

## Starpharma to present at Bell Potter Healthcare Conference

**Melbourne, Australia; 9 November 2021:** Starpharma (ASX: SPL, OTCQX: SPHRY) has been invited to present today at the exclusive virtual 2021 Bell Potter Healthcare Conference. The Bell Potter Healthcare Conference showcases leading companies within the Australian healthcare sector and brings together industry leaders with Bell Potter's network of international and domestic investors, analysts and advisers. The event is available to live-stream via [Bell Potter Client Access](#) on 9 – 11 November.

Starpharma will be presenting an abridged presentation focussing on an overview of the business and recent milestones, including:

- **AZD0466, AstraZeneca's first DEP<sup>®</sup> oncology product** - for which [AstraZeneca will present two scientific posters](#) each accompanied by a presentation at the 2021 American Society of Hematology (ASH) Annual Meeting in December.
- Recent supply arrangements for VIRALEZE™ antiviral nasal spray in [Vietnam](#) and [Italy](#), and data published in several leading international journals, [Viruses](#) and [Nature](#) Biotechnology.
- Update on Starpharma's other partnered programs, including its [DEP<sup>®</sup> Antibody Drug Conjugates \(ADC\)](#) programs with Merck & Co Inc., DEP<sup>®</sup> anti-infective program with Chase Sun, and progress with further commercial discussions with leading companies for additional partnered programs, including in the area of DEP<sup>®</sup> radiopharmaceuticals.
- Brief update on Starpharma's internal DEP<sup>®</sup> products, including its phase 2 clinical programs for DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel and DEP<sup>®</sup> irinotecan.

The presentation is attached and also available on Starpharma's website.

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### About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for respiratory viruses, DEP<sup>®</sup> drug delivery and VivaGel<sup>®</sup>. Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in the UK/Europe and India, and available in certain markets online. VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> BV has been licensed in >160 countries, is registered in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP<sup>®</sup>, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP<sup>®</sup> versions of existing drugs, particularly in the area of anti-cancer therapies. DEP<sup>®</sup> partnerships include oncology programs with AstraZeneca, with Merck in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Starpharma's partnered DEP<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

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### Disclosure

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

**Forward Looking Statements**

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.

## Bell Potter Healthcare Conference 2021

9 November 2021

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DR JACKIE FAIRLEY  
CEO



# Important notice and disclaimer



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

## Key Investment Data

ASX code	SPL
OTCQX code	SPHY
Share price	A\$1.14
Shares on issue	407M
Market capitalisation	~A\$460M
Daily average volume (shares)	~537k
Cash on hand - as at 30/09/21	\$53.4M
Share register	Institutions ~55% Retail ~40% Staff & other ~5%

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

- Unique polymer (dendrimer) platform creating valuable patented healthcare products (>200 patents)
- Deep portfolio of high-value products on-market and clinical stage assets, with near term potential commercial and clinical milestones
- Products address clear unmet medical need for large markets
- Established supply chain and manufacturing
- Proven record of development & commercialization including successful partnerships with leading global companies



**VIRALEZE™ Antiviral Nasal Spray**  
– Registered for sale in the UK/Europe and India, and available in certain markets online



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



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



**VivaGel® condom** – Approved in Japan, Europe, Australia & Canada

# Starpharma's portfolio

High-value assets including VivaGel<sup>®</sup> products on market, SPL7013 antivirals and multiple DEP<sup>®</sup> clinical assets

Extensive & growing pipeline of proprietary assets

Multiple clinical stage assets

Multiple approved products



**INTERNAL & PARTNERED**

**INTERNAL**

**LICENSED**

**LICENCE AFTER PROOF OF CONCEPT**

**FURTHER APPROVALS**

**APPROVED PRODUCTS**

# 2021 HIGHLIGHTS

→ AstraZeneca expanded and expedited its AZD0466 clinical program into a global, multi-centre phase I/II trial



→ Starpharma signed DEP® Research Agreement with Merck & Co., Inc., (MSD) for DEP® Antibody Drug Conjugates (ADCs)



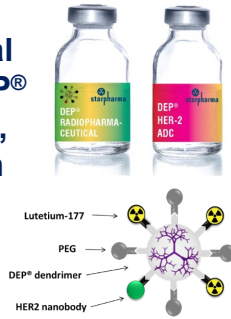
→ Starpharma signed new DEP® partnership with pharmaceutical company Chase Sun



