



## Life Sciences Investor Forum

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**ASX:SPL | OTC:SPHRY**

Dr Jackie Fairley, CEO

*22 June 2023*





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This document is intended for investors and market participants only.

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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<sup>®</sup> assets, multiple corporate partnerships and products on market

## DEP<sup>®</sup> Products

Product	Active / Payload	Target indication	Preclinical	Phase 1	Phase 2
DEP <sup>®</sup> cabazitaxel	Cabazitaxel	Prostate and other cancers			Ph 2 complete
DEP <sup>®</sup> irinotecan	SN38	Colorectal and other cancers			
DEP <sup>®</sup> docetaxel	Docetaxel	Pancreatic and other cancers			Ph 2 Monotherapy complete
AZD0466	AZD4320 (Bcl2/xL inhibitor)	Haematological cancers		Developed by AstraZeneca	AstraZeneca
DEP <sup>®</sup> gemcitabine	Gemcitabine	Solid cancers			
DEP <sup>®</sup> HER-2 ADC	Not disclosed	Solid cancers			
DEP <sup>®</sup> HER-2 radiotherapy	<sup>177</sup> Lu	Solid cancers			
DEP <sup>®</sup> HER-2 radiodiagnostic	<sup>89</sup> Zr	Diagnostic			AstraZeneca
Other collaborations	Various	Various			MSD, Genentech, CHASE SUN

## Marketed Products



## Partnered DEP<sup>®</sup> Products & Programs

Multiproduct DEP<sup>®</sup> license with AstraZeneca, including the development of AZD0466 for multiple indications



Two DEP<sup>®</sup> ADC Research Agreements with MSD (Merck & Co., Inc.)



DEP<sup>®</sup> anti-infective research partnership with Chase Sun



Two DEP<sup>®</sup> 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

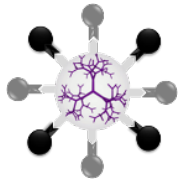
- Further development/co-development
- Continued testing against important infectious pathogens

# DEP<sup>®</sup> Platform

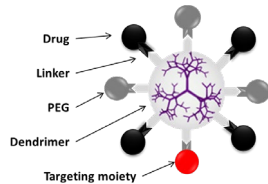
Starpharma's proprietary DEP<sup>®</sup> platform is highly versatile, conveys multiple benefits, and enhances the commercial value of a wide range of drugs

## DEP<sup>®</sup> technology:

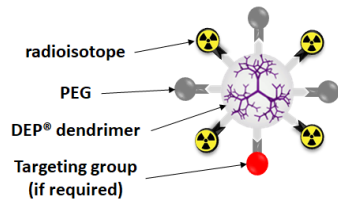
- Based on proprietary, branched polymers called dendrimers
- Represents a platform with significant optionality – applicable to many different drugs



DEP<sup>®</sup> dendrimer-drug conjugate



DEP<sup>®</sup> dendrimer antibody drug conjugate



DEP<sup>®</sup> dendrimer radiotheranostic

## Improved Safety / Reduced side effects

Control release kinetics of drug to reduce C<sub>max</sub> related toxicities

## Improved Efficacy / Performance

DEP<sup>®</sup> achieves drug targeting, improved PK and controlled release

## New IP / Extended Patent Life

DEP<sup>®</sup> creates new intellectual property and extends patent life

## Tumour Targeting

DEP<sup>®</sup> 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<sup>®</sup> is potentially applicable to ~70% of the top 200 pharmaceuticals (by sales)



# Starpharma's DEP<sup>®</sup> platform

*Broad applicability and exceptional optionality*

Multiple DEP<sup>®</sup> therapeutic areas across partnered and internal programs

## DEP<sup>®</sup> platform



AstraZeneca 

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

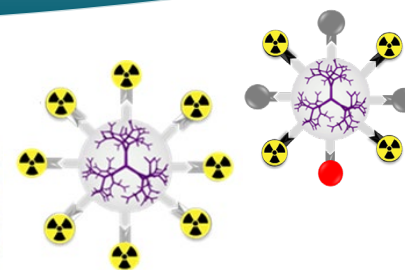
**Chemotherapeutics**



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**

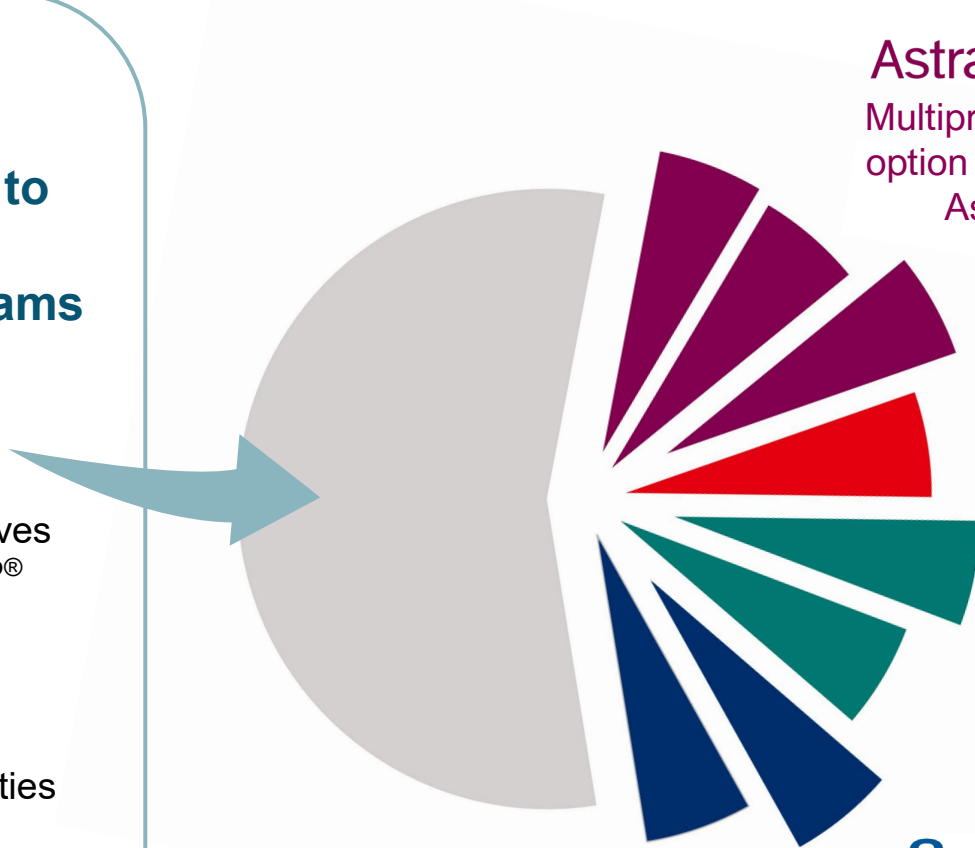
# DEP<sup>®</sup> partnering creates significant value and optionality

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

DEP<sup>®</sup> platform offers significant optionality, enabling multiple licenses to run in parallel without Starpharma funding programs

