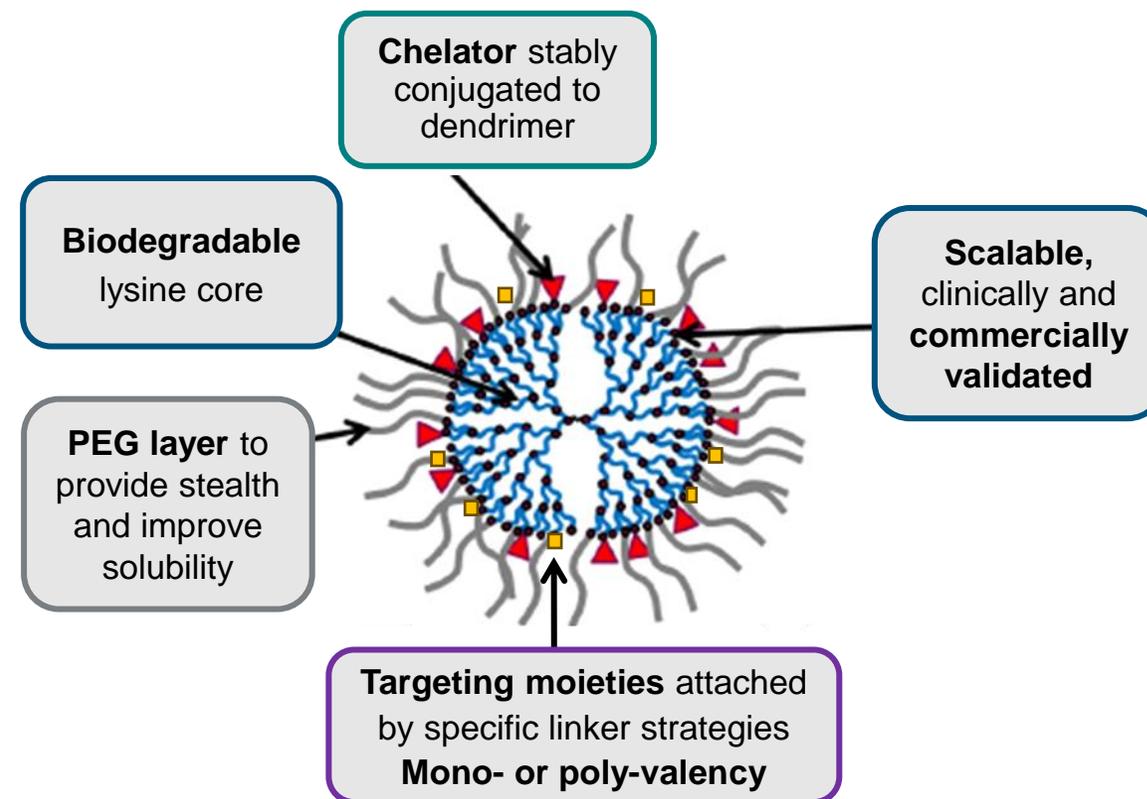
DEP[®] platform - advantages in radiotheranostics

- Can utilise a wide range of targeting moieties
- DEP[®] dendrimers deliver high chelator number (4, 8, 16) per conjugate
- Site specific attachment; precisely manufactured and easily scalable
- Drug-linker strategy can be easily tailored to meet drug release requirements
- Flexibility of payload choice – radioisotope, cytotoxic, ultra toxic, immunomodulator



DEP[®] dendrimers are constructed in concentric layers called generations

DEP[®] dendrimer	<ul style="list-style-type: none">• Clinically validated, safe, biodegradable• Easily scalable; precisely manufactured
Chelator / Isotope	<ul style="list-style-type: none">• Flexible – the type and number of chelators can be varied (e.g., DFO, NOTA, DOTA)
Pharmacokinetics	<ul style="list-style-type: none">• Plasma half-life can be tuned• Dendrimer size and charge can be altered to regulate kidney glomerular filtration
PEG	<ul style="list-style-type: none">• Provides stealth• Controls clearance
Tumour Targeting	<ul style="list-style-type: none">• Flexible targeting moiety (antibody, peptide, small molecule)• Poly-valency easily achieved



