

Life Sciences Investor Forum Presentation

Melbourne, Australia; 23 June 2023: Further to yesterday's announcement, **Starpharma** (ASX: SPL, OTCQX: SPHRY) provides a copy of the investor presentation that was aired during the OTCQX's Virtual Life Sciences Investor Forum on Thursday, 22 June 2023 at 10:00 am EDT (Friday, 23 June 2023, at 12:00 am AEST). The presentation is appended below.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a biopharmaceutical company, focused 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 35 countries*, including in Europe, in the UK, and in 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.

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

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Disclosure

This ASX Announcement was authorised for release by Starpharma 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.



Life Sciences Investor Forum

ASX:SPL | OTC:SPHRY

Dr Jackie Fairley, CEO

22 June 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 \$38.9M (at 31 Mar 2023)

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	Ph 2 complete		
DEP [®] irinotecan	SN38	Colorectal and other cancers			
DEP [®] docetaxel	Docetaxel	Pancreatic and other cancers	Ph 2 Monotherapy complete		
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



Key value drivers and outlook

DEP® Drug Delivery



Internal DEP® Clinical-stage Assets

- Complete and report results Phase 2 DEP® 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 (milestone)



Preclinical DEP® Programs

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

SPL7013 Products



VIRALEZE™ Nasal Spray

- Further commercial roll-out, registrations and product launches
- Complete recruitment and report UK clinical study
- Further distribution arrangements with commercial partners
- Continue to generate clinical and antiviral data to support and expand 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

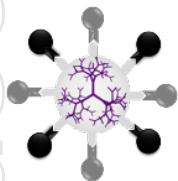
- Further development/co-development
- Continued testing against important infectious pathogens

DEP® Platform

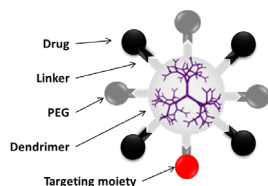
Starpharma's proprietary DEP® platform is highly versatile, conveys multiple benefits, and enhances the commercial value of a wide range of drugs

DEP® technology:

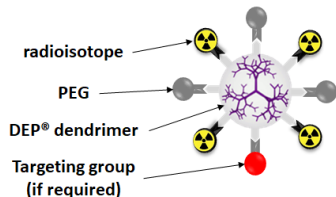
- Based on proprietary, branched polymers called dendrimers
- Represents a platform with significant optionality – applicable to many different drugs



DEP®
dendrimer-drug
conjugate



DEP® dendrimer antibody
drug conjugate



DEP® dendrimer radiotheranostic

Improved Safety / Reduced side effects

Control release kinetics of drug to reduce Cmax related toxicities

Improved Efficacy / Performance

DEP® achieves drug targeting, improved PK and controlled release

New IP / Extended Patent Life

DEP® creates new intellectual property and extends patent life

Tumour Targeting

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

Improved PK & Half-Life

Tuning of drug release and plasma half life to improve performance

Improved Solubility

Highly water-soluble enabling the removal of toxic excipients

Broad applicability

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



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

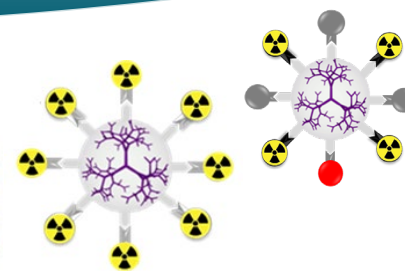
Chemotherapeutics



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

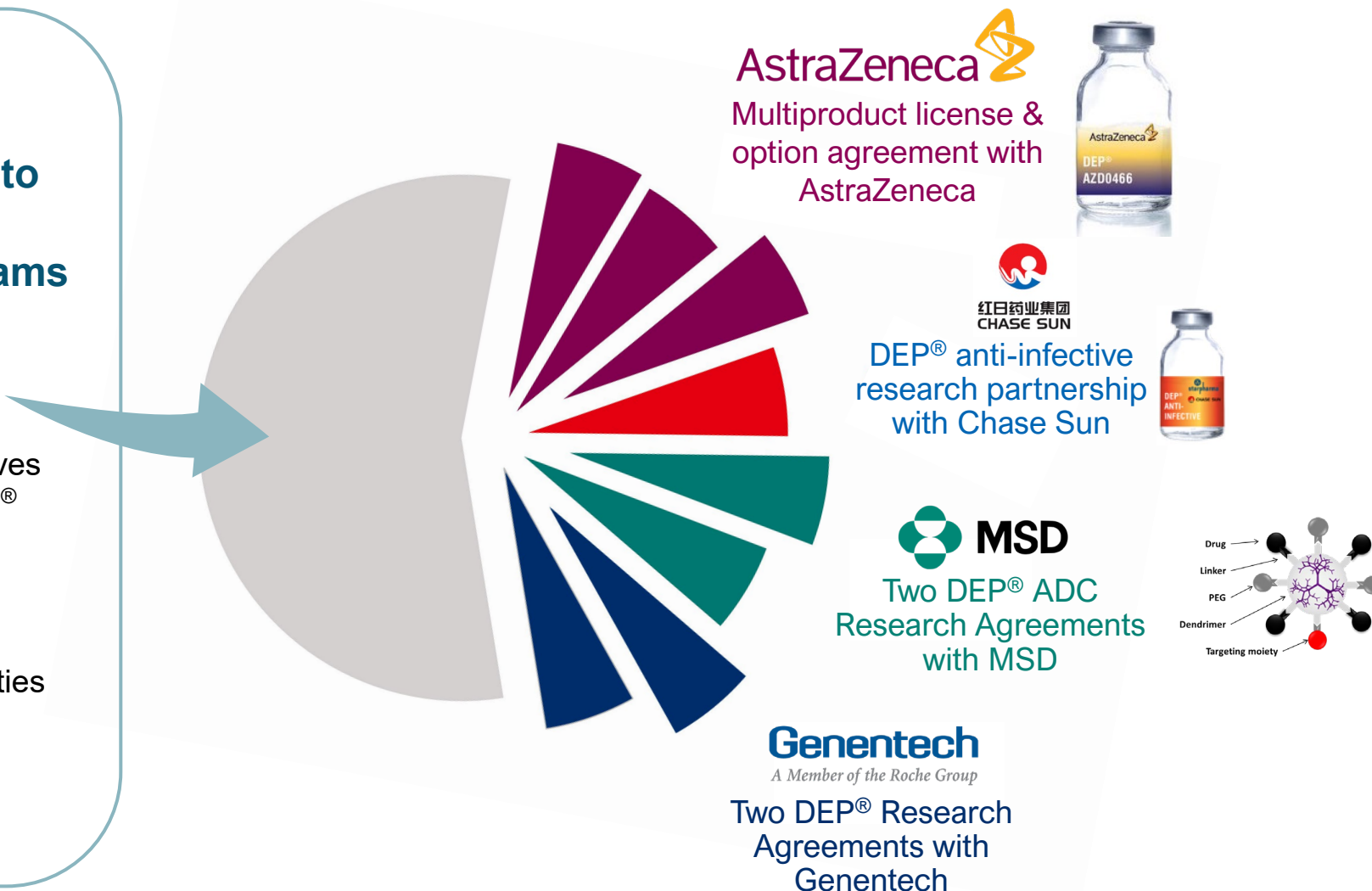
DEP[®] partnering creates significant value and optionality