→ DEP® docetaxel and gemcitabine combination clinical study commences



→ Starpharma's second Radio-pharmaceutical candidate, DEP® HER2-lutetium, outperforms in human breast cancer model



→ TGA approves the expansion of the marketing authorization for VivaGel® BV (Fleurstat BVgel) to include prevention of recurrent BV indication



→ LifeStyles launched the VivaGel® condom in countries in Europe, marketed under Absolute™ DUAL PROTECTION brand



→ VIRALEZE™ antiviral nasal spray registered for sale in UK/Europe, India



→ Starpharma signed a sales and distribution agreement for VIRALEZE™ with LloydsPharmacy, one of the largest pharmacy groups in the UK



→ VIRALEZE™ launched via LloydsPharmacy in the UK; partnered with ADMENTA Italia Group in Italian pharmacies, and through TBL/Nam Hanh Medical in Vietnam



→ Testing for VIRALEZE™ confirms SPL7013 has potent antiviral and virucidal activity *in vitro* in multiple variants of SARS-CoV-2 - it inactivated >99.99% of the Delta variant within 30 seconds



Delta Variant B.1.617.2  
Spreads much faster than other variants\*



→ VIRALEZE™ administered nasally reduced viral load by >99.9% (vs. saline) in the lungs and trachea of animals challenged with SARS-CoV-2 ; study published in the international peer-reviewed journal, *Viruses*



→ Starpharma awarded \$1 million by the Australian MRFF to expedite development of VIRALEZE™



→ Testing for VIRALEZE™ confirms SPL7013 active against other pandemic respiratory viruses "SARS" and "MERS", in laboratory studies



→ Testing for VIRALEZE™ confirms SPL7013 active against human respiratory syncytial virus (RSV), in laboratory studies

→ VIRALEZE™ well tolerated in multiple dose clinical study

# Financial summary

Strong balance sheet – Cash at 30 September 2021 \$53.4M

Key Financial Data	FY21 A\$M	FY20 A\$M
Revenue	2.2	6.6
Other Income	1.3	0.6
Loss for the period	(19.7)	(14.7)
Net operating cash outflows	(14.8)	(10.8)
Net financing & investing cash in/(out) flows	46.1	(0.7)
<b>Net cash burn (excluding capital raise)<sup>1</sup></b>	<b>(16.5)</b>	<b>(11.2)</b>

**Cash as at 30 Sep 2021 is \$53.4M**

## FY21 Result:

- Revenue: ↓ FY20 included \$4.3M (US\$3M) AstraZeneca DEP® milestone
- Other Income includes \$0.9M MRFF grant income for VIRALEZE™
- Investment in R&D Programs: ↑ DEP®, ↑ VIRALEZE™, ↓ VivaGel® BV
- R&D tax incentive ↑: \$7.2M (FY20 \$5.7M) anticipated to be received Q2FY22
- Corporate, Admin & Finance expense ↑: on \$1.1M unfavourable FX movement of foreign cash held
- Net financing cash inflows: \$46.9M net proceeds from equity placement and share purchase plan



<sup>1</sup> Net cash burn is considered a non-IFRS value and has not been audited in accordance with Australian Accounting Standards. Net cash burn is calculated by the movement in cash and cash equivalents between reporting periods, adjusted for the impact of the capital raising during the period.



# VIRALEZE™ - antiviral nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2 (the coronavirus that causes COVID-19)

- Broad-spectrum antiviral nasal spray containing 1% astodrimmer sodium (SPL7013), shown in laboratory studies to inactivate respiratory viruses, including >99.9% of coronavirus SARS-CoV-2 (Paull, 2021)
- Virucidal, irreversibly and rapidly inactivating **>99.9%** of *multiple variants* of coronavirus/SARS-CoV-2, including **Delta**
- Astodrimmer sodium (SPL7013) also irreversibly inactivates a broad spectrum of respiratory viruses
- **VIRALEZE™ is registered for sale in the UK/Europe & India**
- **VIRALEZE™ is partnered with LloydsPharmacy in the UK; ADMENTA Italia Group in Italy; and HealthCo/ TBL & Nam Thanh in Vietnam**
- **VIRALEZE™ regulatory submissions (including TGA) made, others in progress and commercial discussions for multiple countries well advanced**

