

Starpharma presents at ASX Small and Mid-Cap Conference

Melbourne, Australia; 22 March 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) announces that Starpharma CEO Dr Jackie Fairley will present a brief overview of the Company at the ASX Small and Mid-Cap Conference today at 11:00am AEDT. The Conference showcases selected ASX-listed companies to Australian investors.

Starpharma's presentation will include a brief overview of its portfolio, key value drivers and outlook, including:

- the Company's clinical-stage DEP[®] programs;
- multiple DEP[®] partnerships with global companies;
- new AZD0466 data, including preclinical data in small cell lung cancer (SCLC) and clinical data in Phase 1 solid-tumour patients, which will be presented by AstraZeneca at the upcoming American Association for Cancer Research Annual Meeting in April 2023; and
- on-market products including VIRALEZE[™] and VivaGel[®] BV.

Investors are invited to join the Conference by registering online at: <https://www2.asx.com.au/investors/investment-tools-and-resources/events/smid>

The presentation is appended and will also be available on Starpharma's website: www.starpharma.com.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a biopharmaceutical company, focussed on the development of pharmaceutical and medical products for unmet patient needs, including in the areas of oncology and infectious diseases.

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 30 countries*, including in Europe, in the UK, and in Southeast Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel[®] BV, for treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 45 countries, including in the UK, in Europe, in Southeast Asia, South Africa, Australia and New Zealand.

* Note: VIRALEZE[™] is not approved for use or supply in Australia.

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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 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.



ASX Small and Mid-Cap Conference

Company Overview | Starpharma ASX:SPL

Dr Jackie Fairley, CEO

22 March 2023





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.

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.

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 under development; improved, patented versions of widely used cancer medications. Multiple products on market and preclinical stage assets.

Multiple global pharma partnerships

DEP® partnerships with three of the world's top 10 pharmaceutical companies: AstraZeneca, MSD & Genentech. Licenses projected to generate revenues through 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 \$44.0M (at 31 Dec 2022), including receipt of a \$7.1 million R&D tax incentive refund (21 Dec 22). FY22 revenue up 128% to \$4.9M.

Strong institutional share register

Significant shareholders include Allan Gray, Allianz, M&G, and Fidelity. International share register comprising ~55% institutions, ~40% retail, ~5% staff/other.



Starpharma is committed to ESG principles in all activities, governance arrangements, and environment and employment practices.



Starpharma's portfolio of high-value assets

Multiple clinical-stage DEP[®] assets, multiple corporate partnerships and products on market

DEP[®] Products

Product	Active / Payload	Target indication	Preclinical	Phase 1	Phase 2
DEP [®] cabazitaxel	Cabazitaxel	Prostate and other cancers	▶		
DEP [®] irinotecan	SN38	Colorectal and other cancers	▶		
DEP [®] docetaxel	Docetaxel	Pancreatic and other cancers	▶		
AZD0466	AZD4320 (Bcl2/xL inhibitor)	Haematological cancers	Developed by AstraZeneca		
DEP [®] gemcitabine	Gemcitabine	Solid cancers	▶		
DEP [®] HER-2 ADC	Not disclosed	Solid cancers	▶		
DEP [®] HER-2 radiotherapy	¹⁷⁷ Lu	Solid cancers	▶		
DEP [®] HER-2 radiodiagnostic	⁸⁹ Zr	Diagnostic	▶		
Other collaborations	Various	Various	▶		

Marketed Products



Partnered DEP[®] Products & Programs

Multiproduct DEP[®] license with AstraZeneca, including the development of AZD0466 for multiple indications



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



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



Two DEP[®] Research Agreements with Genentech



Financial Summary

Strong balance sheet with revenues from product sales and partnerships

1H FY23 Result

- Strong cash position with \$44.0M as at 31 December 2022
- Loss of \$8.3M for the half-year (H1 FY22: \$8.4M)
- Revenue of \$1.6M, down \$0.3M on the prior corresponding period (H1 FY22: \$1.9M)
- Receipt of a \$7.1M Research and Development (R&D) tax incentive in December 2022

Key Financials

	H1 FY23 A\$M	H1 FY22 A\$M	FY22 A\$M	FY21 A\$M
Revenue	1.6	1.9	4.9	2.2
Other Income	0.1	0.1	0.3	1.3
Loss for the period	(8.3)	(8.4)	(16.2)	(19.7)
Net operating cash outflows	(5.1)	(11.2)	(13.2)	(14.8)

Cash as at 31 Dec 2022: \$44.0M



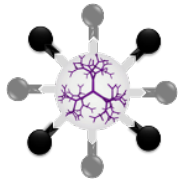
Prior corresponding period: Half-year ended 31 December 2021

DEP[®] Platform

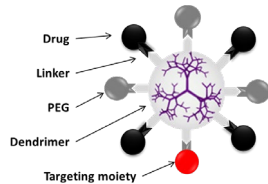
Starpharma's proprietary DEP[®] platform is highly versatile, conveys multiple benefits, and enhances the commercial value of a wide range of drugs

DEP[®] technology:

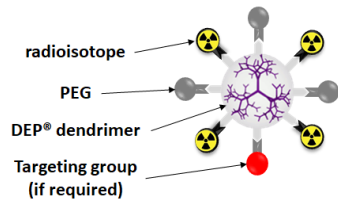
- Based on proprietary, branched polymers called dendrimers
- Represents a platform with significant optionality – applicable to many different drugs



DEP[®] dendrimer-drug conjugate



DEP[®] dendrimer antibody drug conjugate



DEP[®] dendrimer radiotheranostic

Improved Safety / Reduced side effects

Control release kinetics of drug to reduce C_{max} 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)



Starpharma's DEP[®] platform

Broad applicability and exceptional optionality

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

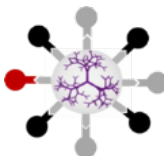
DEP[®] platform



AstraZeneca 

- Franchise extension
- Generic differentiation
- New chemical entities
- Combinations including immuno-oncology

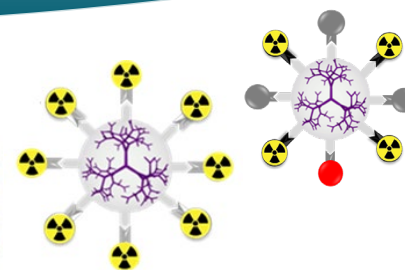
Chemotherapeutics



 MSD

- Flexible technology
- Increased drug antibody ratio
- Targeting group agnostic
- Site selective payload attachment

Antibody Drug Conjugates



- Radiotheranostic applications
- Can use a variety of isotopes and targeting approaches