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'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)**

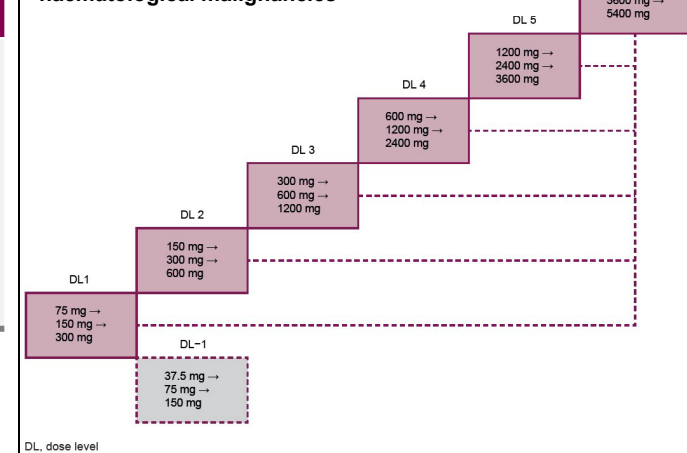
AZD0466 Clinical Program

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))	20 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 24 patients up to 3600mg (at 24 January 2023) AZD0466 well tolerated; no dose-limiting toxicities (DLTs) to date Initial clinical activity observed through reduction of bone marrow blasts following AZD0466 treatment. Mean treatment duration of 4.4 months Further dose escalation underway
Global Phase 1/2 study in non-Hodgkin lymphoma	>20 sites recruiting; 30 planned in total in Australia, US, Canada, EU & Asia	
<i>Additional indication planned</i>	<i>Details TBA</i>	

AstraZeneca



Figure 1. Study design showing dose escalation of AZD0466 from the Phase 1/2 study in advanced haematological malignancies



AZD0466 active in small cell lung cancer models

New data 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)

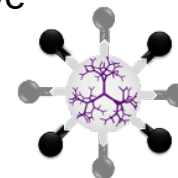
- AZD0466 was active in 50% of SCLC models, resulting in tumour regression in 33% of models.
- Dual Bcl-2/xL inhibitor AZD0466 outperformed marketed Bcl-2 inhibitor venetoclax in 60% of SCLC models.
- Notably, AZD0466 was also active in models resistant to the current standard-of-care treatment for SCLC: platinum/etoposide chemotherapy.

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

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

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.



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







Poster: https://starpharma.com/assets/uploads/2023-04/2023_CLA_AACR_0466inSCLC_Final.pdf

^: <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 [®]) 	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 	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 	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).

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

Encouraging efficacy signals across multiple tumour types enhancing market potential

DEP[®] cabazitaxel

- Phase 2 trial
- 76 patients; enrolment and treatment of patients now complete

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

Positive Interim Results in Prostate Cancer Cohort Presented at ESMO 2022

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

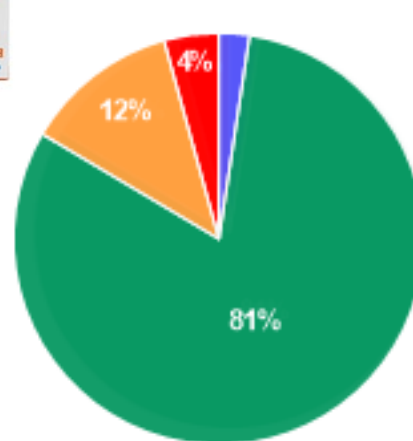
[^]: Eisenberger, M, et al. J Clin Oncol, 2017;35(28):3198-206 .

* Excludes hormonal therapies

Prior Chemotherapy Regimens in Trial Patients*

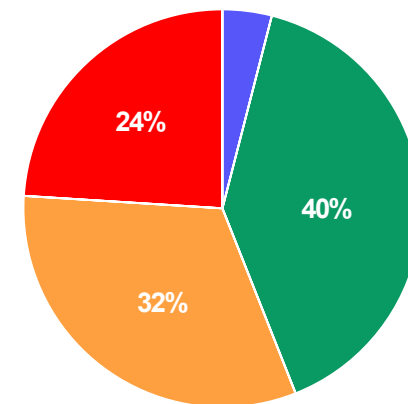


Jevtana[®] - 20mg/m²



- 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

Key interim efficacy and safety findings in prostate cohort vs. Jevtana^{®1,2}

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:

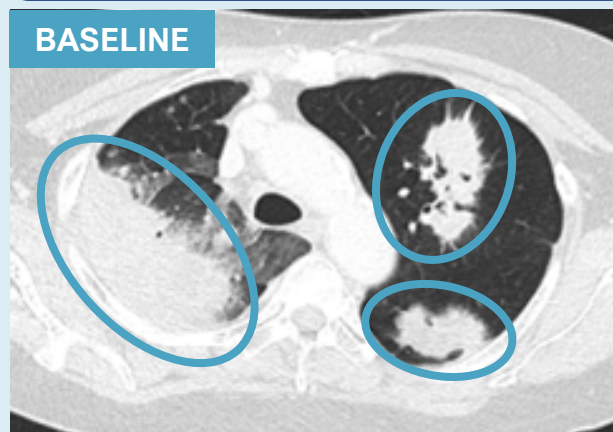
- 12 cycles of two different platinum treatment regimens
- Extensive surgery and radiation therapy
- Extensive lung metastases with long-standing cough and related findings on chest examination