LloydsPharmacy

NAM HANH  
MEDICAL

ADMENTA Italia

VIRALEZE

## VIRALEZE™ advantages

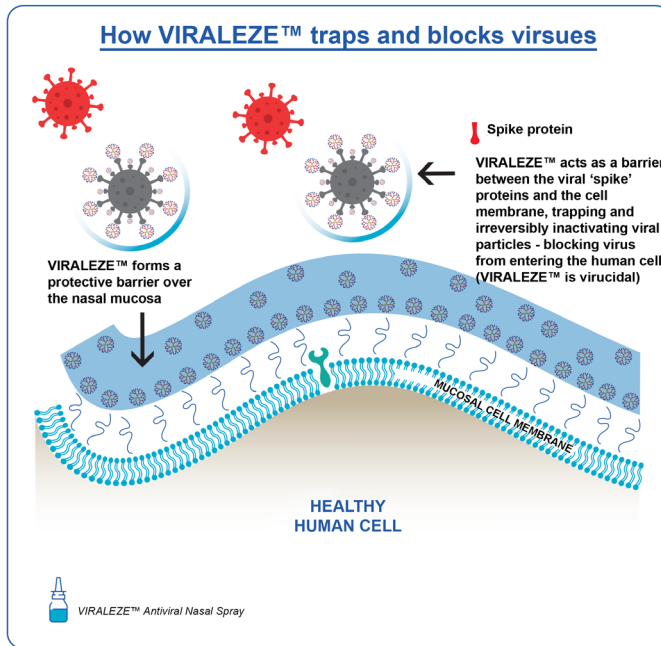
- ✓ Broad-spectrum, works against multiple strains of **SARS-CoV-2 and multiple respiratory viruses**
- ✓ **Virucidal, irreversibly and rapidly inactivating >99.9% of coronavirus/SARS-CoV-2 within one minute (Paull, 2021)**
- ✓ **Potent antiviral activity against multiple strains of SARS-CoV-2, including 'Variants of Concern', Delta, Alpha, Beta and Gamma**
- ✓ Ability to inactivate virus either before or after exposure
- ✓ Well-tolerated; acts locally in the nasal cavity and is not absorbed into the bloodstream<sup>^</sup>
- ✓ Provides a moisturising and protective barrier to help keep nasal tissue hydrated
- ✓ Room temperature storage, easy and convenient for regular use



<sup>^</sup>Starpharma completed a double-blinded, placebo-controlled safety study to support marketing of VIRALEZE™. The study involved 40 healthy volunteers, using the product 4 times a day for 14 days. VIRALEZE™ was well tolerated by all participants, with no notable or serious adverse events reported. Results confirmed that SPL7013 is not absorbed into the bloodstream following nasal application - potential for systemic effects is negligible.

## How VIRALEZE™ works

- SARS-CoV-2 infects human cells by using the characteristic viral surface proteins, or “spikes”, to attach to receptor proteins on the surface of human cells
- **Antiviral agent, SPL7013, irreversibly traps viral spike proteins, inactivating virus and preventing infection**
- VIRALEZE™ nasal spray provides a protective and moisturizing barrier



## VIRALEZE™ antiviral agent (SPL7013) has potent virucidal activity (>99.99%) against Delta variant SARS-CoV-2

- Antiviral testing has confirmed SPL7013 (VIRALEZE™ antiviral agent) has **potent (>99%) virucidal activity against the Delta**, Alpha, Beta and Gamma variant strains of SARS-CoV-2 coronavirus in laboratory studies
- The Delta, Alpha, Beta and Gamma variants of SARS-CoV-2 are all classified ‘Variants of Concern’ due to their increased transmissibility, increased disease severity (COVID-19), and/or reduced effectiveness of current treatments or vaccines
- The broad-spectrum antiviral activity of VIRALEZE™ is an important advantage for the product, especially as new variants of SARS-CoV-2 continue to emerge and spread worldwide

Virus: SPL7013 <sup>†</sup> Incubation Time	Percent Reduction of Infectious Virus vs Virus Control <sup>^</sup>					
	US	Alpha	Beta	Gamma	Delta	Kappa
<b>30 seconds</b>	>99.9%	>99.9%	>99%	>99%	>99.99%	>99.9%



*“It is particularly exciting to see a product with this level of virucidal activity, especially against these Variants of Concern that are much more transmissible than earlier SARS-CoV-2 strains. The latest data are consistent with our previous data showing robust antiviral and virucidal effects of SPL7013 against the US strain of SARS-CoV-2 and suggests a mechanism of action that is not impacted by mutations affecting the virus spike proteins.”*