Radiotheranostics



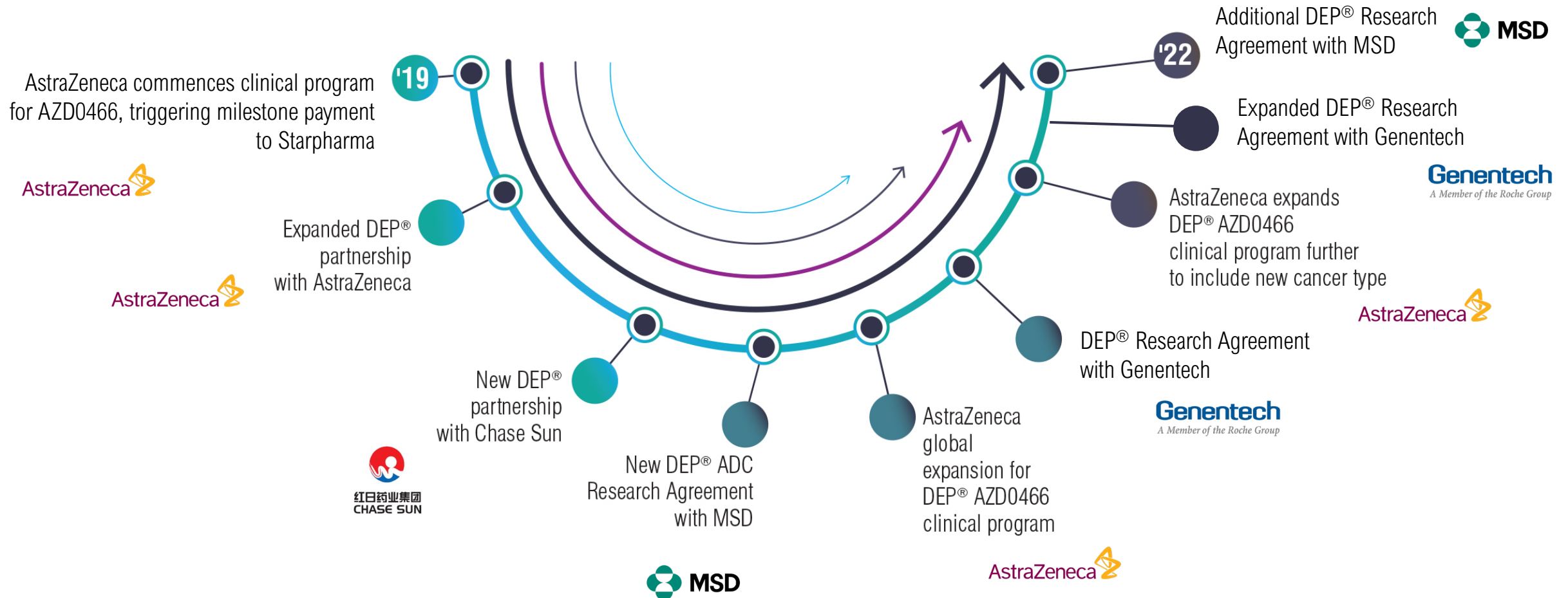
红日药业集团
CHASE SUN

- Applicable to antivirals and anti-infectives
- Endocrinology

Non-oncology

Momentum building for partnered DEP[®] programs

Starpharma has secured partnerships with three of the world's top 10 pharmaceutical companies[^]



[^]<https://pharmaboardroom.com/articles/top-10-global-pharma-companies-2022/>

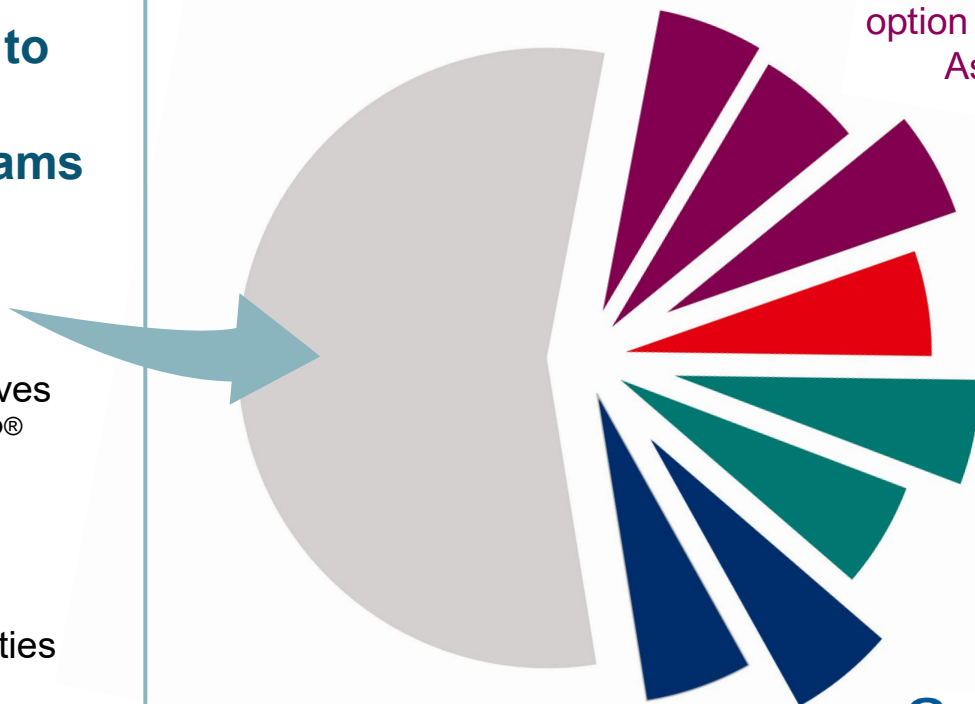
DEP[®] partnering creates significant value and optionality

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



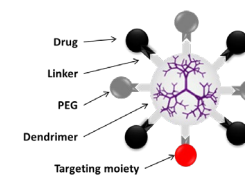
AstraZeneca
 Multiproduct license & option agreement with AstraZeneca



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



Two DEP[®] ADC Research Agreements with MSD



Genentech
 A Member of the Roche Group

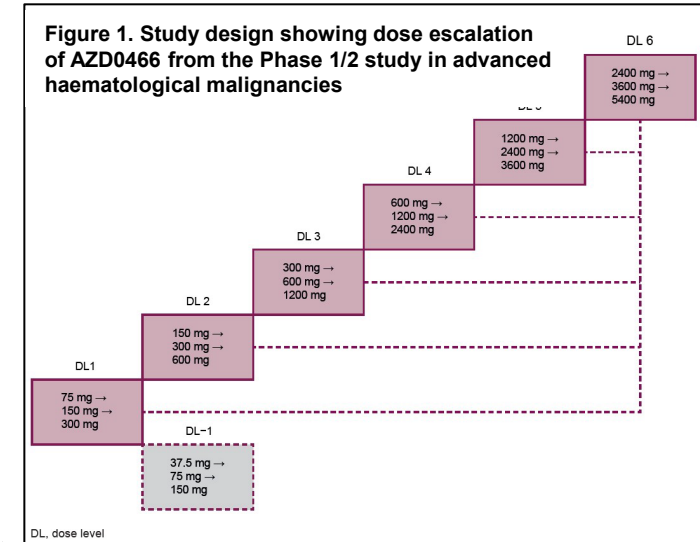
Two DEP[®] Research Agreements with Genentech