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

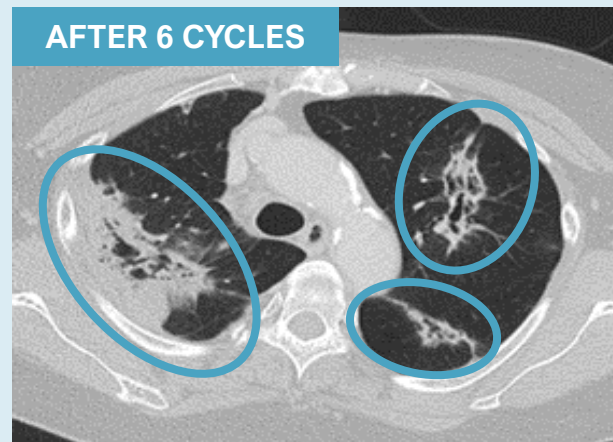
- Partial response (significant tumour shrinkage);
- Up to 43% reduction in size of individual lung metastasis
- Anticancer response maintained for 34 weeks
- 96% reduction in CEA tumour marker
- Cough and chest exam abnormalities resolved after cycle 3

CT scans of lung metastases

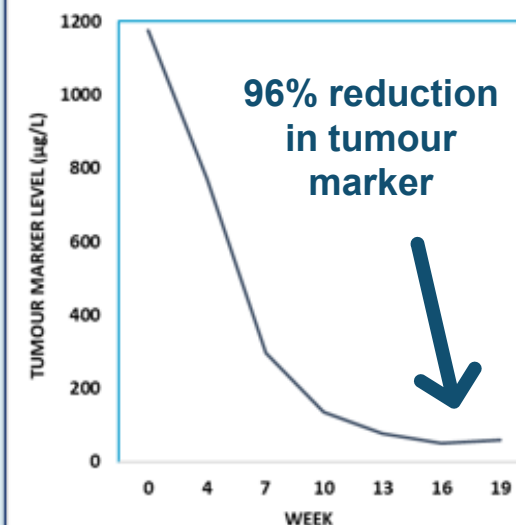
BASELINE



AFTER 6 CYCLES



Reduction in Tumour Marker on DEP[®] cabazitaxel treatment



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
- 94 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



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)

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

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 ≥ 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> SmPC April 2022



56-year-old woman with heavily pre-treated stage IV platinum resistant ovarian cancer

*Stage IV ovarian cancer has a 5-year survival rate of approximately 17%**

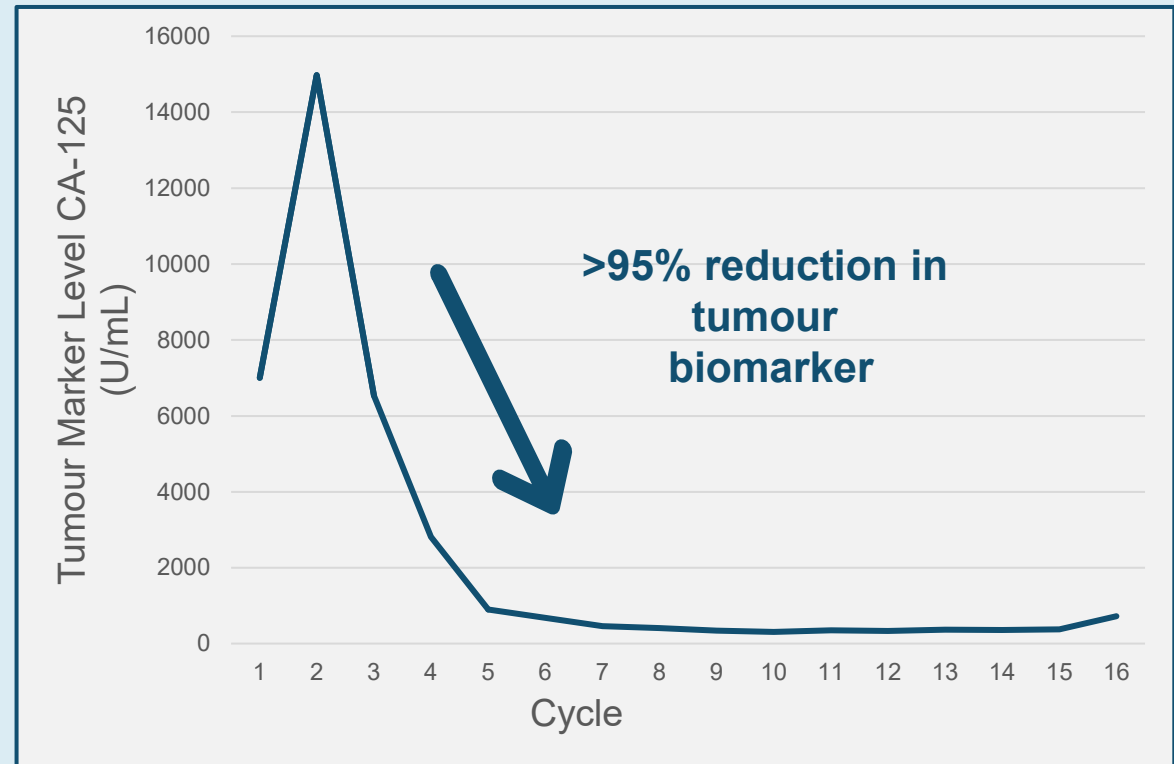
Patient was heavily pre-treated prior to entering the DEP[®] irinotecan study, following

- 16 treatment cycles of 5 different kinds of anti-cancer therapy

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

- Complete resolution of cancer-related ascites and pleural effusion
- >95% reduction in tumour biomarker (CA-125)
- **Response maintained for more than 36 weeks**

*<https://ocrahope.org/patients/about-ovarian-cancer/staging/>



DEP[®] docetaxel

Encouraging efficacy signals across multiple tumour types

DEP[®] docetaxel

- Phase 2 trial; monotherapy recruitment and treatment complete; nintedanib combo complete; gemcitabine combo ongoing
- 80 patients recruited (monotherapy and combination) to date