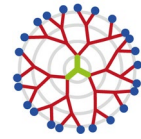
- Professor Philippe Gallay, Scripps Research institute



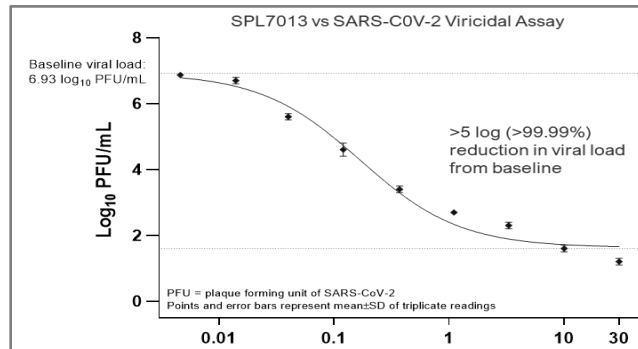
<sup>†</sup>10 mg/mL SPL7013; <sup>^</sup> virus without exposure to SPL7013

# Extensive antiviral efficacy data

- Extensive research has been conducted at **The Scripps Research Institute** in the US and is published in the prestigious, peer reviewed scientific journal, **Antiviral Research**
- A 1% w/w concentration of astodimer sodium (the concentration found in VIRALEZE™) has been shown to **inactivate >99.9% of SARS-CoV-2 within one minute**
- VIRALEZE™ maintains its antiviral effects when **applied either before or after exposure to virus**
- SPL7013 has been shown to have potent antiviral effects against **influenza viruses and human respiratory syncytial virus (RSV)** as well as other respiratory viruses that have caused pandemics, including **SARS, MERS, and Swine Flu (H1N1)** – the last three pandemics before COVID-19



SPL7013  
Astodimer  
Sodium

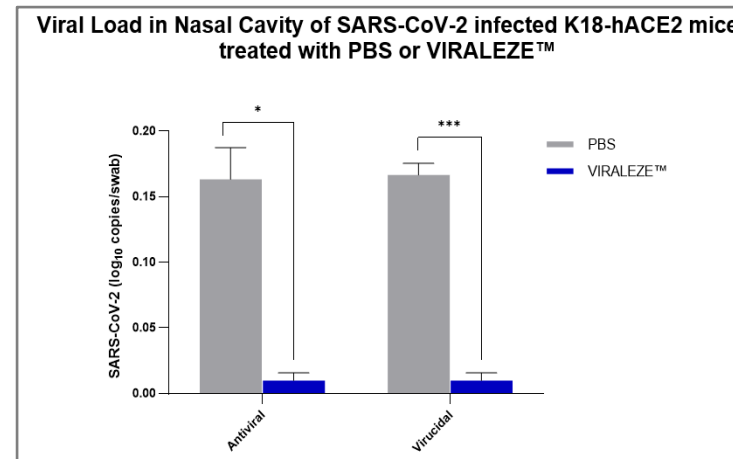


Paull J.R.A., et al. Virucidal and antiviral activity of astodimer sodium against SARS-CoV-2 in vitro. *Antiviral Res* 2021;191:105089 (<https://doi.org/10.1016/j.antiviral.2021.105089>)

# VIRALEZE™ protects against infection in humanised SARS-CoV-2 challenge model

VIRALEZE™ protected animals and significantly reduced their viral load in a WHO recommended, humanized animal model of SARS-CoV-2 infection published in the peer-reviewed journal, **Viruses**