AstraZeneca's DEP[®] nanoparticle AZD0466

Global clinical development program in multiple indications

- AZD0466 is a highly optimised DEP[®] nanoparticle formulation of AstraZeneca's dual Bcl2/xL inhibitor (AZD4320)
- Dual Bcl2/xL inhibition with AZD0466 has potential for broader activity than the marketed Bcl2 inhibitor, venetoclax (Venclexta[®]). In 2021, Venclexta[®] had sales of ~US\$1.82 billion
- Clinical program significantly expanded – now includes two Phase 1/2 multi-centre trials with others under consideration**
 - Phase 1/2 clinical trial in patients with advanced haematological malignancies (AML, ALL)**
 - Phase 1/2 trial is aimed at seamless transition to Phase 2, to facilitate expedited marketing approval**
- AZD0466 is the first candidate in Starpharma's multiproduct license with AstraZeneca; US\$7M in milestones received to date
- Total AZD0466 eligible milestone receipts of up to US\$124M plus royalties (total estimated receipts up to A\$2.4B to Starpharma over the product life)**

AZD0466 Clinical Program		
Trial Type & Indications	Trial Status and Sites	Preliminary Results
Global Phase 1/2 study in advanced haematological malignancies (acute myeloid leukaemia (AML) or acute lymphoblastic leukaemia (ALL))	18 sites recruiting; >30 planned in total in Australia, US, EU & Asia	<ul style="list-style-type: none"> Multiple dose escalations successfully completed AZD0466 dosed in 33 patients up to 2400mg AZD0466 well tolerated; no dose-limiting toxicities (DLTs) to date Initial clinical activity observed through reduction of bone marrow blasts following AZD0466 treatment. Further dose escalation underway
Global Phase 1/2 study in non-Hodgkin lymphoma	10 sites recruiting; >20 planned in total in Australia, US, Canada, EU & Asia	
<i>Additional indication planned</i>	<i>Details TBA</i>	



AZD0466 active in small cell lung cancer models

New data to be presented at AACR Meeting in April 2023

Small cell lung cancer (SCLC) is an aggressive malignancy with a 5-year survival rate of ~7%^ and a critical need for new therapies

AZD0466, a dendrimer based BCL-2/XL inhibitor, was evaluated for efficacy in a panel of SCLC patient-derived models (xenografts)

- AZD0466 was active in 50% of patient-derived SCLC xenografts, with regression in 33% of models.
- AZD0466 was active in 70% of sub-type-A SCLC xenografts
- AZD0466 outperformed marketed BCL-2 inhibitor venetoclax in 60% of models.
- Notably, AZD0466 was active in models *resistant* to the standard-of-care treatment for SCLC (platinum/etoposide).

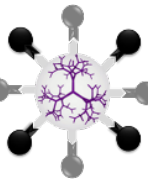
“Data suggest BCL-2/XL inhibition has therapeutic potential in SCLC”

– Andersen et al. (2023) AACR Abstract 6150/12: AZD0466, a dual BCL-2/XL targeting nanomedicine, is active in small cell lung cancer models

Link: <https://www.abstractsonline.com/pp8/#!/10828/presentation/1959>

Clinical development status of AZD0466

- First-in-human trial treated 9 patients with advanced solid tumors (NCT04214093) at doses from 50-200mg, all of which were well-tolerated. Responses (SD) observed in 33% patients for up to 5.5 months.
- AZD0466 is now also under evaluation in patients with leukemias and non-Hodgkin lymphoma.
- AZD0466 has been dosed in 33 patients up to 2400mg. No DLTs have been reported to date. Initial clinical activity has been observed through reduction of bone marrow blasts following AZD0466 treatment.
- AZD0466 exhibits linear PK, consistent across solid tumor and leukemia patients.









AstraZeneca 



^: <https://www.cancer.org/cancer/lung-cancer/detection-diagnosis-staging/survival-rates.html>

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.
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.
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.


COMMERCIAL OBJECTIVE


Create value through clinical proof-of-concept (Phase 2)


License following Phase 2 clinical data; platform validation

+

Clinical data adds value to partnered programs


Utilise accelerated development/reg. pathways (i.e. 505(b)(2)) for optimal ROI

#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 ongoing

Encouraging efficacy signals across multiple tumour types enhancing market potential

DEP[®] cabazitaxel

- Phase 2 trial, ongoing
- 76 patients recruited to date, with final recruitment focused on gastro-oesophageal cancer
- Recruitment in final stages

Interim observations

- Encouraging efficacy signals, including significant tumour shrinkage and substantial tumour biomarker reductions, observed in multiple cancers, including the original Jevtana[®] indication (prostate cancer), as well as new indications, including **ovarian, gastro-oesophageal, cholangiocarcinoma and head & neck cancer**.
- These impressive tumour responses have been observed in heavily pre-treated patients, some of which have failed multiple other lines of cancer treatment, and hard-to-treat tumours.
- Significantly fewer and less severe side effects, particularly bone marrow toxicity (myelosuppression), than published data on Jevtana[®].

Trial Sites



Jevtana[®]

2021 sales
~US\$500M



FDA “Black Box” warnings:

1. Neutropenic deaths (febrile neutropenia)
2. 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)

DEP[®] cabazitaxel Phase 2 Trial Prostate Cancer Cohort

- 25 heavily pre-treated patients with Stage IV hormone-refractory prostate cancer
- Prior to entering the DEP[®] cabazitaxel study, patients had received:
 - Average of 4 prior anti-cancer treatments and >70 months/cycles
 - >95% had received prior taxanes, including docetaxel and cabazitaxel (Jevtana[®])
 - 56% had received ≥ two prior chemotherapy regimens (compared to 16%[^] of Jevtana[®] patients in published trial data)
- **DEP[®] cabazitaxel patients did not need prophylactic steroids** or antihistamines as polysorbate-80 free aqueous formulation
- **DEP[®] cabazitaxel required no primary G-CSF¹ prophylaxis**, despite older patient cohort and low neutrophil counts

1: G-CSF: granulocyte-colony stimulating factor, is used as a therapy for myelosuppression

2: 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

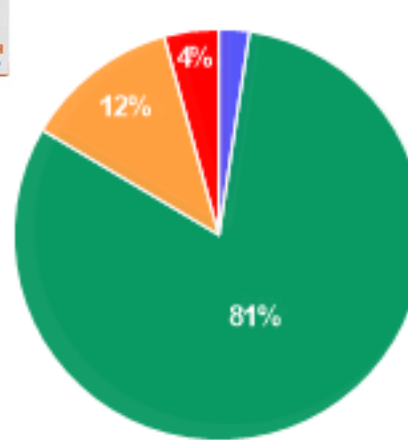
[^]: Eisenberger, M, et al. J Clin Oncol, 2017;35(28):3198-206 .