## DEP<sup>®</sup> partnering process

- **Research Phase** - typically involves Starpharma making multiple DEP<sup>®</sup> 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**

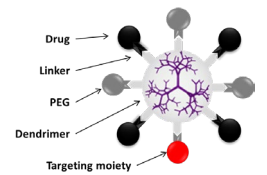
Multiproduct license & option agreement with AstraZeneca



DEP<sup>®</sup> anti-infective research partnership with Chase Sun



Two DEP<sup>®</sup> ADC Research Agreements with MSD



**Genentech**

A Member of the Roche Group

Two DEP<sup>®</sup> Research Agreements with Genentech



# AstraZeneca's DEP<sup>®</sup> nanoparticle AZD0466

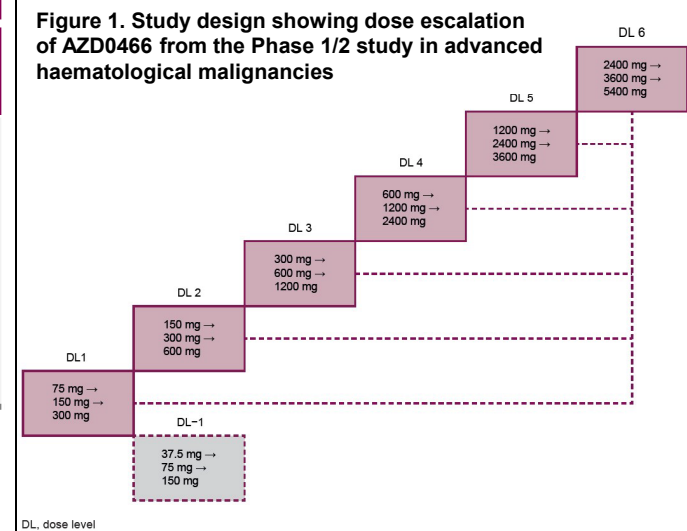
Global clinical development program in multiple indications

- AZD0466 is a highly optimised DEP<sup>®</sup> 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<sup>®</sup>). In 2021, Venclexta<sup>®</sup> 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 ( <b>acute myeloid leukaemia (AML)</b> or <b>acute lymphoblastic leukaemia (ALL)</b> )	20 sites recruiting; >30 planned in total in Australia, US, EU & Asia	<ul style="list-style-type: none"> <li>• Multiple dose escalations successfully completed</li> <li>• AZD0466 dosed in 24 patients up to 3600mg (at 24 January 2023)</li> <li>• AZD0466 well tolerated; no dose-limiting toxicities (DLTs) to date</li> <li>• Initial clinical activity observed through reduction of bone marrow blasts following AZD0466 treatment.</li> <li>• Mean treatment duration of 4.4 months</li> <li>• Further dose escalation underway</li> </ul>
Global Phase 1/2 study in <b>non-Hodgkin lymphoma</b>	>20 sites recruiting; 30 planned in total in Australia, US, Canada, EU & Asia	
<i>Additional indication planned</i>	<i>Details TBA</i>	

AstraZeneca



# 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*

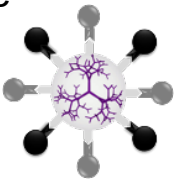


**Abstract:** <https://www.abstractsonline.com/pp8/#!/10828/presentation/1959>

**Poster:** [https://starpharma.com/assets/uploads/2023-04/2023\\_CLA\\_AACR\\_0466inSCLC\\_Final.pdf](https://starpharma.com/assets/uploads/2023-04/2023_CLA_AACR_0466inSCLC_Final.pdf)

## 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<sup>®</sup> oncology portfolio

Multiple clinical-stage assets with high commercial value potential

DEP <sup>®</sup> Program	Original Drug Formulation	Advantages of DEP <sup>®</sup> Product <sup>**</sup>
<b>DEP<sup>®</sup> cabazitaxel (Phase 2)</b> 	Dendrimer version of leading prostate cancer drug cabazitaxel (Jevtana <sup>®</sup> ) 	Cabazitaxel (Jevtana <sup>®</sup> ) – global sales of ~US\$500M for 2021 despite having multiple US FDA “Black Box” warnings.
<b>DEP<sup>®</sup> docetaxel (Phase 2)</b> 	Dendrimer version of docetaxel (Taxotere <sup>®</sup> ) – widely used for breast, lung & prostate cancer 	Docetaxel (Taxotere <sup>®</sup> ) was a blockbuster cancer drug with peak global sales >US\$3B despite having multiple US FDA “Black Box” warnings.
<b>DEP<sup>®</sup> irinotecan (Phase 2)</b> 	Dendrimer version of irinotecan (Camptosar <sup>®</sup> ) - predominantly used for colorectal cancer 	Camptosar <sup>®</sup> had peak global sales of US\$1.1B despite having multiple US FDA “Black Box” warnings.


**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<sup>®</sup> such as bone marrow toxicity, anaphylaxis, severe diarrhoea and hair-loss

\*Multiple preclinical studies have established improved efficacy, survival and safety with DEP<sup>®</sup> with many different drugs

# DEP<sup>®</sup> cabazitaxel: Phase 2 trial

*Encouraging efficacy signals across multiple tumour types enhancing market potential*

## DEP<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>.

### Trial Sites



## Jevtana<sup>®</sup>

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<sup>®</sup> 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<sup>®</sup> cabazitaxel Phase 2 Trial Prostate Cancer Cohort

- 25 heavily pre-treated patients with Stage IV hormone-refractory prostate cancer
- Prior to entering the DEP<sup>®</sup> 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<sup>®</sup>)
  - 56% had received ≥ two prior chemotherapy regimens (compared to 16%^ of Jevtana<sup>®</sup> patients in published trial data)
- **DEP<sup>®</sup> cabazitaxel patients did not need prophylactic steroids** or antihistamines as polysorbate-80 free aqueous formulation
- **DEP<sup>®</sup> cabazitaxel required no primary G-CSF<sup>1</sup> 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<sup>®</sup> cabazitaxel and had an applicable efficacy assessment conducted post treatment. 3 patients were not evaluable for efficacy

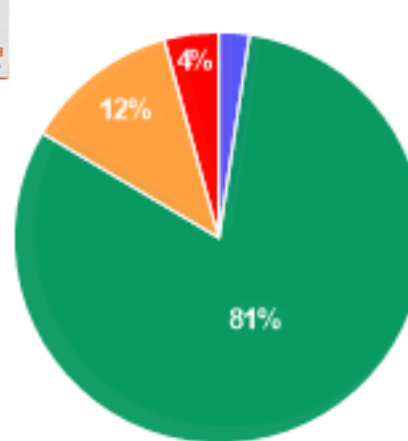
^: Eisenberger, M, et al. J Clin Oncol, 2017;35(28):3198-206 .