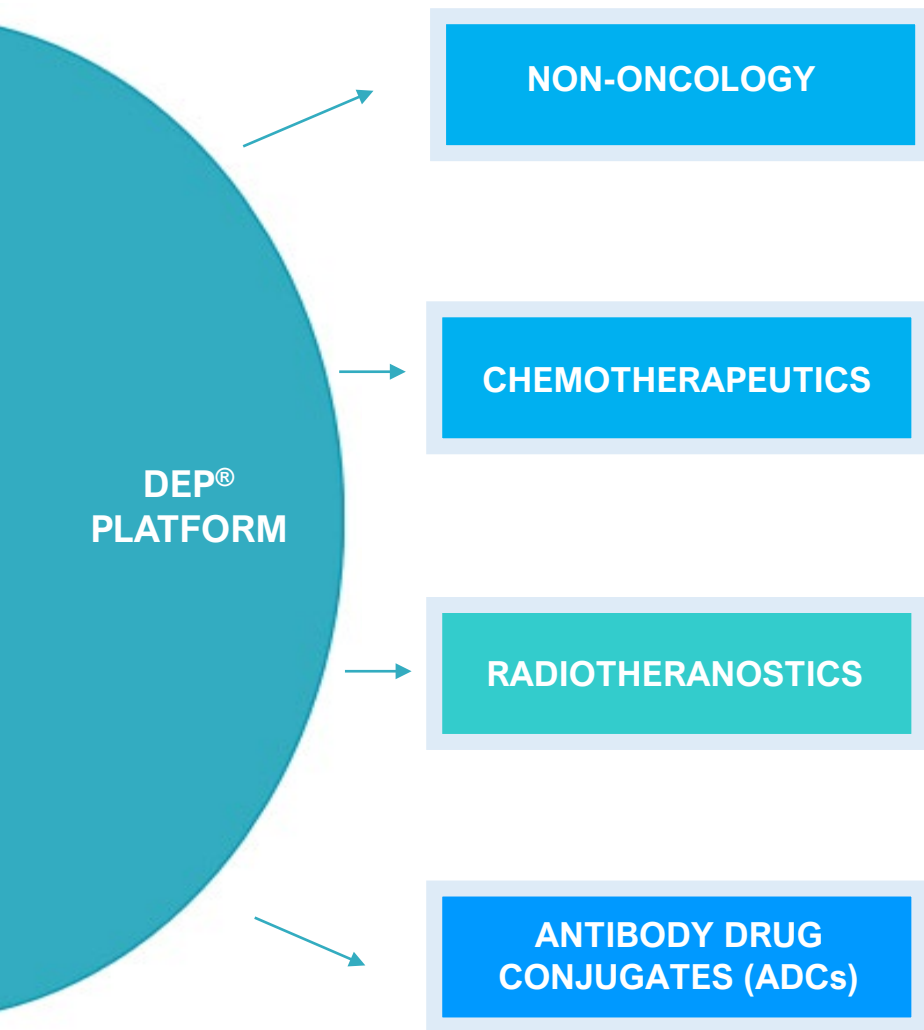
- **VIRALEZE™ administered nasally reduced viral load by >99.9% in the lungs and trachea** (vs. saline control) of animals challenged with SARS-CoV-2
- **Viral load in the nasal cavity** of animals treated with VIRALEZE™ was also **significantly lower (>90%)** compared with the control animals
- VIRALEZE™ treated animals had no infectious virus detected in brain or liver, in contrast to all control animals
- Pro-inflammatory cytokines (IL-6, IL-1α, IL-1β, TNFα and TGFβ) in serum, lung and trachea were significantly lower in VIRALEZE™ treated animals compared with the control animals



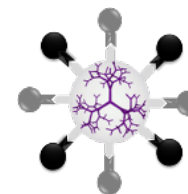
<https://www.mdpi.com/1999-4915/13/8/165>

**Figure 2.** The number of SARS-CoV-2 (USA-WA1/2020) viral genome copies (qRT-PCR) on Day 7 per nasal swab from K18-hACE2 mice treated with PBS or VIRALEZE™ nasal spray and infected with SARS-CoV-2 (USA-WA1/2020) (Antiviral) or infected with SARS-CoV-2 (USA-WA1/2020) inoculum pre-incubated with PBS or VIRALEZE™ nasal spray (Virucidal). Columns and error bars represent mean ± SEM. \* p < 0.05, \*\*\* p < 0.001, paired t-tests.

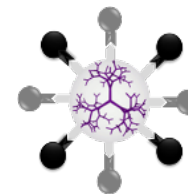
# DEP<sup>®</sup> is a technology platform with multiple commercial opportunities in oncology and beyond



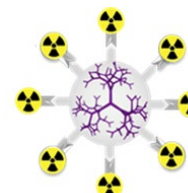
- Antiviral
- Anti-infective
- Endocrinology



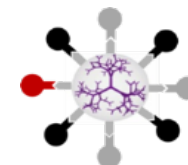
- Franchise extension
- Generic differentiation
- New Chemical Entities
- Combinations including immuno-oncology