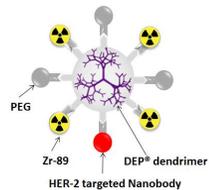
HER2-targeted DEP[®] radiodiagnostic and radiotherapeutic pair

- HER2 is overexpressed in ~20%-30% of breast (HER2^{hi}), gastric & gastro-oesophageal cancers (HER2^{hi}); also expressed at a low levels (HER2^{lo}) in other carcinomas including colorectal, endometrial & lung.
- HER2+ breast cancer treatment market was \$9.7 billion[^] in 2021 and is expected to increase to \$11.2 billion in 2025 (US, Japan, EU5).
- Global HER2-positive gastric cancer market is currently valued at ~US\$ 1.3 billion in 2023.

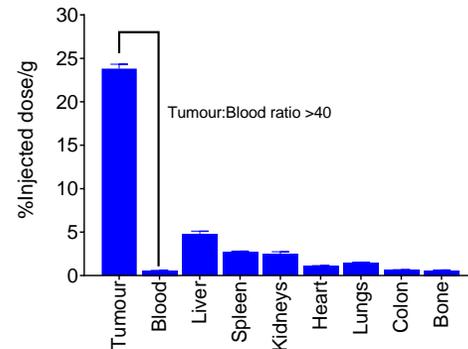
DEP[®] HER2-zirconium (radiodiagnostic)

DEP[®] HER2-zirconium has demonstrated imaging benefits in a HER2⁺ breast cancer model, including:

- More **rapid tumour accumulation and superior PK** than HER2 mAb, trastuzumab (Herceptin[®]), labelled with zirconium;
- Favourable biodistribution profile, with **excellent imaging contrast between tumour and normal tissues**;
- High **tumour-to-organ ratios, delivering excellent specificity** in imaging HER2+ tumours; and
- Highly desirable “fast-in”/“fast-out” kinetics, meaning it accumulates rapidly in the tumour and is cleared quickly from the bloodstream.



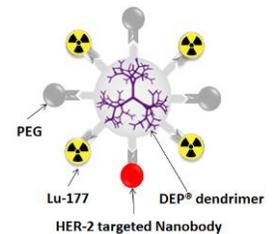
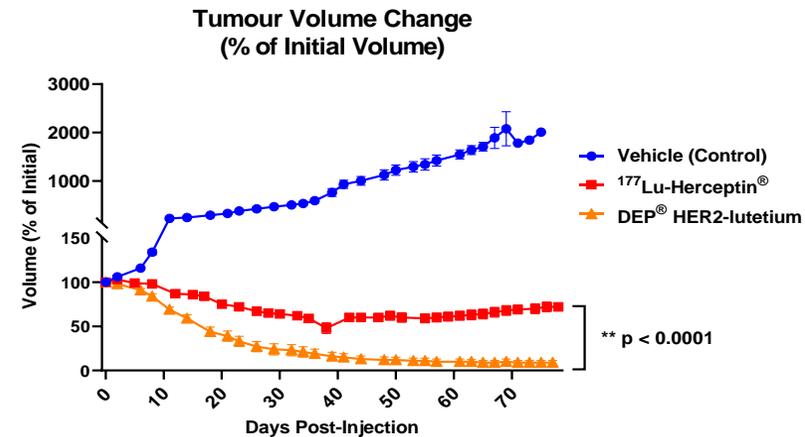
Tumour and normal tissue levels of DEP[®] HER2-zirconium at 120 hours.



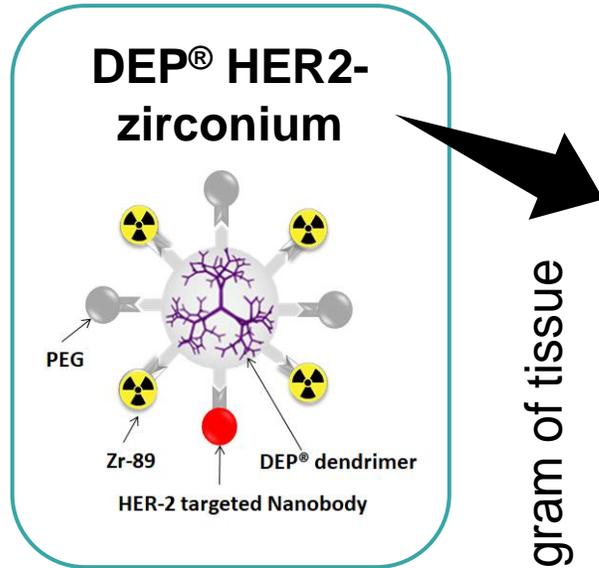
DEP[®] HER2-lutetium (radiotheranostic)