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

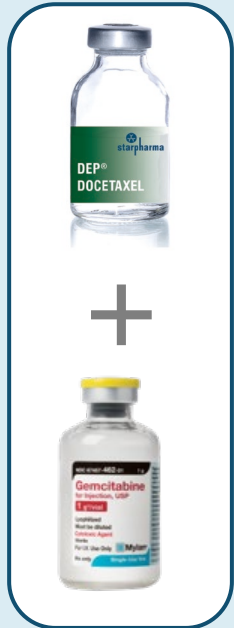
New/extended IP

- 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



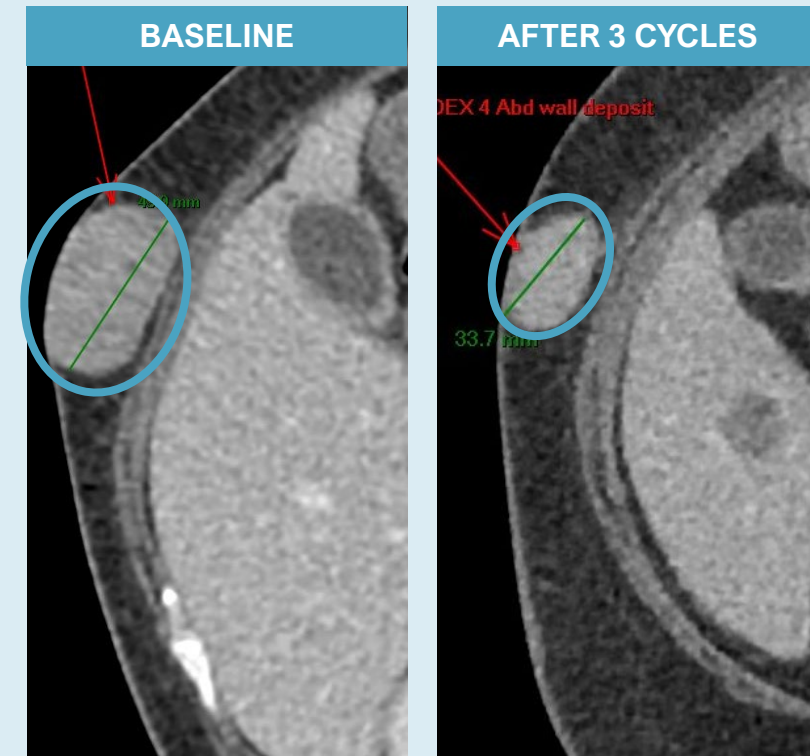
Patient heavily pre-treated prior to entering the study:

- >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[®] 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 Jul 2020	US\$2.75B Nov 2020	€1.2B Dec 2020	US\$3.1B Jun 2021	US\$1.7B Feb 2022	US\$936M Jul 2022	US\$1.1B Feb 2023

*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>

HER2-targeted DEP[®] SN-38 ADC outperforms in HER2+ human cancer model

Starpharma has developed a **HER2-targeted DEP[®] ADC**, utilising the active metabolite of irinotecan, **SN-38**, which outperformed Enhertu[®], showing significantly **greater anti-tumour activity** and **improved survival in a HER2+ human cancer xenograft model**.

Key advantages of Starpharma's DEP[®] platform for ADCs include:

- Ability to achieve higher DAR, and higher drug payload than conventional ADCs Greater flexibility in terms of linker strategies to precisely control drug release profiles;
- Capacity to widen the therapeutic index of toxic drug payloads; and
- Flexibility in terms of compatible targeting agents, including biologics (whole antibodies and fragments), small molecules, peptides and other approaches.

ADCs represent an **innovative and growing area of cancer treatment**. The **global ADC market** grew from USD ~\$5.8 billion in 2021 to USD ~\$8.0 billion in 2022 and is **projected to reach USD ~\$22.9 billion in 2030**.

HER2 ADCs Drug-to-Antibody Ratios, Drug Payload

HER2 ADC	Approximate Drug-to-Antibody Ratio (DAR)	Drug Payload
Kadcyla[®] (Genentech/Roche)	3.5	DM-1 (emtansine)
Enhertu[®] (AstraZeneca/Daiichi-Sankyo)	8	DXd (exatecan derivative)
HER2-targeted DEP[®] SN-38 ADC (Starpharma)	13	SN-38

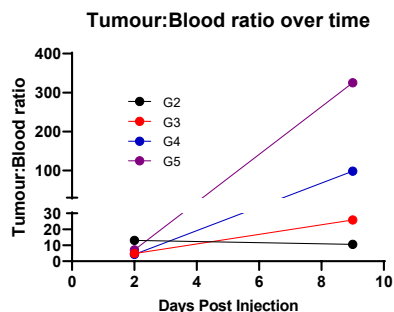
Effect of HER2-targeted DEP[®] SN-38 ADC vs. Enhertu[®] on Tumour Volume Over Time

SKOV-3 tumour growth rates -
Mean ± S.E.M.

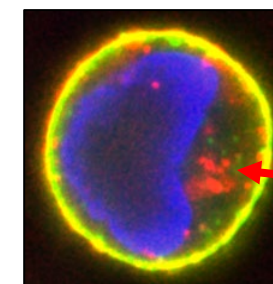
DEP[®] ADCs offer multiple benefits

Benefits of DEP[®] ADCs

Can be tuned to provide optimal characteristics



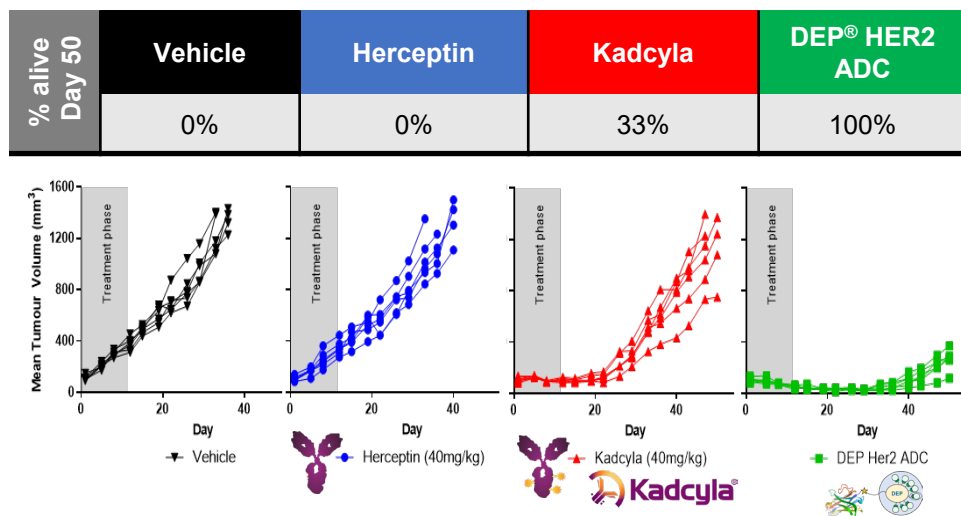
Penetrate deeply into tumours, bind strongly to target cells and are internalised for enhanced performance