- Radiotheranostic applications
- Can use variety of radioisotopes



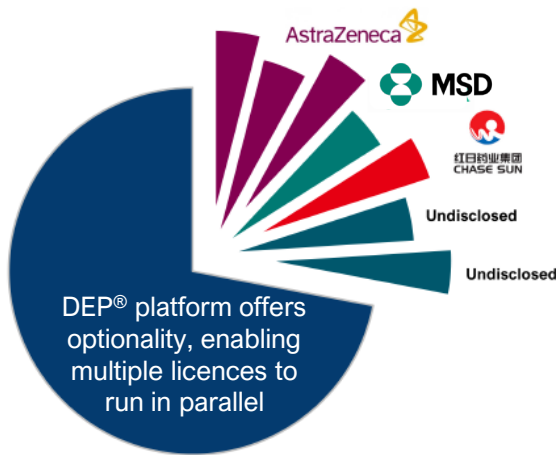
- Flexible technology
- Increased drug antibody ratio
- Targeting group agnostic
- Site selective payload attachment



# 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 allows for multiple partnerships



Starpharma has several disclosed/undisclosed partnered DEP<sup>®</sup> programs, including with large pharma companies: AstraZeneca, Merck and Chase Sun

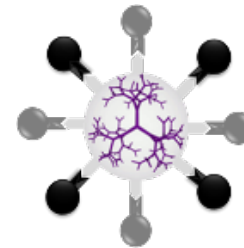
## AstraZeneca's novel DEP<sup>®</sup> nanoparticle AZD0466



- Dual Bcl2/xL inhibitor with DEP<sup>®</sup> significantly improving its therapeutic index
- Phase I trial significantly expanded and advanced in 2021, to a multi-region, global phase I/II clinical trial in advanced haematological malignancies aimed at seamless transition to phase II, to facilitate marketing approval
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AZ; US\$7M in milestones received to date
- **Total AZD0466 deal up to US\$124M + royalties (est. up to A\$2.4B revenue to SPL)**



AstraZeneca describes AZD0466 as having the **potential to be a "best-in-class" agent with a broad application in both solid and haematological tumours**



AZD0466 featured at AACR 2020 Meeting: [https://starpharma.com/drug\\_delivery/dep-posters](https://starpharma.com/drug_delivery/dep-posters)



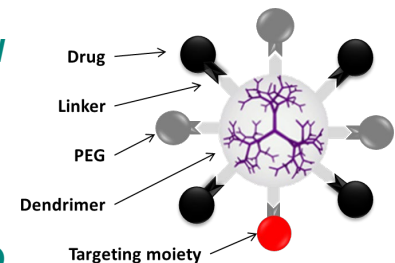
Starpharma has signed a DEP<sup>®</sup> research agreement with MSD for dendrimer-based ADCs using DEP<sup>®</sup> technology

### Recent ADC deals demonstrate strong interest

- AstraZeneca & Daiichi Sankyo, **US\$6.9 billion**, July 2020.
- Gilead & Immunomedics, **US\$21 billion**, Sep 2020.
- Seattle Genetics & Merck, **\$6.8 billion**, Sep 2020.
- Merck & VelosBio, **\$2.75B**, Nov 2020.
- Boehringer Ingelheim, **€1.2B (\$1.5B)**, Dec 2020.
- BMS & Eisai, **US\$3.1B**, June 2021.

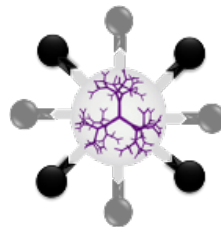
*"MSD is a recognised leader in oncology, and we are delighted to have signed this new Research Agreement in such an innovative and valuable area"*

**Dr Jackie Fairley, CEO Starpharma**



# AstraZeneca to present AZD0466 posters at 2021 ASH Meeting (Annual Society of Hematology)

- AZD0466 is a highly optimised nanomedicine formulation of AstraZeneca's novel dual Bcl-2/xL inhibitor that utilises Starpharma's DEP® technology.
- Dual Bcl-2/xL inhibition with AZD4320/AZD0466 has potential for broader activity than the marketed Bcl-2-specific inhibitor, venetoclax (Venclexta). In 2020, Venclexta had sales of ~US\$1.34 billion (+69 % cf. 2019)
- AZD0466 phase I/II trial design will facilitate seamless transition into phase II; the large global trial with multiple trial sites in the **US, Asia, EU & Australia**, for rapid recruitment.
- This development investment and expansion is being undertaken to facilitate expedited development of AZD0466 with the objective of obtaining regulatory approval as soon as possible for specific indication(s) of high unmet clinical need.