DEP[®] HER2-lutetium has demonstrated therapeutic benefits in a breast cancer model.

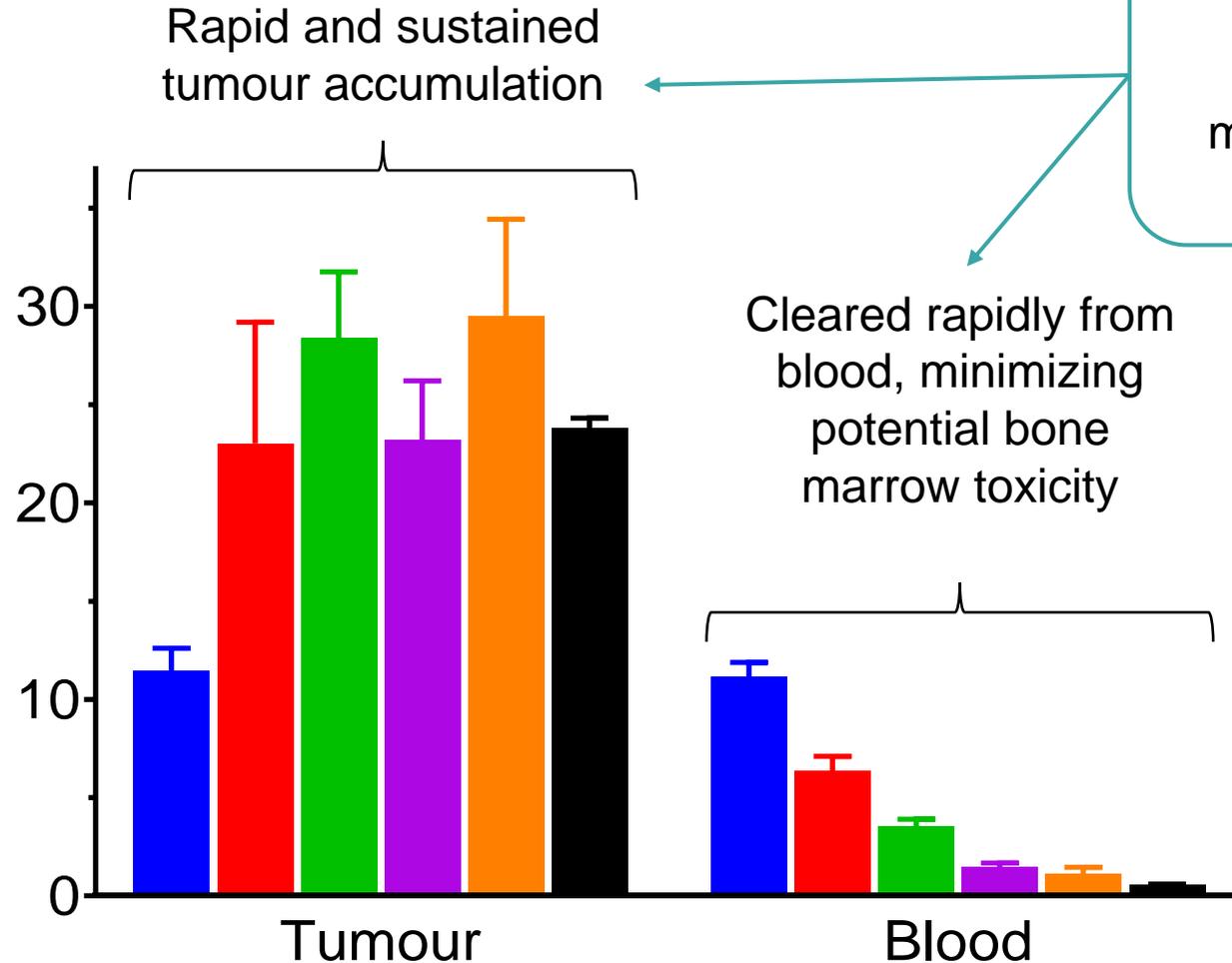
- **Achieved complete tumour regression**; well tolerated.
- Anti-tumour effect was radiation dose-dependent.
- 100% survival throughout the experiment.