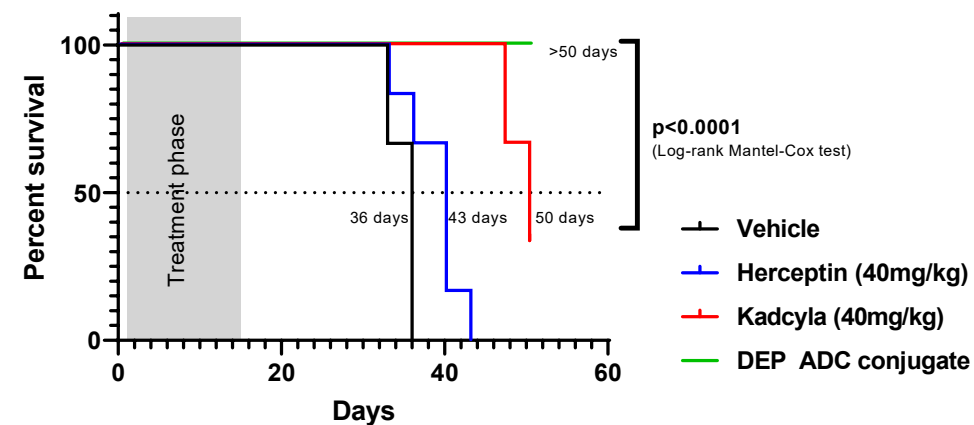
Target Cell

DEP[®] ADC (red)

Highly efficacious – enhanced anticancer activity*



Enhanced efficacy leads to enhanced survival*



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



Significant Corporate Deals in Radiotheranostics



						
US\$3.9B Oct 2017	US\$2.1B Oct 2018	US\$641M Oct 2019	€418M Jan 2021	US\$300M Mar 2021	€520M Dec 2021	~US\$2B Nov 2022

[^]MEDDraysintell Nuclear medicine report Edition 2022

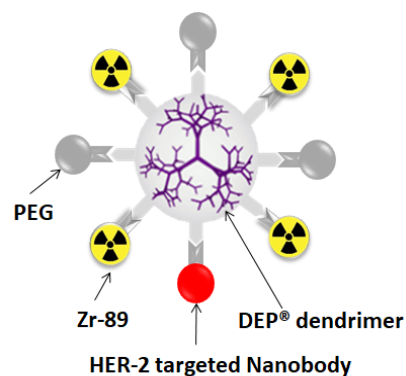
*https://www.medraysintell.com/_files/ugd/1beeab_6bc27b0bbe664527aca68f41bf7de2bc.pdf

Novel DEP[®] radiotheranostics (radiodiagnostic and radiotherapeutic)

DEP[®] radiodiagnostic

DEP[®] HER2-zirconium

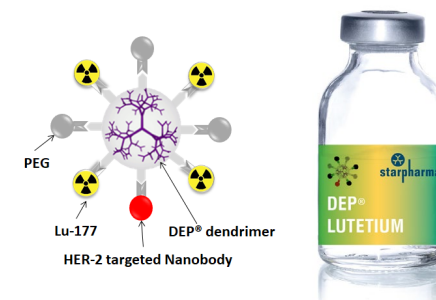
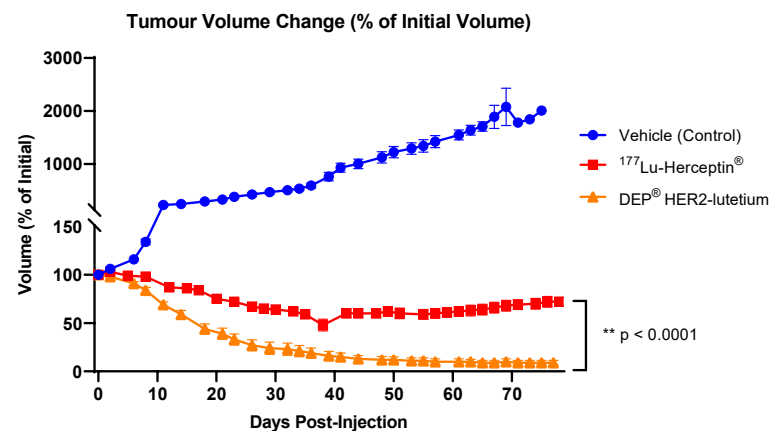
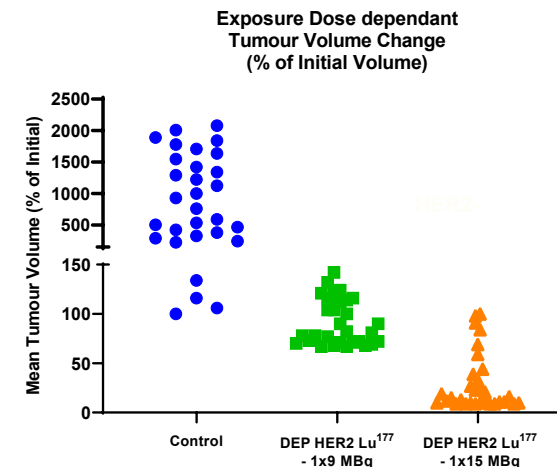
- Achieved significant tumour accumulation: >100x in tumour vs. blood in a preclinical human HER2-positive ovarian cancer model
- DEP[®] HER2-zirconium pharmacokinetics allow for optimal visualisation in PET imaging