## Poster 1: 2353 NIMBLE: A Phase I/II Study of AZD0466 Monotherapy or in Combination in Patients with Advanced Hematological Malignancies

→ Provides an overview of the phase I/II clinical study of AZD0466 as a monotherapy or in combination in patients with advanced hematological malignancies (blood cancers).

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

## Poster 2: 1867 Combination Therapy of Bcl-2/XL dual Inhibitor AZD0466 with Acalabrutinib to Overcome Therapeutic Resistance in Aggressive R/R Mantle Cell Lymphoma

→ Highlights a study, conducted at the MD Anderson Cancer Center, of AZD0466 in combination with acalabrutinib to overcome therapeutic resistance in aggressive venetoclax-resistant mantle cell lymphoma (MCL) models. Compared to single agents AZD4320/AZD0466 and acalabrutinib, combination therapy demonstrated significant anti-MCL synergy both *in vitro* and *in vivo*.

<https://ash.confex.com/ash/2021/webprogram/Paper151609.html>

AZD0466 studies in a human mesothelioma model were recently [published in Nature](#), **nature**

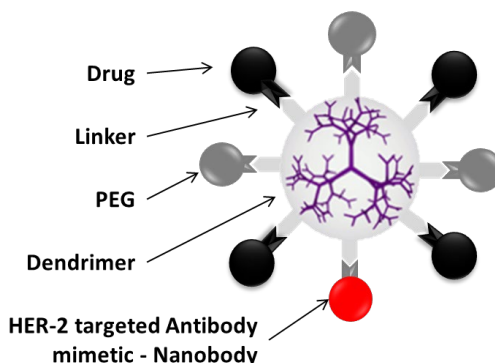
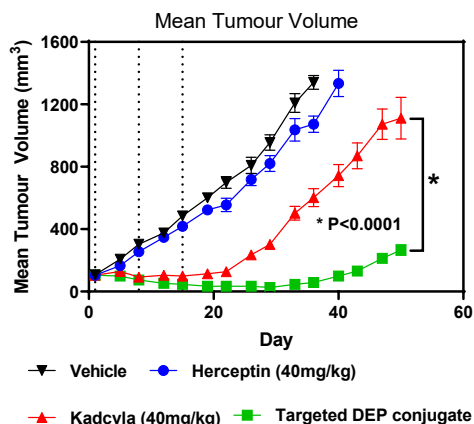
# DEP<sup>®</sup> Antibody Drug Conjugates (ADCs) further build the value of the platform

Starpharma's DEP<sup>®</sup> technology provides enhanced therapeutic benefits to ADCs including greater homogeneity, site specific attachment, and higher drug antibody ratio (DAR), than conventional ADC approaches



DEP<sup>®</sup> demonstrated significant tumour regression and 100% survival, outperforming Herceptin & Kadcylla in a human ovarian cancer model

## DEP<sup>®</sup> HER-2 ADC:



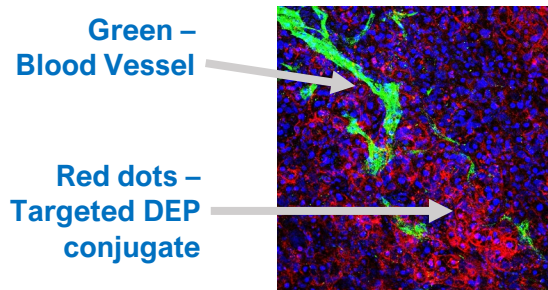
Starpharma has signed a DEP<sup>®</sup> research agreement with MSD for dendrimer-based ADCs using DEP<sup>®</sup> technology

### Recent ADC deals – growing interest

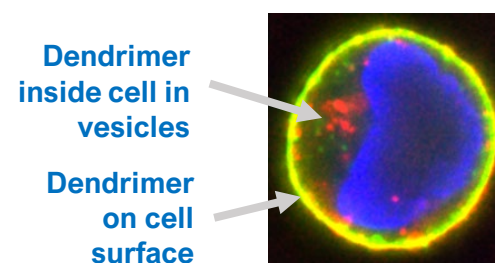
- AstraZeneca & Daiichi Sankyo, **US\$6.9 billion**, July 2020
- Gilead & Immunomedics, **US\$21 billion**, Sep 2020
- Seattle Genetics & Merck, **\$6.8 billion**, Sep 2020
- Merck & VelosBio, **\$2.75B**, Nov 2020
- Boehringer Ingelheim, **€1.2B (\$1.5B)**, Dec 2020
- BMS & Eisai, **US\$3.1B**, June 2021