DEP[®] HER2-zirconium (radiodiagnostic): favourable imaging characteristics in a HER2⁺ breast cancer model



% injected dose / gram of tissue



These characteristics are also desirable for a radiotherapeutic to maximise efficacy and minimise toxicity

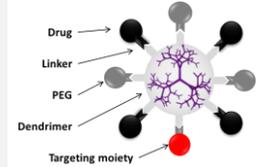
DEP[®] antibody-drug conjugate (ADC) partnerships with leading companies



- The innovative therapeutic area of ADCs continues to grow, with many high value deals signed in recent years
- The ADC market is expected to reach to more than US\$15 billion by 2030*
- 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 the DEP[®] technology.

DEP[®] ADC benefits include:

- Can be tuned to provide optimal characteristics
- Highly efficacious, providing enhanced anti-cancer activity
- Penetrates deeply into tumours, binding strongly to target cells, and internalised for enhanced performance
- Enhanced efficacy leading to enhanced survival



Significant corporate activity in ADCs

  	 	 	 	 	 	  	 
US\$6B <i>Jul 2020</i>	US\$2.75B <i>Nov 2020</i>	€1.2B <i>Dec 2020</i>	US\$3.1B <i>Jun 2021</i>	US\$1.7B <i>Feb 2022</i>	US\$936M <i>Jul 2022</i>	US\$1.1B <i>Feb 2023</i>	US\$4B + up to US\$22B <i>Oct 2023</i>

*Colombo and Rich, The therapeutic window of antibody drug conjugates: A dogma in need of revision, Cancer Cell (2022), <https://doi.org/10.1016/j.ccell.2022.09.016>

Marketed products

Multiple revenue streams with a growing distribution network



VIRALEZE™ Antiviral Nasal Spray

VIRALEZE™ is a broad-spectrum antiviral nasal spray intended to provide a moisturising and protective barrier in the nose that traps and blocks cold/respiratory viruses.

VIRALEZE™ is registered in more than 35 countries and is sold in the UK, Europe, and Southeast Asia. Brand name and product claims may differ by market.

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

amazon.co.uk

LloydsPharmacy

ADMENTA Italia



Etqan & Nazahah Company



VivaGel® BV

VivaGel® BV is a novel, non-antibiotic gel for the treatment of bacterial vaginosis and the prevention of recurrent BV and its symptoms.

VivaGel® BV is registered as a medical device in more than 50 countries and has been commercialised under different brand names in a number of markets including the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.



VivaGel® Condom

Starpharma's VivaGel® Condom is the world's first and only antiviral condom. The condom lubricant contains VivaGel® (SPL7013, or astodimer sodium), which is an antiviral agent proven, in laboratory studies only, to inactivate HIV, herpes simplex virus (HSV) and human papillomavirus (HPV), which are viruses that cause STIs.

The physical barrier of the condom provides primary protection against sexually transmitted infections (STIs). The VivaGel® condom has been commercialised under different brand names in a number of markets, including in Japan, Australia, Canada, and Europe.