\* Excludes hormonal therapies

## Prior Chemotherapy Regimens in Trial Patients\*

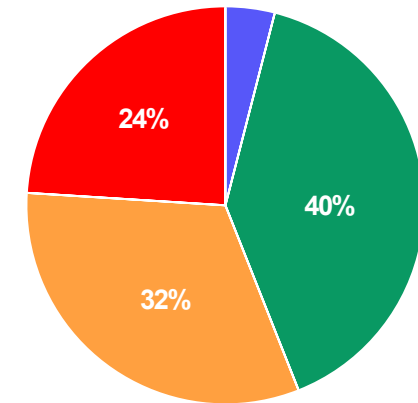


Jevtana<sup>®</sup> - 20mg/m<sup>2</sup>



- Only 16%\* of Jevtana<sup>®</sup> patients had received ≥2 prior regimens whereas

DEP<sup>®</sup> Cabazitaxel



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

# DEP<sup>®</sup> cabazitaxel Phase 2 trial

Key interim efficacy and safety findings in prostate cohort vs. Jevtana<sup>®1,2</sup>

## Key Efficacy Measures

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



## Key Safety Measures

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

DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®1</sup> (20 mg/m <sup>2</sup> ) (N=580 <sup>†</sup> )	Jevtana <sup>®1</sup> (25 mg/m <sup>2</sup> ) (N=595 <sup>†</sup> )
7.5%	39.7%	54.5%

## Longer Progression-Free Survival (PFS) (median)

DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®1</sup> (20 mg/m <sup>2</sup> ) (N=598*)	Jevtana <sup>®1</sup> (25 mg/m <sup>2</sup> ) (N=602*)	Jevtana <sup>®2</sup> (25 mg/m <sup>2</sup> ) (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<sup>1,2</sup> also included pain progression

\* Intent-to-treat populations

Safety Outcomes	DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®2</sup> (20 mg/m <sup>2</sup> ) (N=580 <sup>†</sup> )
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

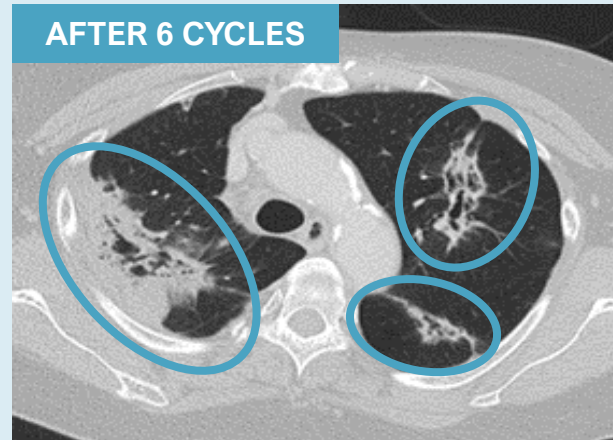
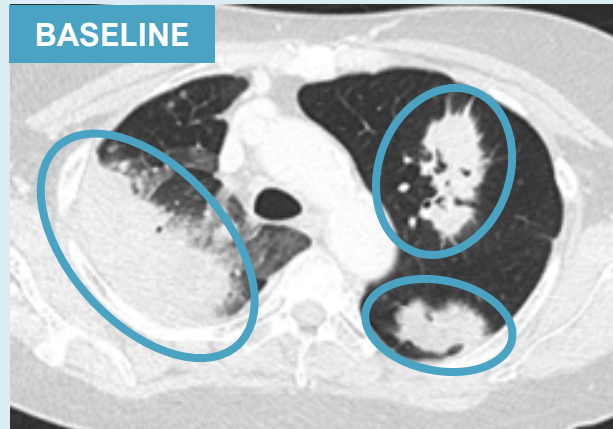
**Patient's cancer had progressed prior to entering the DEP<sup>®</sup> cabazitaxel study, following:**

- 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

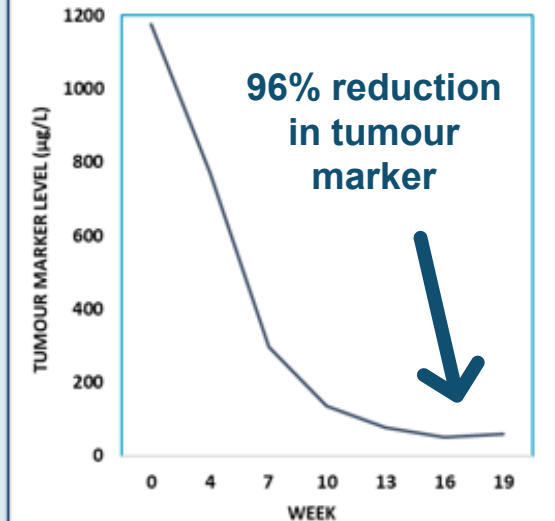
**Following treatment with DEP<sup>®</sup> cabazitaxel (6 cycles), the patient achieved:**

- 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<sup>®</sup> cabazitaxel treatment



# DEP<sup>®</sup> irinotecan: Phase 2 trial ongoing

Encouraging efficacy signals across multiple tumour types enhancing market potential

## DEP<sup>®</sup> 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<sup>®</sup> irinotecan – this side effect is experienced by 20-40% of patients with conventional irinotecan, and often requires hospitalisation<sup>^</sup>.
- Less severe side effects than typically associated with Camptosar<sup>®</sup>; AEs observed included nausea, vomiting, alopecia and neutropenia.

### Combination study (recruiting):

- DEP<sup>®</sup> irinotecan + 5-FU + Leucovorin ('FOLFIRI')

### Trial Sites



<sup>^</sup> 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<sup>®</sup>

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<sup>®</sup> irinotecan

(SN38 nanoparticle formulation)



- No severe diarrhoea observed;
- Less myelosuppression / neutropenia

DEP<sup>®</sup> 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<sup>®</sup> irinotecan - improved tolerability profile c.f. published data on Camptosar<sup>®†</sup>

### Gastro-intestinal toxicity much improved with DEP<sup>®</sup> irinotecan treatment:

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

### No cholinergic syndrome:

- ~47% colorectal cancer patients treated with Camptosar<sup>®</sup> experienced cholinergic syndrome
- **No DEP<sup>®</sup> 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 <sup>®</sup> irinotecan*	Camptosar <sup>®†^</sup>
<b>GASTROINTESTINAL</b>		
Diarrhoea ≥ grade 3	0	~20-40%
Nausea ≥ grade 3	2.2%	~10%
Vomiting ≥ grade 3	1.1%	~10%
<b>NERVOUS SYSTEM</b>		
Cholinergic Syndrome	0%	~47%