* Excludes hormonal therapies

Prior Chemotherapy Regimens in Trial Patients*

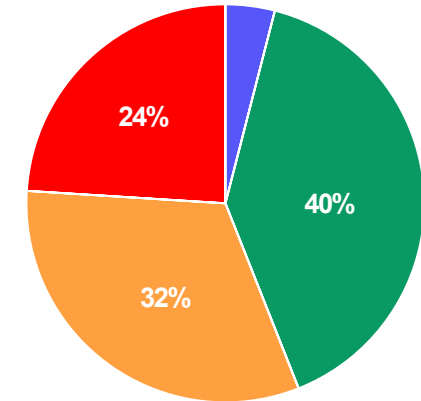


Jevtana[®] - 20mg/m²



- Only 16%* of Jevtana[®] patients had received ≥2 prior regimens whereas

DEP[®] Cabazitaxel



- 56% of DEP[®] cabazitaxel patients had received ≥2 prior regimens and
- >95% of DEP[®] cabazitaxel patients and received prior taxanes, including docetaxel and cabazitaxel (Jevtana[®])

DEP[®] cabazitaxel Phase 2 Trial Interim Results in Prostate Cancer

- Highly encouraging anti-tumour activity, including RECIST partial response for more than 45 weeks, and stable or improved bone disease for up to 45 weeks
- **Median progression-free survival (PFS) of 3.9 months - more than 30% longer than published PFS data for standard cabazitaxel (2.9 months[^])**
- **100% of evaluable patients² achieved a response in ≥ 1 measure of efficacy**
- **52% of patients evaluable for PSA achieved PSA reduction $\geq 50\%$ 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 Adverse Events ('AEs') similar in character to those observed with standard cabazitaxel

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



Key Efficacy Measures

Efficacy Measure	DEP [®] cabazitaxel (20 mg/m ²)	Jevtana ^{®1} (20 mg/m ²)
PSA Reduction ≥50%	52.4%	29.5%
Partial Response [#]	18.2%	18.5%
Improved/stable Bone Disease	83.3%	Not reported



Key Safety Measures

DEP[®] cabazitaxel had significantly fewer Grade 3/4 Treatment Related Adverse Events vs. Jevtana[®]

DEP [®] cabazitaxel (20 mg/m ²) (N=25)	Jevtana ^{®1} (20 mg/m ²) (N=580 [†])	Jevtana ^{®1} (25 mg/m ²) (N=595 [†])
7.5%	39.7%	54.5%

Longer Progression-Free Survival (PFS) (median)

DEP [®] cabazitaxel (20 mg/m ²) (N=25)	Jevtana ^{®1} (20 mg/m ²) (N=598*)	Jevtana ^{®1} 25 mg/m ² (N=602*)	Jevtana ^{®2} (25 mg/m ²) (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^{1,2} also included pain progression

* Intent-to-treat populations

Safety Outcomes	DEP [®] cabazitaxel (20 mg/m ²) (N=25)	Jevtana ^{®2} (20 mg/m ²) (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 – de Bono, JS, et al. *Lancet*, 2010;376(9747):1147-54.

Partial Response: ≥30% reduction in measurable target tumour size

† Safety populations (received at least 1 dose)



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

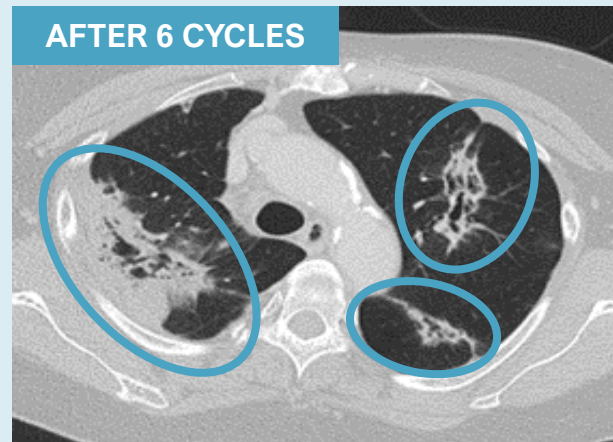
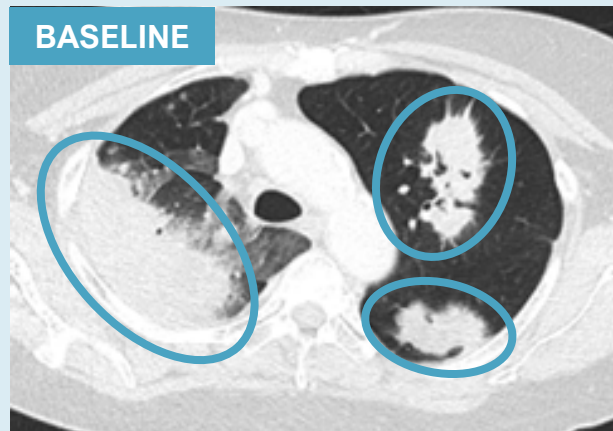
Patient's cancer had progressed prior to entering the DEP[®] cabazitaxel study, following:

- 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

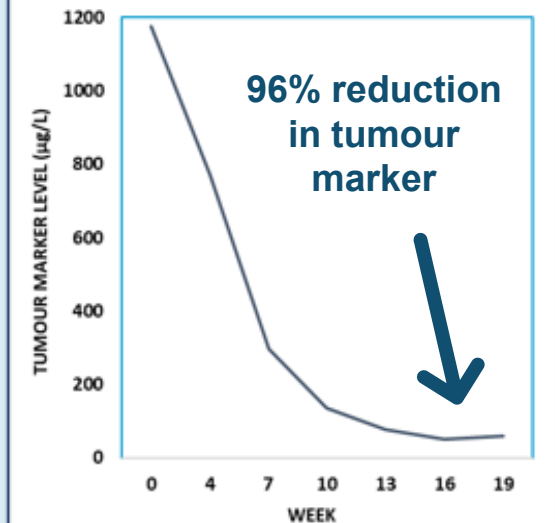
Following treatment with DEP[®] cabazitaxel (6 cycles), the patient achieved:

- 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



DEP[®] docetaxel

Encouraging efficacy signals across multiple tumour types

DEP[®] docetaxel

- Phase 2 trial, ongoing
- 76 patients recruited (monotherapy and combination)
- Monotherapy recruitment in final stages