VIRALEZE™ antiviral nasal spray

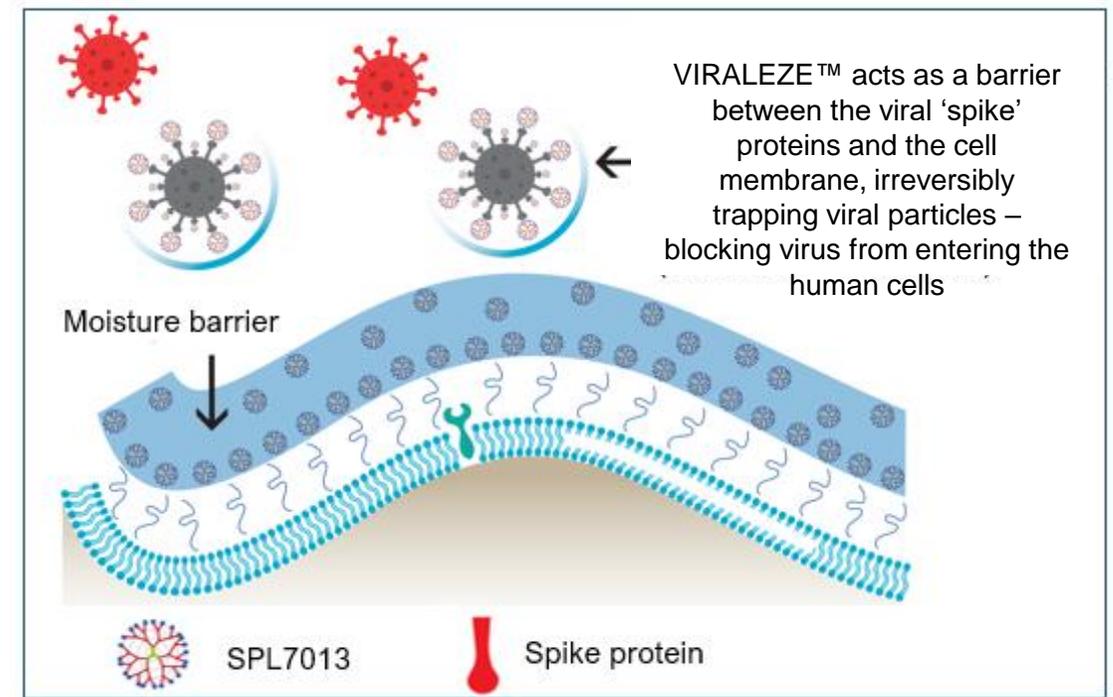
VIRALEZE™ features

- Broad-spectrum antiviral nasal spray
- Contains a novel dendrimer molecule, SPL7013, which traps and blocks multiple cold/respiratory viruses including influenza, RSV, coronaviruses (including SARS-CoV-2)
- Blocks virus replication in lab studies both before and after exposure of cells to virus
- Well tolerated; acts locally in the nasal cavity and is not absorbed into the bloodstream
- Provides a protective moisture barrier to help keep nasal tissue hydrated
- Room temperature storage
- Convenient for use in a range of settings, including travel, work, events, and other crowded environments



How VIRALEZE™ works

- 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 VIRALEZE™, SPL7013, physically traps and blocks viral spike proteins thus preventing infection of cells

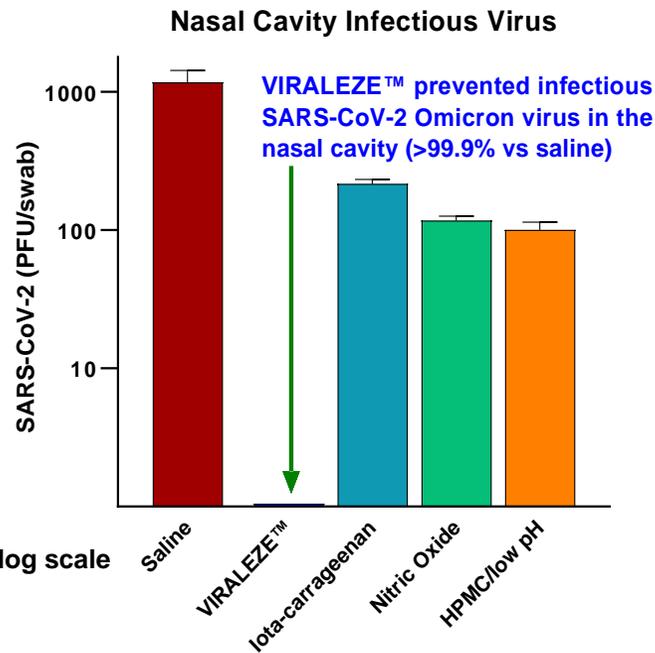


VIRALEZE™ protects against SARS-CoV-2 Omicron and reduces infectivity in challenge model