DEP[®] radiotherapeutics

DEP[®] HER2-lutetium

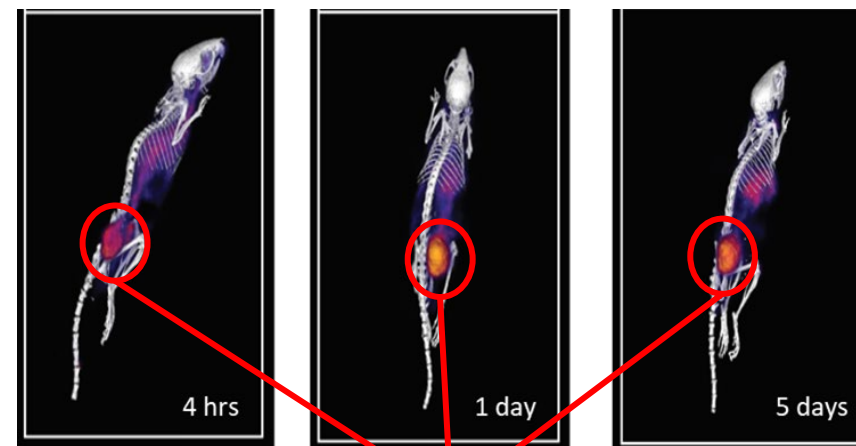
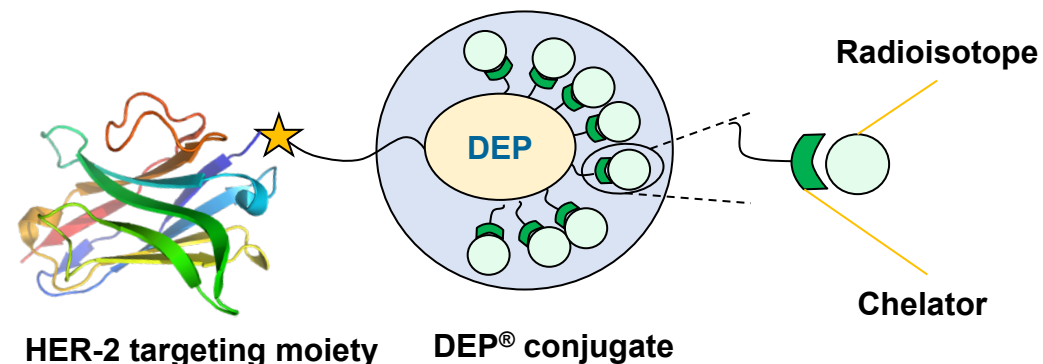
- Achieved complete tumour regression in a preclinical human HER2-positive breast cancer model
- Was extremely well tolerated
- 100% survival throughout experiment
- Anti-tumour effect was dose-dependent
- Outperformed HER2 antibody, Herceptin[®], labelled with ¹⁷⁷Lu



Targeted DEP® radiotheranostics offer multiple benefits

DEP® 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



High levels of accumulation in tumour tissue allows targeted DEP® radio conjugates to be valuable in radiotheranostics



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**

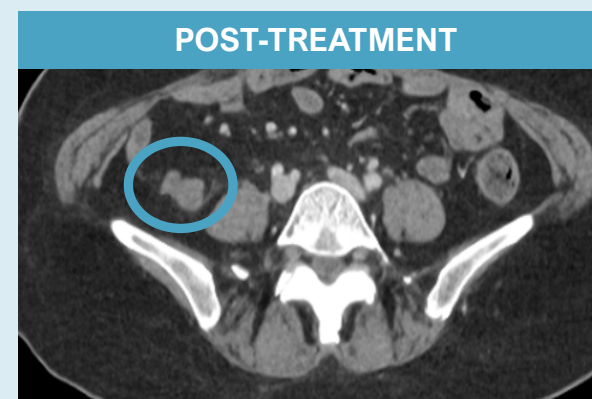
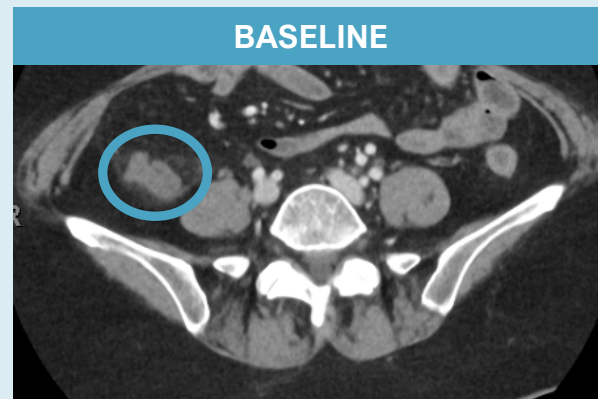
Patient was heavily pre-treated prior to entering the DEP[®] irinotecan study, following:

- 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.