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 studies

- 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

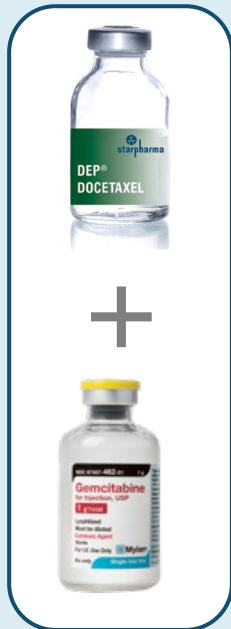
New/extended IP

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

DEP[®] docetaxel: clinical case study

DEP[®] docetaxel in combination with gemcitabine

60-year-old woman with stage IV uterine cancer



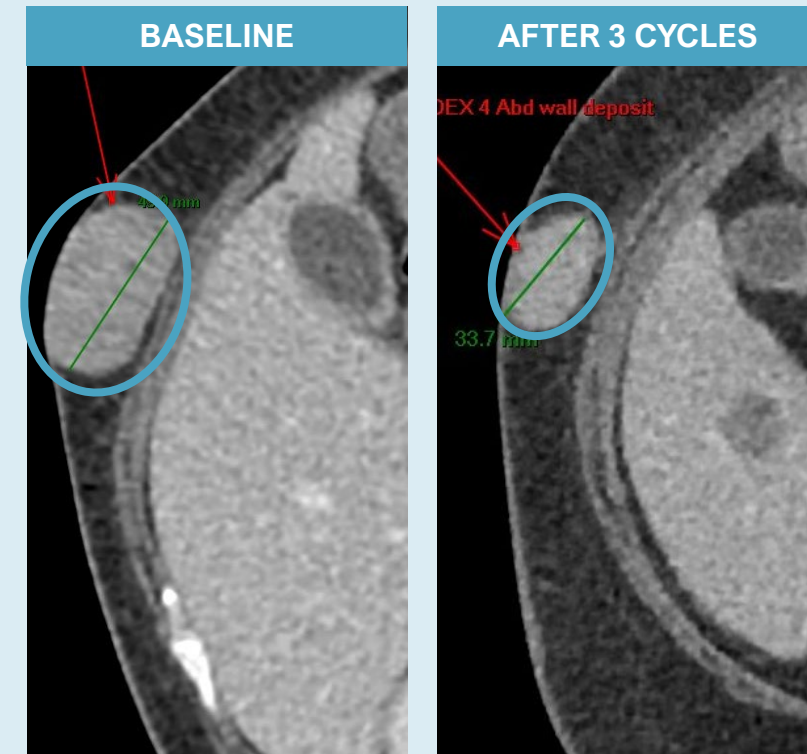
Patient heavily pre-treated prior to entering the study:

- >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[®] irinotecan: Phase 2 trial ongoing

Encouraging efficacy signals across multiple tumour types enhancing market potential

DEP[®] irinotecan

- Phase 2 trial underway; encouraging efficacy signals observed
- 89 patients recruited to date (monotherapy and combination)
- Monotherapy recruitment in final stages

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, alopecia and neutropenia.

Combination study (recruiting):

- 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 SN-38 (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 - 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 ≥ grade 3	0	~20-40%
Nausea ≥ grade 3	2.2%	~10%
Vomiting ≥ grade 3	1.1%	~10%
NERVOUS SYSTEM		
Cholinergic Syndrome	0%	~47%

*(8 - 15 mg/m² SN38)
Q3W | N=90

^(350 mg/m²)
Q3W | N=765

†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> UK SmPC April 2022



55-year-old woman with stage IV colorectal cancer

*Colorectal cancer is the 3rd most commonly diagnosed cancer and 4th leading cause of cancer death worldwide**

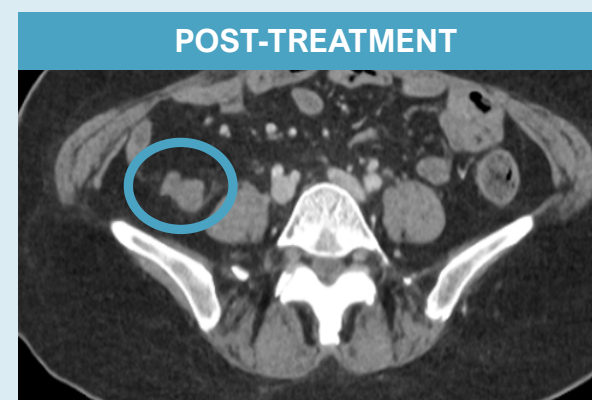
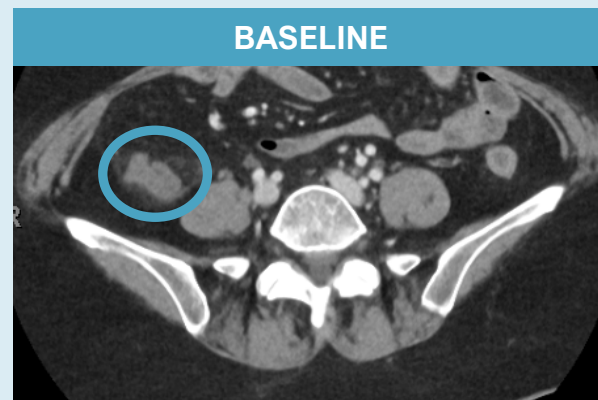
Patient was heavily pre-treated prior to entering the DEP[®] irinotecan study, following:

- 19 treatment cycles of 4 different kinds of anti-cancer therapy
- Progressed on prior irinotecan combination therapy

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

- Significant shrinkage of tumour lesions and reduction in tumour biomarkers
- Up to 74% reduction in tumour biomarkers
- Response maintained for more than 27 weeks

24% reduction in tumour after treatment with DEP[®] irinotecan



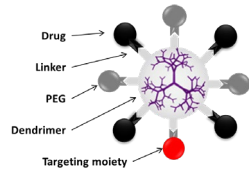
*Favoriti et al, Worldwide burden of colorectal cancer: a review. Updates in Surgery: 68, 7-11, 2016.

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>

*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>

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

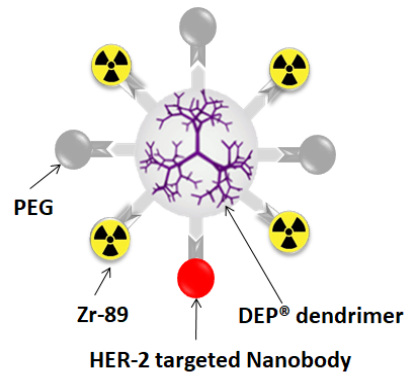
*https://www.meddraysintell.com/_files/ugd/1beeab_6bc27b0bbe664527aca68f41bf7de2bc.pdf

Novel DEP[®] radiotheranostics (radiodiagnostic and radiotherapeutic)