VIRALEZE™ significantly outperformed comparator nasal sprays in:

- reducing SARS-CoV-2 Omicron viral load by **99.4%** vs saline; and
- reducing the level of infectious virus in nasal cavity, lung, trachea[^]

Nasal Spray	Reduction in Infectious SARS-CoV-2 Omicron in Lung vs Saline
VIRALEZE™	>99.9%
Iota-carrageenan (e.g., Cold Defence)	49.9%
Nitric Oxide (NONS™, SaNOTize)	74.9%
HPMC/low pH (Vicks® First Defence)	74.9%

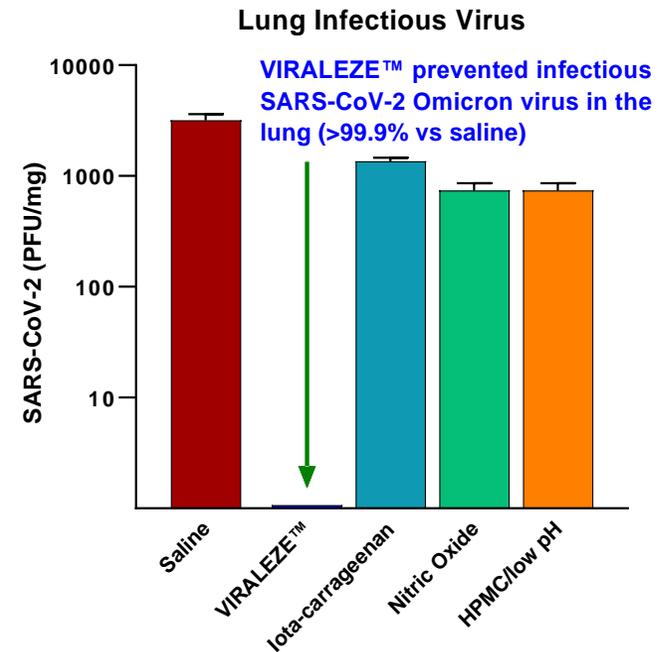


Scripps Research

Full data presented at International Virology Conference, Respi DART 2022 in Mexico

Respi DART 2022

LOS CABOS, MEXICO • 6-8 DECEMBER 2022



NB: Y axis = log scale

[^]Day 7 post-challenge

*VIRALEZE™ is not approved for use or supply in Australia

Bell Potter Healthcare Conference 2023

[^]N=6

VIRALEZE™ market and regulatory activity

- **VIRALEZE™** antiviral nasal spray is registered in more than 35 countries around the world*.
- Marketed via pharmacies, retail outlets and online in a number of markets.
- Partnered with:
 - ✦ **LloydsPharmacy amazon.co.uk** in the UK;
 - ✦ **ADMENTA Italia** Group in Italy;
 - ✦ **TRUONG BAO LAND** in Vietnam;
 - ✦ **Etqan & Nazahah Company** in countries in the Middle East; and
 - ✦ **恒安集团 HENGAN** in Hong Kong and Macau
- Other VIRALEZE™ regulatory submissions are in progress and commercial discussions for multiple regions/countries are underway.
- VIRALEZE™ post-market clinical study completed recruitment, with ~200 participants enrolled.



Starpharma is also in discussions with multiple potential commercial partners in other regions with a focus on *commercially attractive* markets which have rapid regulatory pathways

*VIRALEZE™ is not approved for use or supply in Australia

VIRALEZE™ clinical trial in patients with COVID-19 has completed recruitment

- Small, post-market randomised clinical study of VIRALEZE™ vs. placebo nasal spray in patients with COVID-19 will generate valuable clinical data to support ongoing marketing, commercialisation and regulatory activities.
- Will examine the antiviral performance and ability of VIRALEZE™ to reduce viral load, as well as to monitor its impact on duration of symptoms and disease progression.
- Primary endpoint: cumulative SARS-CoV-2 viral load, or “area under the curve”, over a seven-day treatment period.
- Trial design is based on other similar studies of products that VIRALEZE™ outperformed in nonclinical studies.
- Recruitment has completed, with ~200 participants diagnosed with COVID-19 enrolled; results are expected to be reported in Q2 FY24, following completion of data and statistical analyses.