Marketed products

Multiple revenue streams with a growing distribution network



VIRALEZE™ Nasal Spray



VivaGel® BV



VivaGel® Condom



LloydsPharmacy

ADMENTA Italia



Etqan & Nazahah Company



VIRALEZE™ antiviral nasal spray

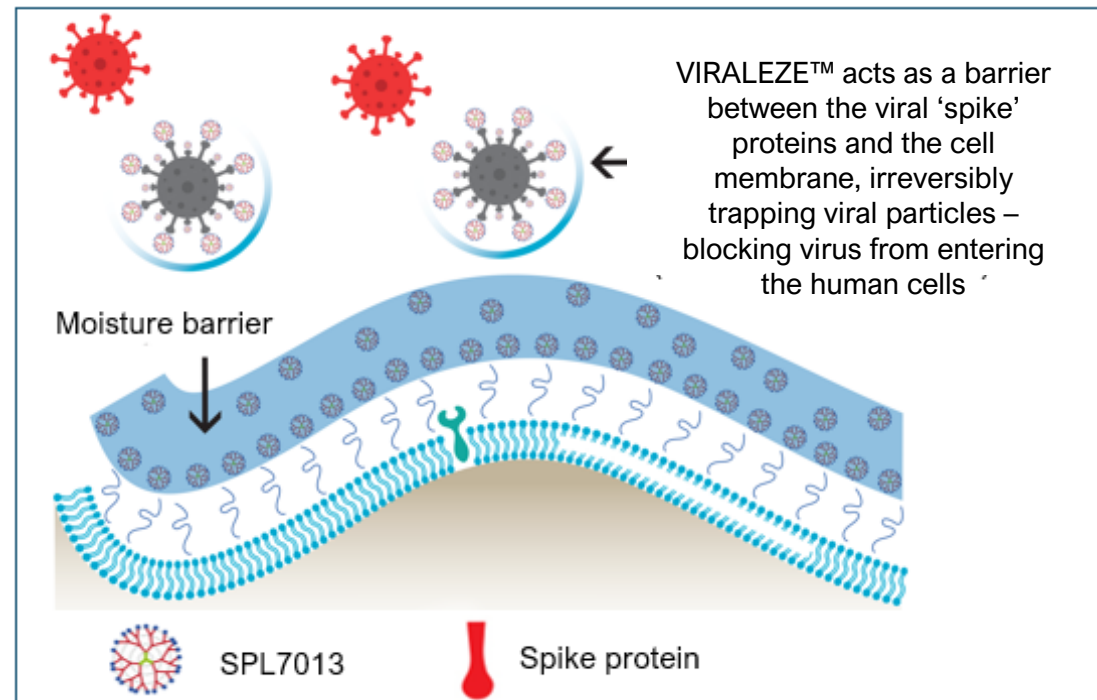
VIRALEZE™ features

- 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

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

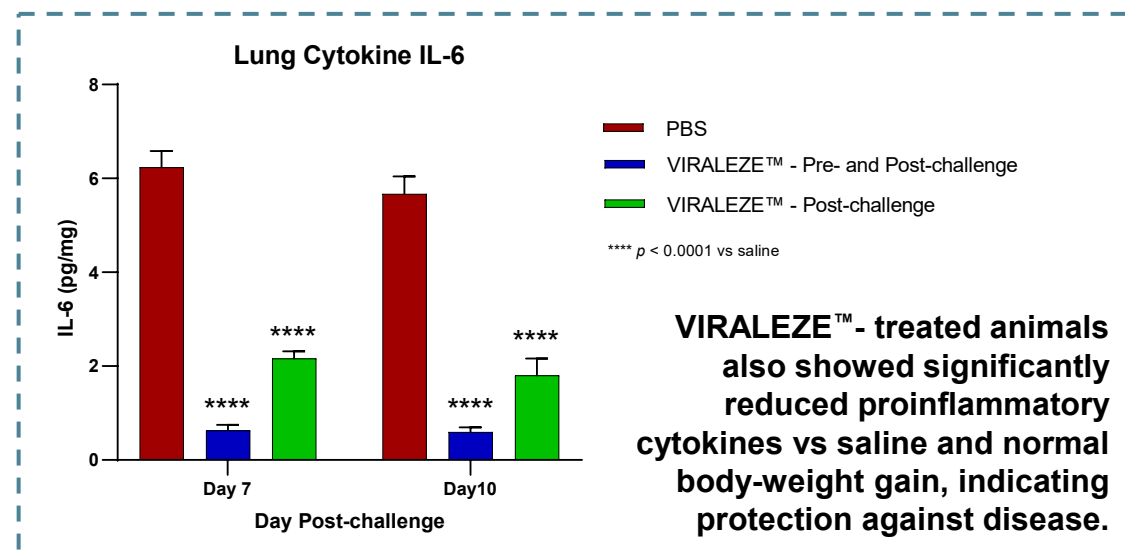
VIRALEZE™ treated animals showed markedly reduced infectious SARS-CoV-2 virus in the respiratory tract

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

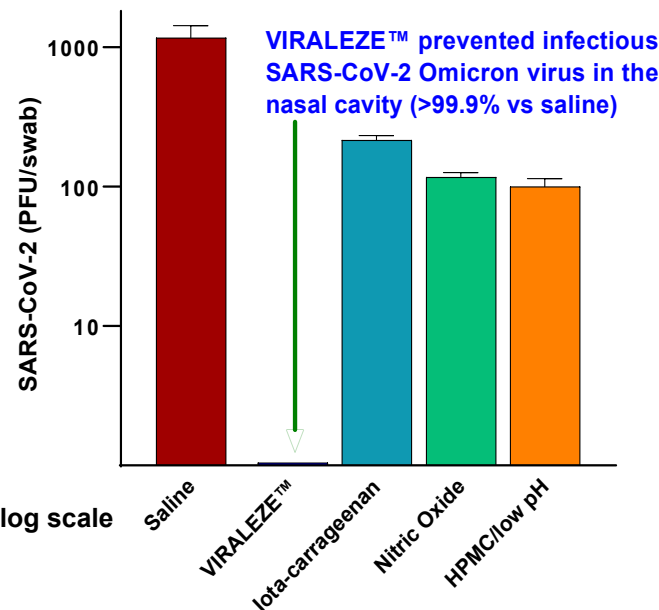
New data presented at International Virology Conference – Dec '22

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™	&gt99.9%
Iota-carrageenan (e.g., Cold Defence)	49.9%
Nitric Oxide (NONS™ , SaNOtize)	74.9%
HPMC/low pH (Vicks® First Defence)	74.9%

Nasal Cavity Infectious Virus



NB: Y axis = log scale

 **Scripps Research**

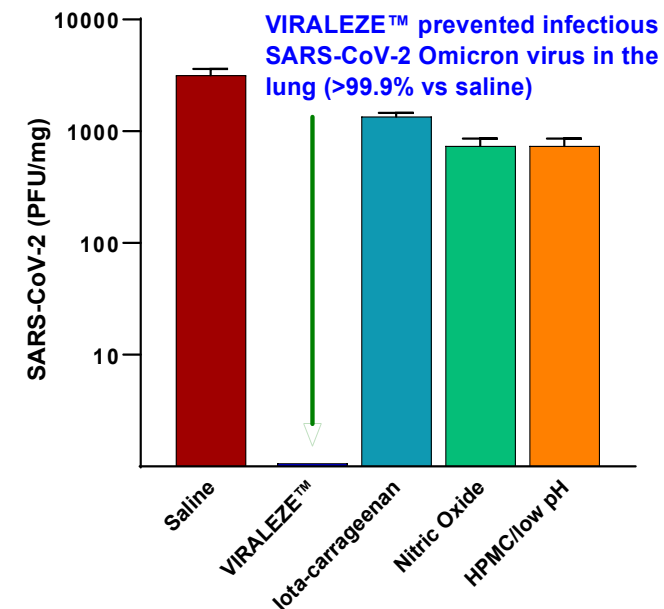
Full data presented at Respi DART 2022 conference in Mexico