\*(8 - 15 mg/m<sup>2</sup> SN38)  
Q3W | N=90

^(350 mg/m<sup>2</sup>)  
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

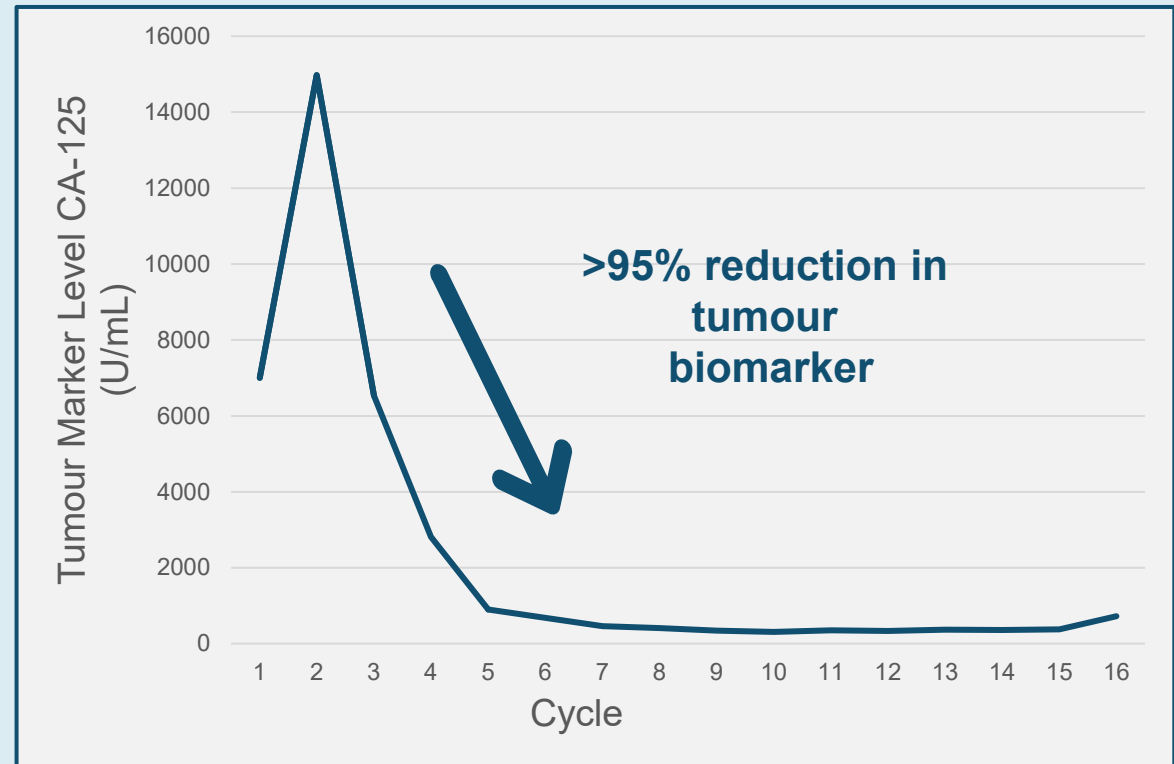
*Stage IV ovarian cancer has a 5-year survival rate of approximately 17%\**

**Patient was heavily pre-treated prior to entering the DEP<sup>®</sup> irinotecan study, following**

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

**Following treatment with DEP<sup>®</sup> 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<sup>®</sup> docetaxel

Encouraging efficacy signals across multiple tumour types

## DEP<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> docetaxel + gemcitabine (Gemzar<sup>®</sup>)
- DEP<sup>®</sup> docetaxel + nintedanib (Vargatef<sup>®</sup>)

### Trial Sites



## Taxotere<sup>®</sup>

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<sup>®</sup> 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

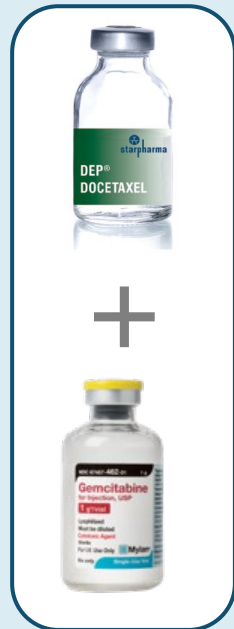
### New/extended IP

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

# DEP<sup>®</sup> docetaxel: clinical case study

DEP<sup>®</sup> docetaxel in combination with gemcitabine

## 60-year-old woman with stage IV uterine cancer



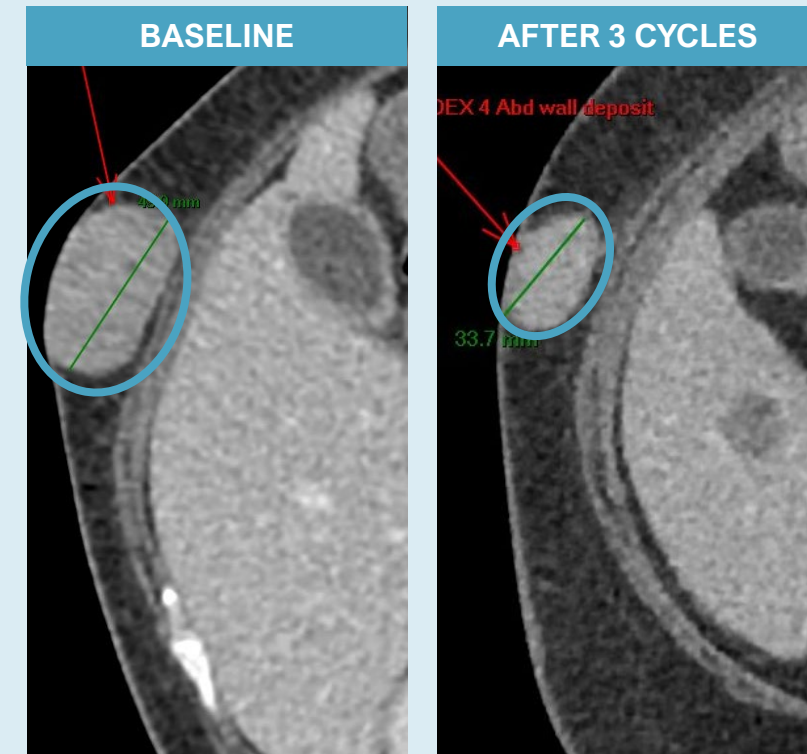
### Patient heavily pre-treated prior to entering the study:

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

### Following treatment with DEP<sup>®</sup> 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



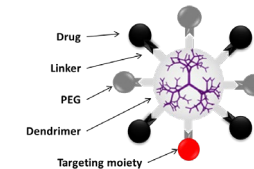


# DEP<sup>®</sup> antibody drug conjugate (ADC) partnerships with leading companies

- 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<sup>®</sup> technology represents a valuable partnering platform which has the potential to generate revenue through royalties and milestones
- Starpharma has two DEP<sup>®</sup> research agreements with MSD for dendrimer-based ADCs using the DEP<sup>®</sup> technology.