DEP[®] radiodiagnostic

DEP[®] HER2-zirconium

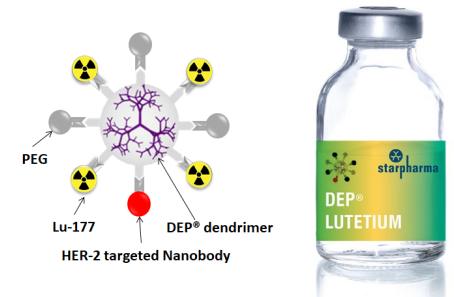
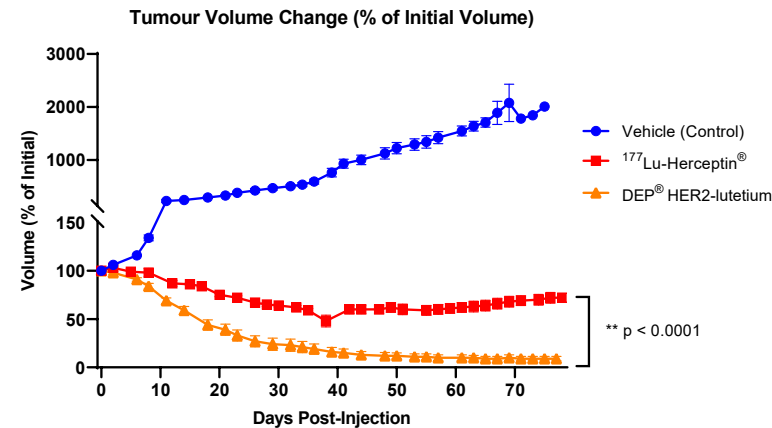
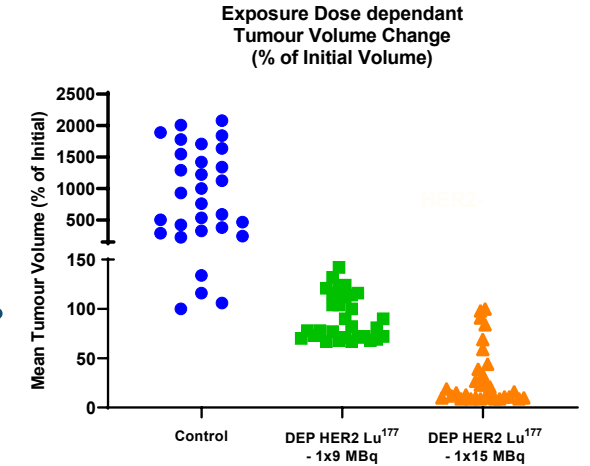
- Achieved significant tumour accumulation: >100x in tumour vs. blood in a preclinical human HER2-positive ovarian cancer model
- DEP[®] HER2-zirconium pharmacokinetics allow for optimal visualisation in PET imaging



DEP[®] radiotherapeutics

DEP[®] HER2-lutetium

- Achieved complete tumour regression in a preclinical human HER2-positive breast cancer model
- Was extremely well tolerated
- 100% survival throughout experiment
- Anti-tumour effect was dose-dependent
- Outperformed HER2 antibody, Herceptin[®], labelled with ¹⁷⁷Lu



Marketed products

Multiple revenue streams with a growing distribution network



VIRALEZE™ Nasal Spray



VivaGel® BV



VivaGel® Condom



Etqan & Nazahah Company



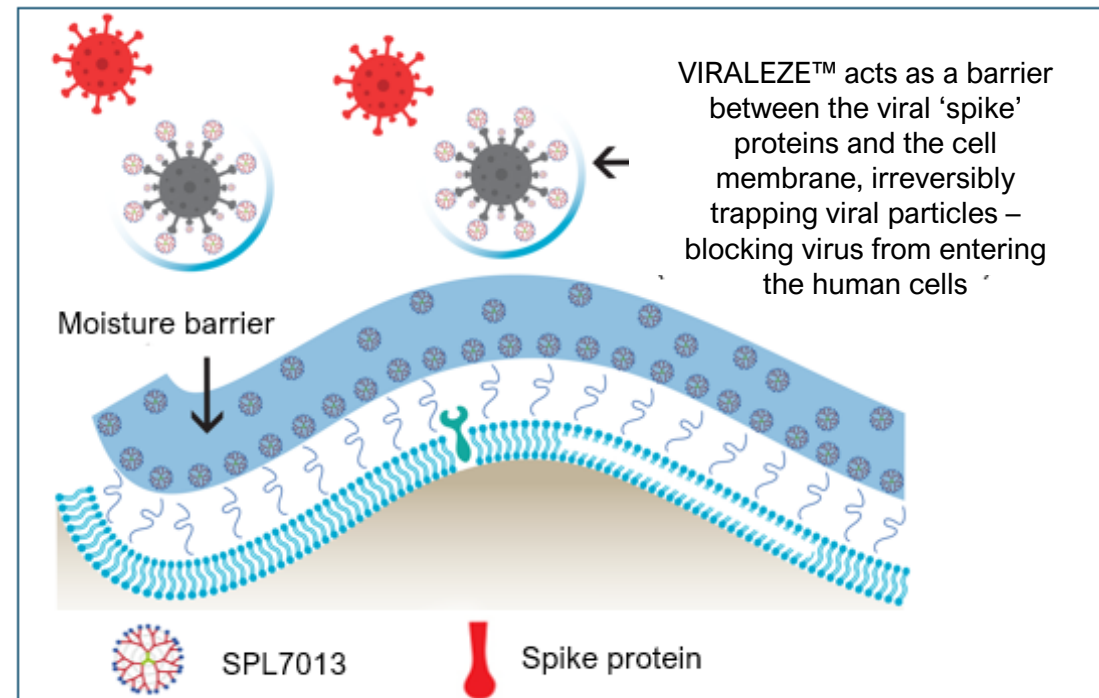
VIRALEZE™ features

- 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™** antiviral nasal spray is registered in more than 30 countries around the world*
- Available in pharmacies, retail outlets and online in a number of markets
- Partnered with:
 - ✦ **LloydsPharmacy** 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 underway
- VIRALEZE™ post market clinical study recruiting well in the UK



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

Viraleze™ Barrier nasal spray
 Helps trap colds and respiratory viruses

EUROPE

UK

MIDDLE EAST

ASIA

SALE OFF CỰC SỐC
 Combo Siêu Tiết Kiệm
 Bất Từ Giữa Rừng F0
 Giảm giá từ 20% đến 50%

Banitore
 噴鼻愛
 隱形口罩

CROSS HARBOUR TUNNEL

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
 Starpharma Holdings Limited: Investor Presentation

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

New data presented at International Virology Conference – Dec '22

VIRALEZE™ treated animals showed markedly reduced viral load after challenge with SARS-CoV-2 virus

VIRALEZE™ effectively eliminated SARS-CoV-2 Omicron virus ($\geq 99.999\%$ reduction in viral load) in lung and trachea of mice challenged with virus when compared with saline-treated animals, even when administered only after exposure to virus.