Respi **DART** 2022

LOS CABOS, MEXICO • 6-8 DECEMBER 2022



Lung Infectious Virus



[^]Day 7 post-challenge

VIRALEZE™ is not approved for use or supply in Australia

Starpharma Holdings Limited: Investor Presentation

VIRALEZE™ market and regulatory activity

- **VIRALEZE™** antiviral nasal spray is registered in more than 35 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 well advanced in the UK, with >80% of participants recruited



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™ clinical trial in patients with COVID-19 underway

- 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
- Study is recruiting patients at Ashford and St Peter's Hospital, UK, an experienced site that has conducted other nasal spray studies; with other sites as necessary
- 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



VIRALEZE

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

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



**Registered indications may differ by market*

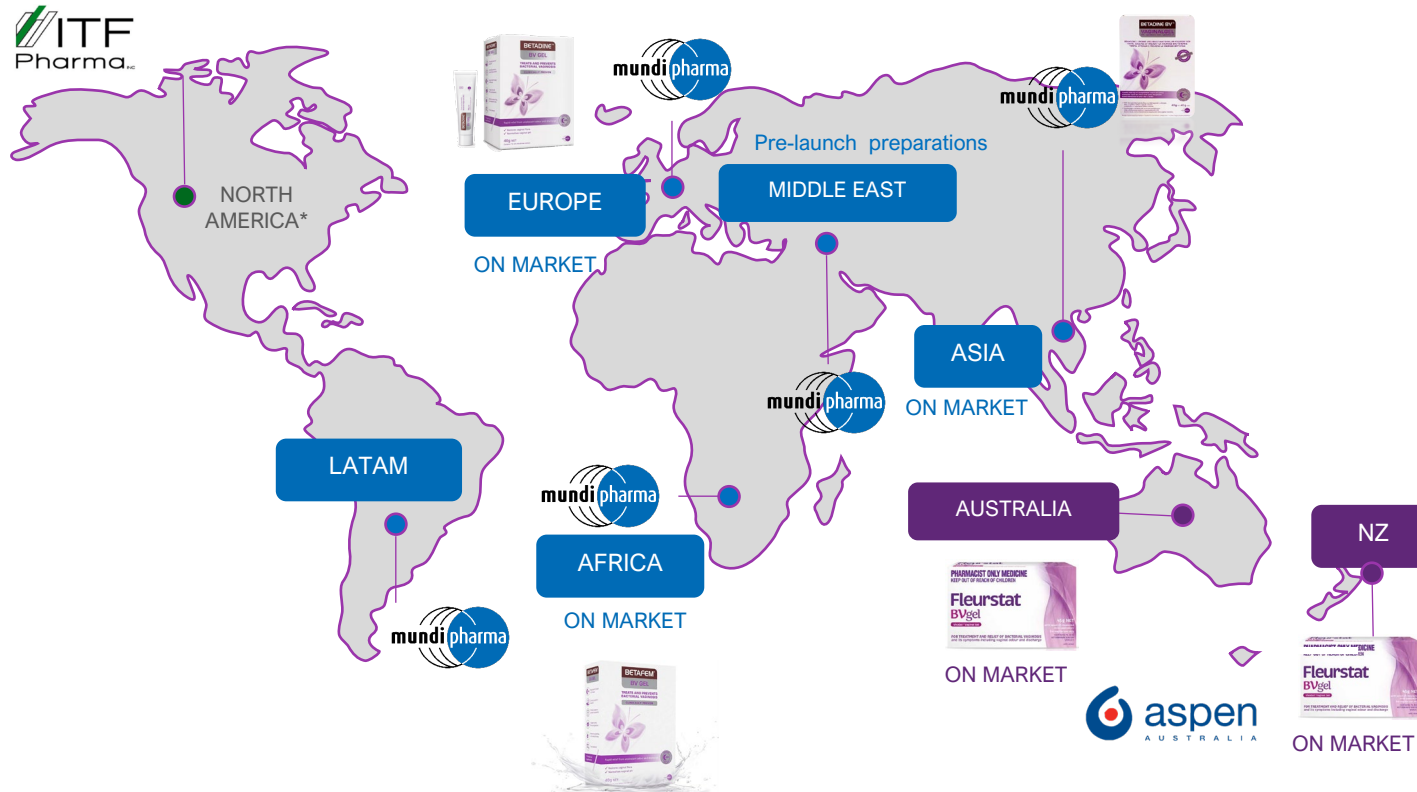
1. Peebles K, et al., (2019). High global burden and costs of bacterial vaginosis: a systematic review and meta-analysis. *Sex Transm Dis* 46(5), 304.

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

VivaGel® BV distribution network and regulatory activity



- Registered in >45 countries
- Launched in Europe, the UK, Asia, South Africa, Australia & New Zealand
- Further launches and regulatory submissions progressing in multiple regions

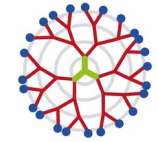


*In the US, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV.

As part of this process, Starpharma has had extensive external advice, met with FDA multiple times and made a number of submissions of data and analyses to FDA. Starpharma continues to work with its advisors, and the FDA, as part of this ongoing dispute resolution process and we are planning a further submission in 2023.



- 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

Financial Summary

Strong balance sheet with revenues from product sales and partnerships

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 Mar 2023: \$38.9M

Q3 FY23 Highlights

- Strong cash position with \$38.9M as at 31 March 2023
- Completed enrolment and treatment of patients for the Phase 2 monotherapy trials of DEP® cabazitaxel and DEP® docetaxel
- AstraZeneca's AZD0466 DEP® program reported encouraging results and progress at AACR Annual Meeting
- HER2-targeted DEP® SN-38 ADC outperformed the marketed ADC product, Enhertu®, with significant anti-tumour activity
- VIRALEZE™ post-market study well advanced, with more than 70% of participants recruited



Key value drivers and outlook

DEP® Drug Delivery



Internal DEP® Clinical-stage Assets

- Complete and report results Phase 2 DEP® 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 (milestone)



Preclinical DEP® Programs

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

SPL7013 Products



VIRALEZE™ Nasal Spray

- Further commercial roll-out, registrations and product launches
- Complete recruitment and report UK clinical study
- Further distribution arrangements with commercial partners
- Continue to generate clinical and antiviral data to support and expand 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

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