VIRALEZE

VIRALEZE™ is not approved for use or supply in Australia

VivaGel® BV: A breakthrough product for the treatment of BV and prevention of recurrent BV*

About Bacterial Vaginosis ('BV')

- Bacterial vaginosis or BV is the most common vaginal infection worldwide, affecting 1 in 3 women globally¹. BV is associated with causing complications related to the reproductive health of women².
- BV treatment has typically involved antibiotics (e.g., metronidazole). Antibiotic resistance is a global problem, antibiotics have unpleasant side effects, and there is demand for alternative approaches. Other current BV therapies do not prevent BV recurring.

VivaGel® BV

- Novel, non-antibiotic therapy.
- Prevents pathogenic bacteria from adhering to the vaginal wall and disrupts and inhibits the formation of pathogenic bacterial biofilms.
- Well tolerated, with vulvovaginal candidiasis being the only treatment-related adverse event reported to occur more often than with the placebo.



VivaGel® BV commercialisation

- Registered in more than 50 countries.
- Launched in Europe, the UK, South Africa, Australia, and New Zealand.
- Further launches and regulatory submissions progressing in multiple regions.
- Partnered with Aspen for marketing in Australia and New Zealand.
- Starpharma received A\$6.6M from Mundipharma in August 2023, as part of a settlement, in which it also regained all rights to VivaGel® BV in their previously licensed territories. Starpharma is now pursuing new partners.



In the US, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV. Starpharma is preparing to lodge a further submission to the FDA in CY23, which will include precedents of other recent FDA approvals.

1. Peebles K, et al., (2019). High global burden and costs of bacterial vaginosis: a systematic review and meta-analysis. *Sex Transm Dis* 46(5), 304.

2. Turovskiy Y, et al., (2011). The aetiology of bacterial vaginosis. *J Appl Microbiol* 110(5), 1105.

*Registered indications may differ by market

DEP[®] Drug Delivery



Internal DEP[®] Clinical-stage Assets

- Report results from Phase 2 DEP[®] trials, including value-adding combination arms
- Licensing discussions continuing in parallel



Partnered/Funded DEP[®] Programs

- Progress existing partnerships with MSD, Genentech, Chase Sun, and AstraZeneca
- New and/or expanded DEP[®] partnerships, increasing optionality of potential revenue streams and value creation



Preclinical DEP[®] Programs

- Advance/partner DEP[®] radiotheranostics
 - DEP[®] HER2-zirconium (radiodiagnostic)
 - DEP[®] HER2-lutetium (radiotherapeutic)
- Advance/partner DEP[®] ADCs
- Other DEP[®] candidates

SPL7013 Products



VIRALEZE[™] Antiviral Nasal Spray

- Further commercial roll-out, registrations and product launches
- Further distribution arrangements with commercial partners
- Continue to generate clinical and antiviral data to support and expand commercialisation, including UK post-market study results



VivaGel[®] BV

- Execute new marketing and distribution arrangements
- Further regulatory approvals and commercial launches
- FDA review process



VivaGel[®] Condom

- Approvals/launches in additional countries



SPL7013

- Further development/co-development
- Continued testing against important infectious pathogens

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



ENVIRONMENT



Appropriate systems in place to comply with relevant federal, state, and local government environment regulations.



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

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



View our [Climate Change Position Statement online](#).

SOCIAL



52% of roles, including leadership and management roles are held by women. 51% of all roles held by women.

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

19 countries represented by a small, diverse group of employees.



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

GOVERNANCE

Compliance with ASX Corporate Governance Principles and Recommendations.

No breaches of:

- Code of Conduct
- Anti-bribery
- Whistleblowing



Director Independence



BOARD 83%
COMMITTEES 100%

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.

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

[Download ESG Report](#)



Investor Relations Queries

investor.relations@starpharma.com

Head office

4-6 Southampton Crescent

Abbotsford VIC 3067

www.starpharma.com