VIRALEZE™ Regimen	Tissue	Reduction in SARS-CoV-2 Omicron Viral Load vs Saline
Pre- and Post-challenge	Lung	>99.999%
Post-challenge		>99.999%
Pre- and Post-challenge	Trachea	>99.999%
Post-challenge		99.999%
Pre- and Post-challenge	Nasal Swab	99.4%
Post-challenge		82.9%

Full data presented at Respi DART 2022 Conference in Mexico

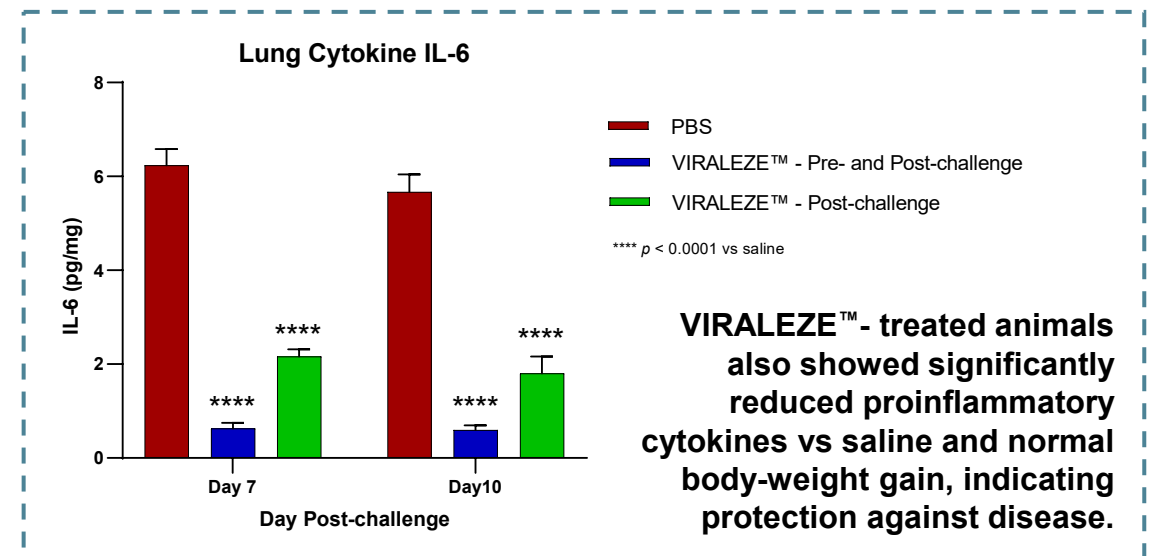
VIRALEZE™ treated animals showed markedly reduced infectious SARS-CoV-2 virus in the respiratory tract

100% of animals[^] treated with VIRALEZE™ showed **no evidence of infectious SARS-CoV-2 Omicron virus** in

- lung,
- trachea,
- nasal cavity, and
- blood.



Reduced infectivity



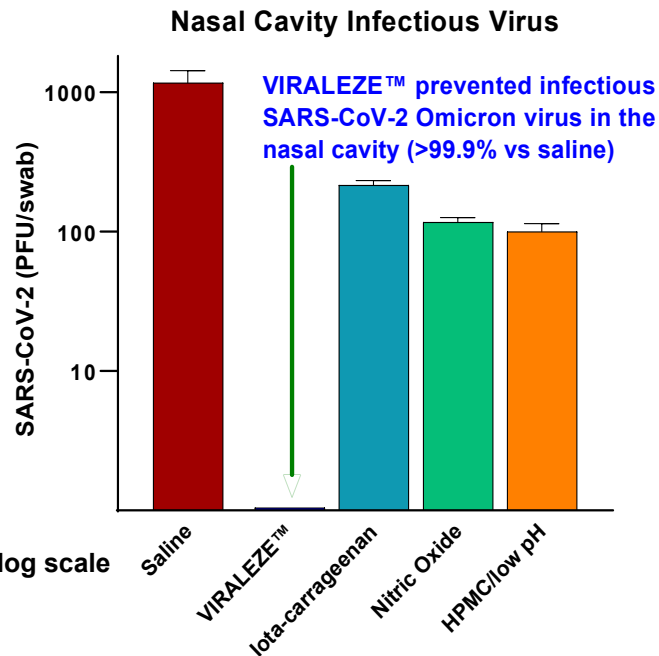
VIRALEZE™ antiviral nasal spray outperforms comparators in SARS-CoV-2 Omicron challenge model

New data presented at International Virology Conference – Dec '22

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%
lota-carrageenan (e.g., Cold Defence)	49.9%
Nitric Oxide (NONS™ , SaNOtize)	74.9%
HPMC/low pH (Vicks® First Defence)	74.9%