## DEP<sup>®</sup> 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

<b>US\$6B</b> <i>Jul 2020</i>	<b>US\$2.75B</b> <i>Nov 2020</i>	<b>€1.2B</b> <i>Dec 2020</i>	<b>US\$3.1B</b> <i>Jun 2021</i>	<b>US\$1.7B</b> <i>Feb 2022</i>	<b>US\$936M</b> <i>Jul 2022</i>	<b>US\$1.1B</b> <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>

# HER2-targeted DEP<sup>®</sup> SN-38 ADC outperforms in HER2+ human cancer model

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

## Key advantages of Starpharma's DEP<sup>®</sup> 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
<b>Kadcyla<sup>®</sup></b> (Genentech/Roche)	3.5	DM-1 (emtansine)
<b>Enhertu<sup>®</sup></b> (AstraZeneca/Daiichi-Sankyo)	8	DXd (exatecan derivative)
<b>HER2-targeted DEP<sup>®</sup> SN-38 ADC</b> (Starpharma)	13	SN-38

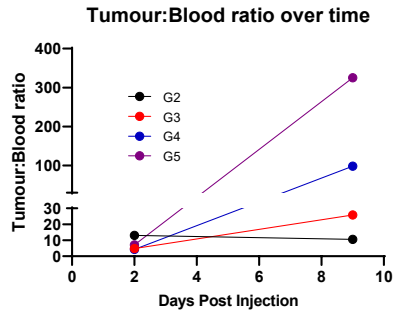
## Effect of HER2-targeted DEP<sup>®</sup> SN-38 ADC vs. Enhertu<sup>®</sup> on Tumour Volume Over Time

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

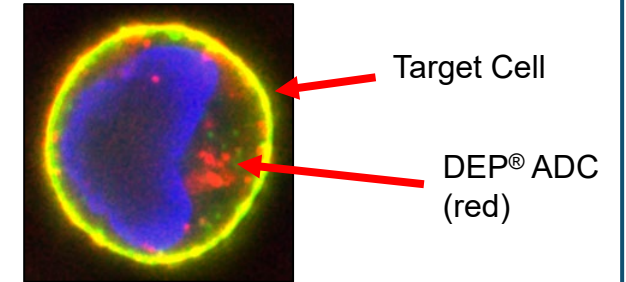
# DEP<sup>®</sup> ADCs offer multiple benefits



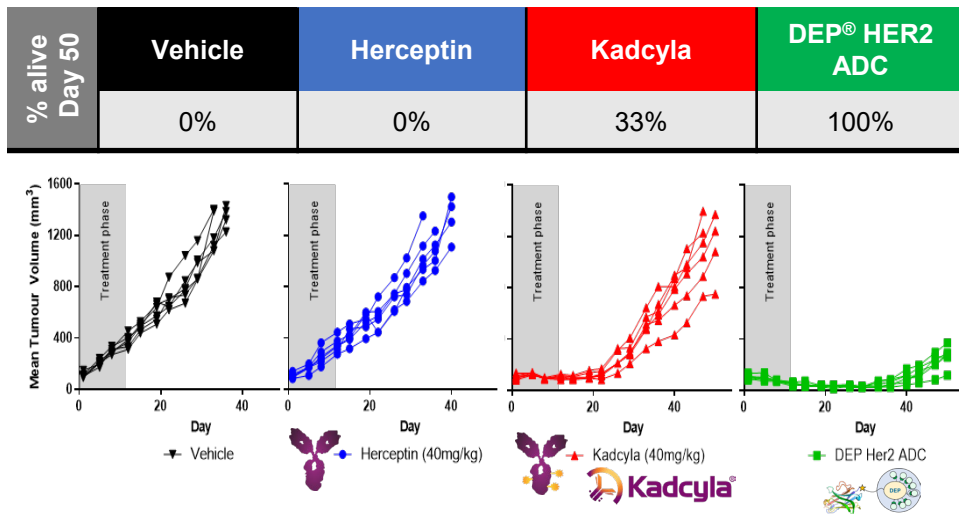
## Can be tuned to provide optimal characteristics



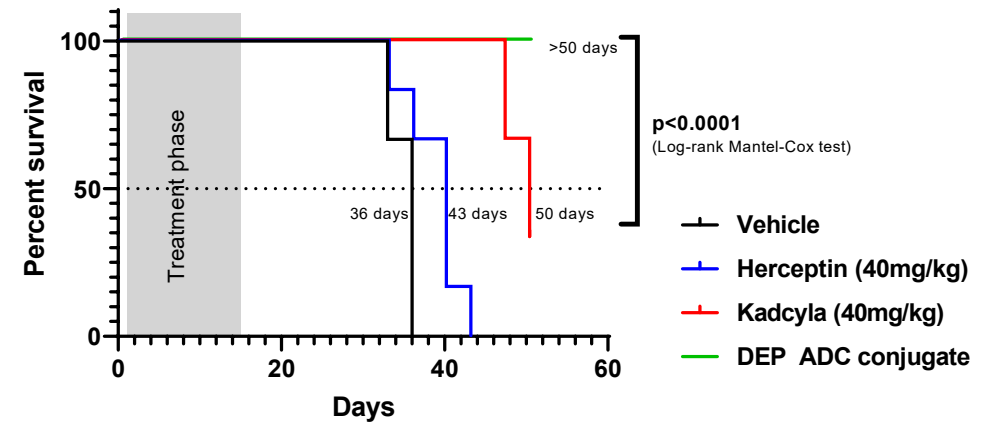
## Penetrate deeply into tumours, bind strongly to target cells and are internalised for enhanced performance



## Highly efficacious – enhanced anticancer activity\*



## Enhanced efficacy leads to enhanced survival\*



# DEP<sup>®</sup> - 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<sup>^</sup>
- **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<sup>®</sup> platform has yielded multiple radiotheranostic DEP<sup>®</sup> 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<sup>®</sup> platform

## DEP<sup>®</sup> 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<sup>®</sup> in diagnostic and therapeutic approaches



## Significant Corporate Deals in Radiotheranostics



 	  ENDOCYTE	 LANTHEUS	 	 	 PASSION FOR PRECISION	 远大健康 CGE HEALTHCARE	 LANTHEUS
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	

<sup>^</sup>MEDDraysintell Nuclear medicine report Edition 2022

\*[https://www.meddraysintell.com/\\_files/ugd/1beeab\\_6bc27b0bbe664527aca68f41bf7de2bc.pdf](https://www.meddraysintell.com/_files/ugd/1beeab_6bc27b0bbe664527aca68f41bf7de2bc.pdf)