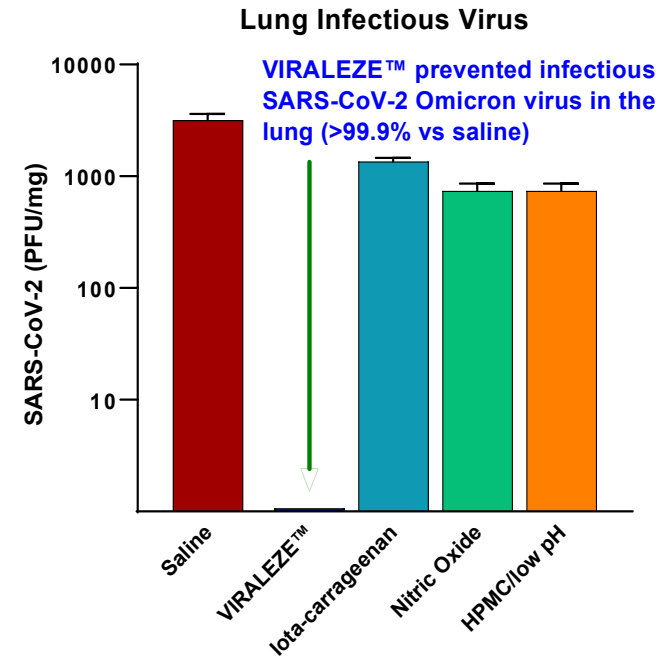
NB: Y axis = log scale



Full data presented at Respi DART 2022 conference in Mexico

Respi DART 2022

LOS CABOS, MEXICO • 6-8 DECEMBER 2022



[^]Day 7 post-challenge

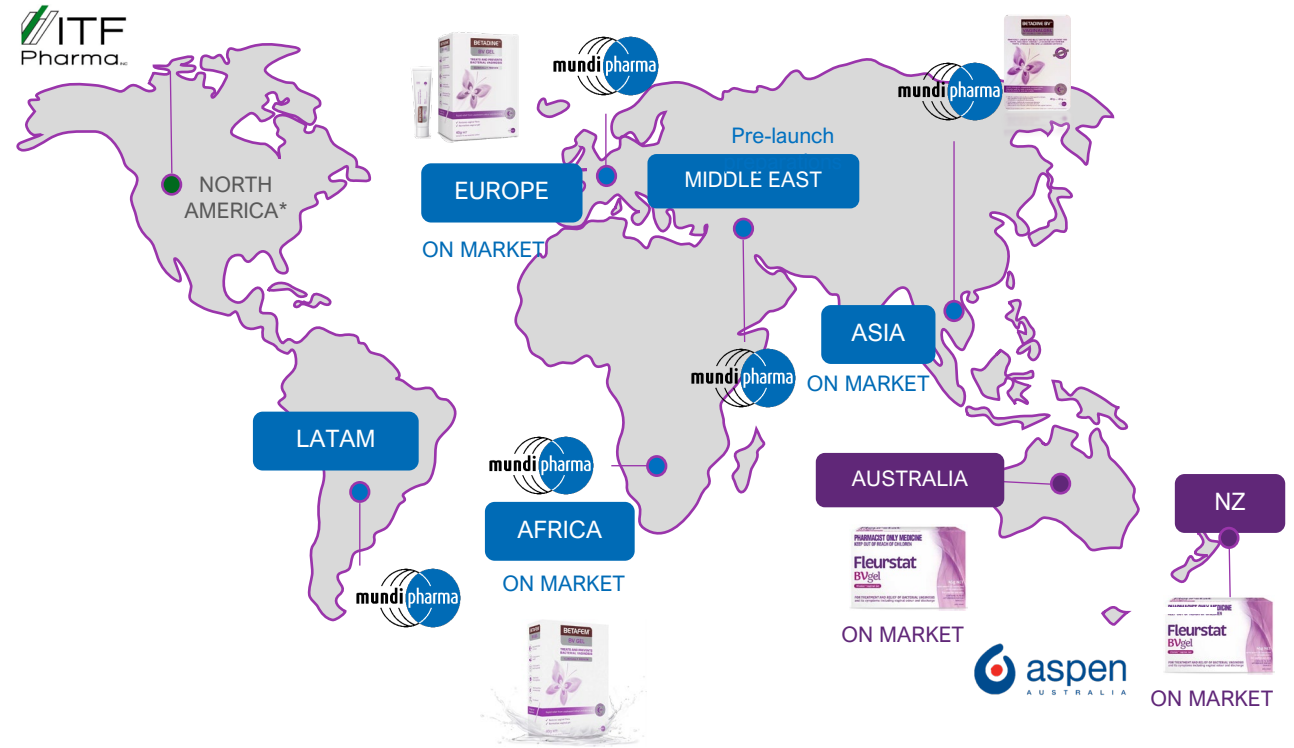
VIRALEZE™ is not approved for use or supply in Australia

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 problem, antibiotics have unpleasant side effects, and there is demand for alternative approaches.
- Other current BV therapies do not prevent BV recurring

BREAKTHROUGH THERAPY FOR A SIGNIFICANT UNMET NEED

- Rapid relief of odour in 24 hours
- Blocks BV-causing bacteria
- Helps restore vaginal flora and normalise pH levels
- Clinically proven to prevent recurrent BV*
- Clinically proven to treat BV
- Non-antibiotic and not absorbed into the blood stream



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

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.

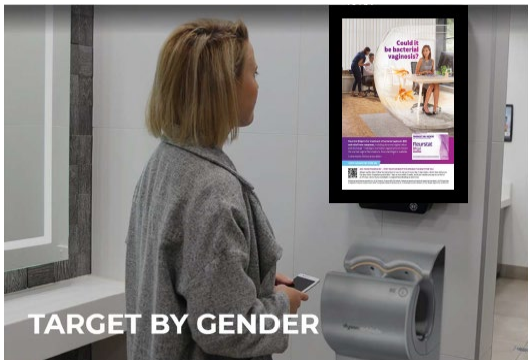
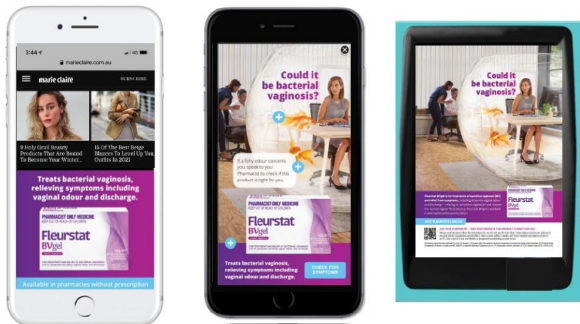
VivaGel® BV marketing activities

Include multichannel promotions and publications to support clinical guidelines

Marketing Campaigns by Partners to build Brand Awareness and Sales



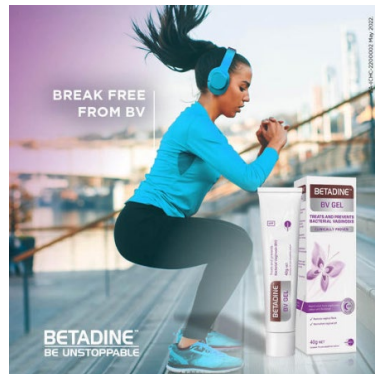
Consumer marketing, including digital marketing campaigns and washroom advertising



TARGET BY GENDER



Healthcare professional marketing



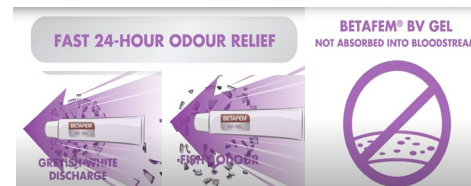
Peer-reviewed journal articles to support clinical guideline inclusion



“Astodimer sodium has the potential to improve outcomes for patients with BV as there is no potential to cause antibiotic resistance, it is not systemically absorbed, and the gel adheres to the vaginal wall, avoiding vaginal leakage. Non-antibiotic BV treatment represents significant progress in the treatment of BV and may benefit women affected by this widespread condition.”

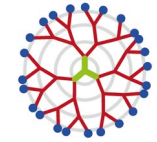


Prof Dr Werner Mendling & Prof Dr Holzgreve Wolfgang
(2022) Astodimer sodium and bacterial vaginosis: a mini review. Arch Gynecol Obstet 306(1), 101.





- The VivaGel® condom incorporates SPL7013 antiviral, which has demonstrated activity in HIV, HSV-2, HPV
- Okamoto launched an additional VivaGel® condom range in Japan, under the brand name *Pure Marguerite*, targeting youth and female segments of the market
- Starpharma continues to support its marketing partner, Okamoto, to progress registration in multiple countries in Asia to support further commercialisation of the VivaGel® condom



SPL7013

Key value drivers and outlook

DEP® Drug Delivery



Internal DEP® Clinical-stage Assets

- Complete Phase 2 trials
- Progress value-adding combination studies



Partnered DEP® Programs

- Progress existing partnerships with AstraZeneca, MSD, Chase Sun, and Genentech
- Execute new and/or expand existing DEP® partnerships



AZD0466 Clinical Program

- AstraZeneca clinical progress - completion of dose escalation - Phase 2 start, expansion and receipt of milestones



Preclinical DEP® Programs

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

SPL7013 Products



VIRALEZE™ Nasal Spray

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



VivaGel® BV

- Commercialisation in Europe, Asia and in other markets
- Further regulatory approvals and launches for VivaGel® BV; milestones, product sales/royalties
- 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



43% of roles, including leadership roles are held by women. 50% 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.

18 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 80%

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](#)



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www.starpharma.com
ASX:SPL | OTC:SPHRY