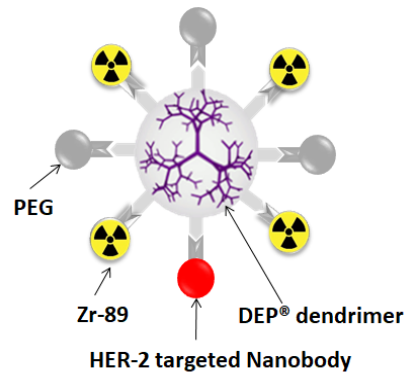


# Novel DEP<sup>®</sup> radiotheranostics (radiodiagnostic and radiotherapeutic)

## DEP<sup>®</sup> radiodiagnostic

### DEP<sup>®</sup> HER2-zirconium

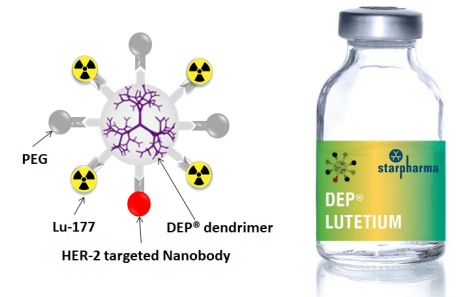
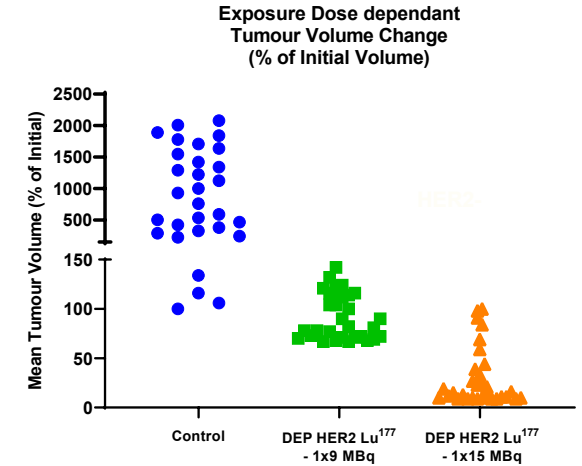
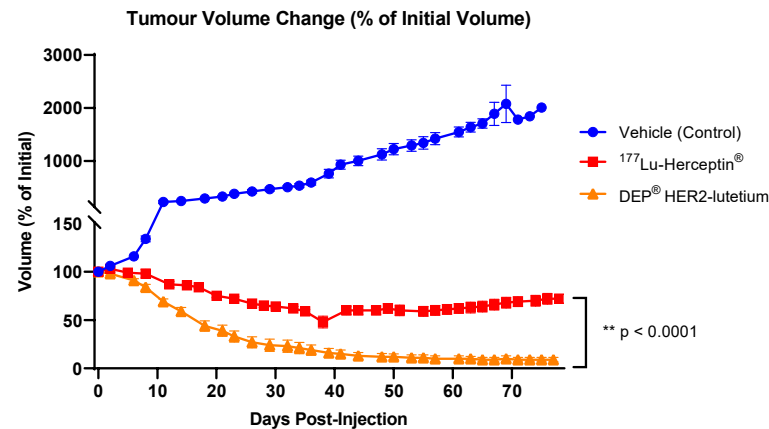
- Achieved significant tumour accumulation: >100x in tumour vs. blood in a preclinical human HER2-positive ovarian cancer model
- DEP<sup>®</sup> HER2-zirconium pharmacokinetics allow for optimal visualisation in PET imaging



## DEP<sup>®</sup> radiotherapeutics

### DEP<sup>®</sup> HER2-lutetium

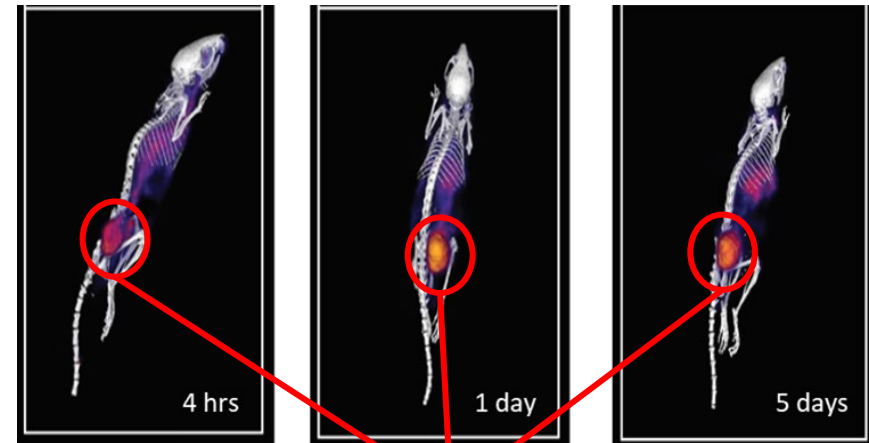
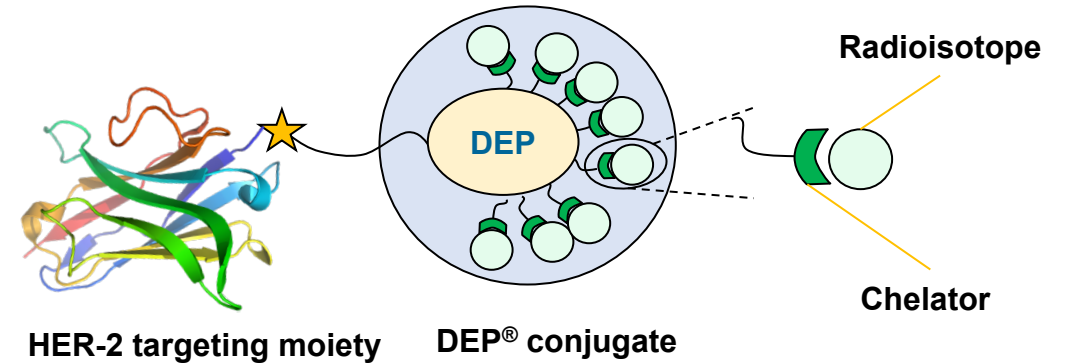
- Achieved complete tumour regression in a preclinical human HER2-positive breast cancer model
- Was extremely well tolerated
- 100% survival throughout experiment
- Anti-tumour effect was dose-dependent
- Outperformed HER2 antibody, Herceptin<sup>®</sup>, labelled with <sup>177</sup>Lu



# Targeted DEP<sup>®</sup> radiotheranostics offer multiple benefits

## DEP<sup>®</sup> 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<sup>®</sup> in diagnostic and therapeutic approaches



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



## 55-year-old woman with stage IV colorectal cancer

*Colorectal cancer is the 3<sup>rd</sup> most commonly diagnosed cancer and 4<sup>th</sup> leading cause of cancer death worldwide\**

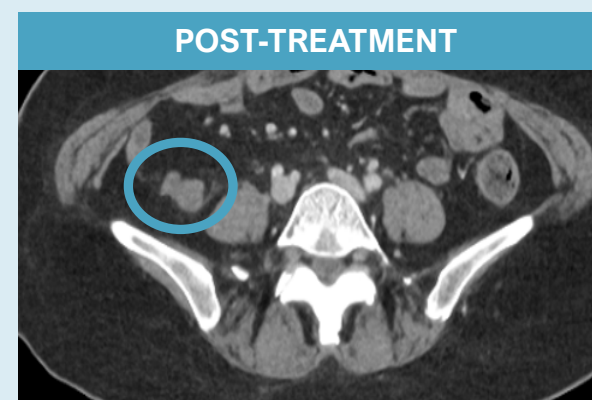
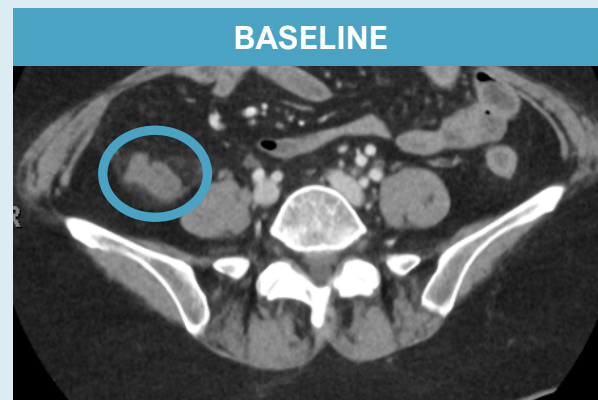
**Patient was heavily pre-treated prior to entering the DEP<sup>®</sup> irinotecan study, following:**

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

**Following treatment with DEP<sup>®</sup> 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<sup>®</sup> 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



恒安集团  
HENGAN

Etqan & Nazahah Company



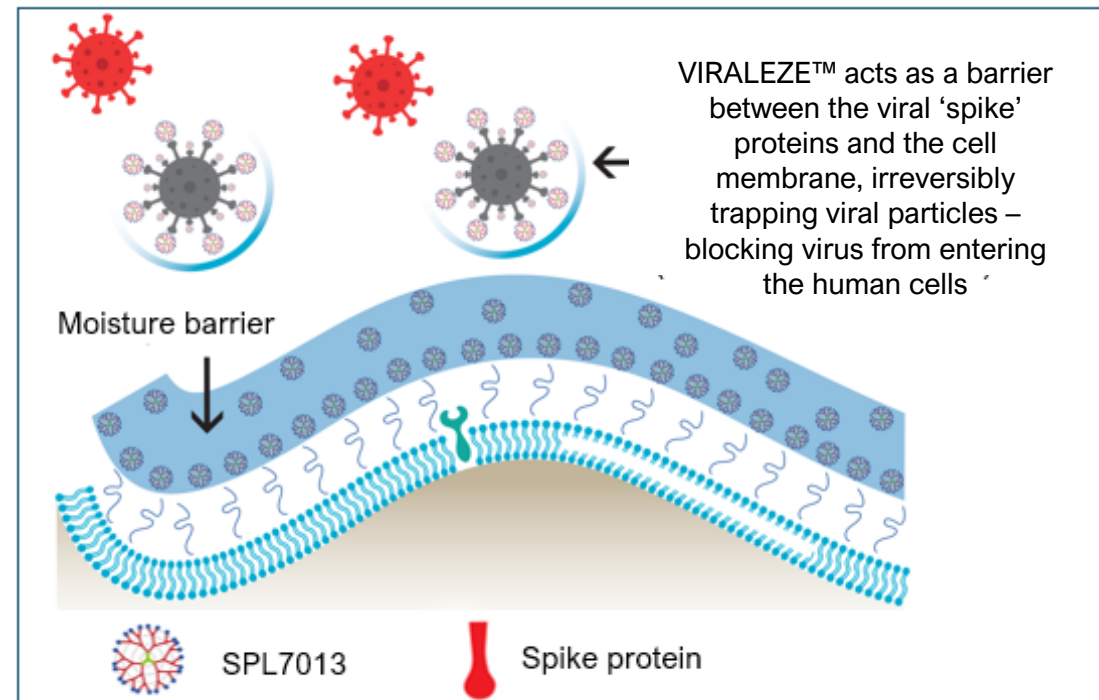
## VIRALEZE™ features

- 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™ 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 (≥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

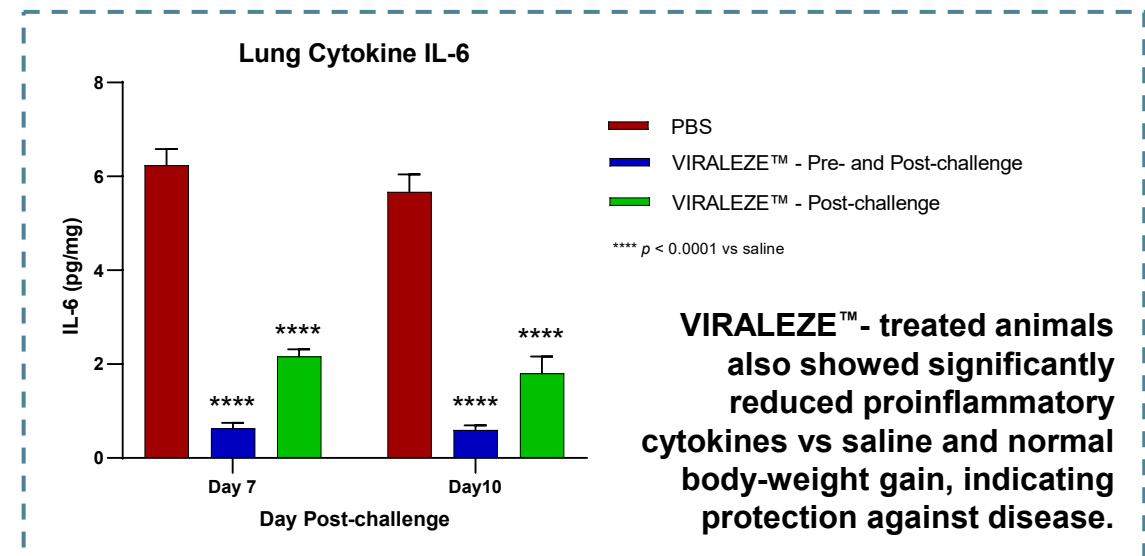
**VIRALEZE™ treated animals showed markedly reduced infectious SARS-CoV-2 virus in the respiratory tract**

**100% of animals<sup>^</sup> treated with VIRALEZE™ showed no evidence of infectious SARS-CoV-2 Omicron virus in**

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



**Reduced infectivity**



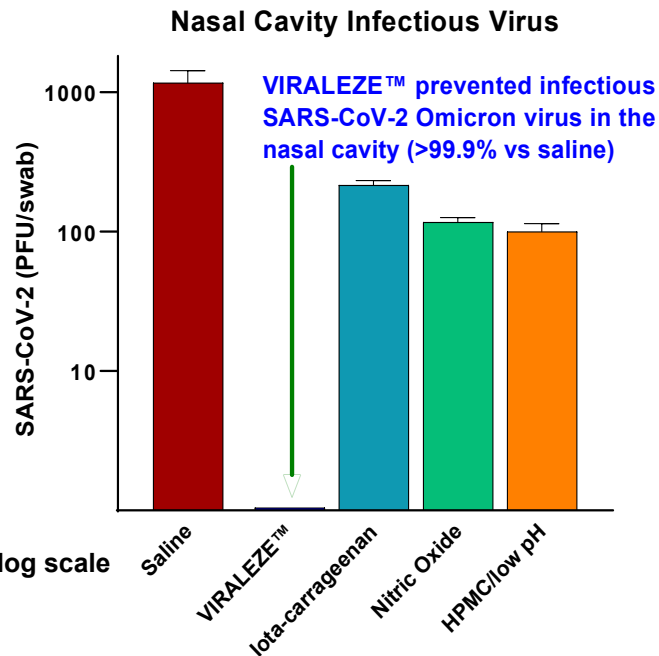
# VIRALEZE™ antiviral nasal spray outperforms comparators in SARS-CoV-2 Omicron challenge model

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<sup>^</sup>

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



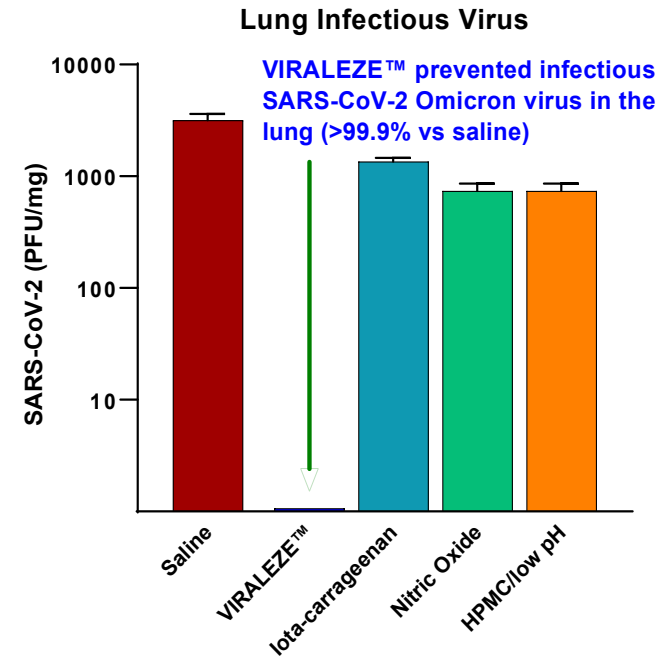
NB: Y axis = log scale



Full data presented at Respi DART 2022 conference in Mexico




Respi DART 2022

LOS CABOS, MEXICO • 6-8 DECEMBER 2022



<sup>^</sup>Day 7 post-challenge

VIRALEZE™ is not approved for use or supply in Australia

- **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;
  - ✦  in Vietnam;
  - ✦ **Etqan & Nazahah Company**  in countries in the Middle East; and
  - ✦  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

# 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 globally<sup>1</sup>. BV is associated with causing complications related to the reproductive health of women<sup>2</sup>
- 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



**BETADINE BV GEL**  
BACTERIAL VAGINOSIS  
REZOLVING EN 48 URE  
BETADINE 400 mg

**PHARMACIST ONLY MEDICINE**  
KEEP OUT OF REACH OF CHILDREN  
**Fleurstat BVgel**  
VAGINAL GEL  
FOR TREATMENT AND RELIEF OF BACTERIAL VAGINOSIS  
AND ITS SYMPTOMS INCLUDING VAGINAL COLOUR AND DISCHARGE

**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

*\*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.

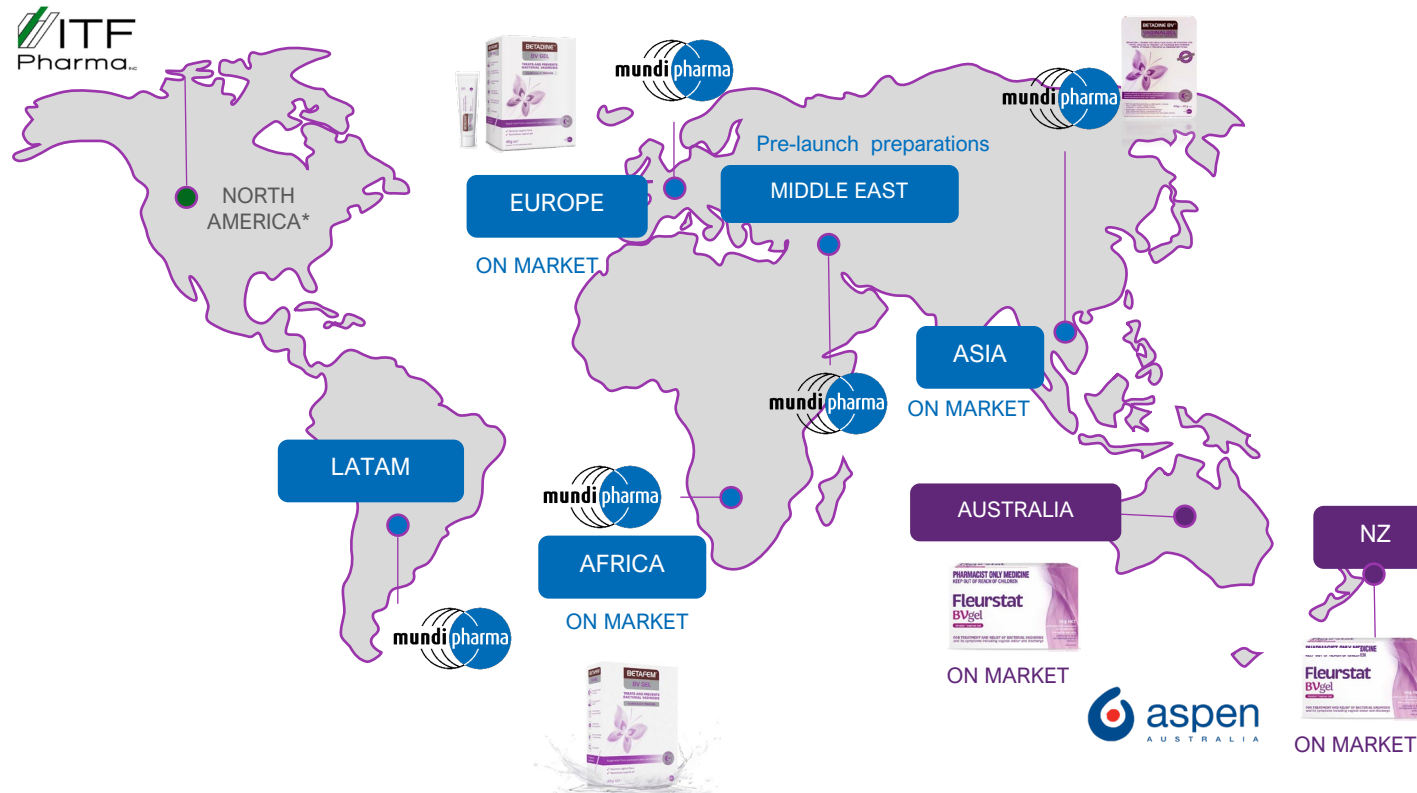
2. Turovskiy Y, et al., (2011). The aetiology of bacterial vaginosis. *J Appl Microbiol* 110(5), 1105.



# 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

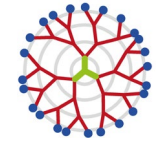


\*In the US, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV.

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<sup>®</sup> condom incorporates SPL7013 antiviral, which has demonstrated activity in HIV, HSV-2, HPV
- Okamoto launched an additional VivaGel<sup>®</sup> 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<sup>®</sup> 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

> [Download ESG Report](#)





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