**Kadcyla**<sup>®</sup> 2019 sales of Roche's Kadcyla<sup>®</sup> US\$1.62B and Adcetris >US\$1B



Targeted DEP<sup>®</sup> penetrates deep into the tumour (left) and then binds and is internalised into tumour cells (right) for antitumour effect



# DEP<sup>®</sup> internal oncology programs

## Multiple clinical-stage assets with high commercial value potential

### COMMERCIAL OBJECTIVE



Create value through clinical proof-of-concept in one or more cancer types – alone and/or in combination



License following proof-of-concept clinical data; platform validation



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

### PHASE II



**DEP<sup>®</sup> DOCETAXEL:**  
Enhanced 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

**Advantages of DEP<sup>®</sup> docetaxel<sup>##</sup>:**  
Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; tumour-targeting (~70x more); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).

### PHASE II



**DEP<sup>®</sup> CABAZITAXEL:**  
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>)

Cabazitaxel (Jevtana<sup>®</sup>) – global sales of ~US\$500M for 2019 despite having multiple US FDA “Black Box” warnings

**Advantages of DEP<sup>®</sup> cabazitaxel<sup>\*</sup>:**  
Improved toxicity profile; detergent-free formulation; no steroid pre-treatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).

### PHASE II



**DEP<sup>®</sup> IRINOTECAN:**  
Improved 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.

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



Starpharma's deep preclinical pipeline includes DEP<sup>®</sup> chemotherapeutic candidates including:

- DEP<sup>®</sup> gemcitabine
- DEP<sup>®</sup> radiotherapeutic candidates
- DEP<sup>®</sup> antibody drug conjugate (ADC) candidates
- Further therapeutic candidates

<sup>##</sup>Clinical studies have demonstrated reduction in important side effects with DEP<sup>®</sup> including bone marrow toxicity, anaphylaxis, oedema and hair-loss

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



# DEP<sup>®</sup> internal oncology clinical programs

## Multiple clinical-stage assets with high commercial value potential

### COMMERCIAL OBJECTIVE



Create value through clinical proof-of-concept in one or more cancer types – alone and/or in combination



License following proof-of-concept clinical data; platform validation



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

### PHASE II



**DEP<sup>®</sup> DOCETAXEL:**  
Enhanced version of docetaxel (Taxotere<sup>®</sup>) – widely used for breast, lung & prostate cancer

Phase II trial ongoing, 64 patients recruited<sup>^</sup>

- **Encouraging efficacy signals** observed, including prolonged stable disease and significant tumour shrinkage in heavily pre-treated patients in tumours including lung, pancreatic, oesophageal, cholangiocarcinoma and gastric cancers.
- **Notable lack of bone marrow toxicity** (e.g., neutropenia) and other common side effects inc. hair-loss, mouth ulcers, anaphylaxis and oedema.

### PHASE II



**DEP<sup>®</sup> CABAZITAXEL:**  
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>)

Phase II, ongoing, 47 patients recruited<sup>^</sup>

- **Encouraging efficacy signals** have been observed in its major indication, prostate cancer, including radiological responses, significant reductions in prostate-specific antigen (PSA) and lack of new bone metastases. In addition, efficacy signals have also been seen in heavily pre-treated patients with gastro-oesophageal, ovarian, cholangiocarcinoma, lung, thymic and head and neck cancers.
- **Significantly less toxicity** than is usually associated with Jevtana<sup>®</sup>.

### PHASE II



**DEP<sup>®</sup> IRINOTECAN:**  
Improved version of irinotecan (Camptosar<sup>®</sup>) - predominantly used for colorectal cancer

Phase II, ongoing, 60 patients recruited<sup>^</sup>

- **Encouraging efficacy signals** observed including impressive and prolonged tumour shrinkage and reductions in tumour marker levels for multiple tumour types, including colorectal, breast, ovarian, pancreatic, lung and oesophageal cancer.
- **No severe high-grade diarrhea seen with DEP<sup>®</sup> irinotecan** which is experienced by 20-40% of patients with conventional irinotecan & often requires hospitalisation.



Starpharma's deep preclinical pipeline includes DEP<sup>®</sup> chemotherapeutic candidates including:

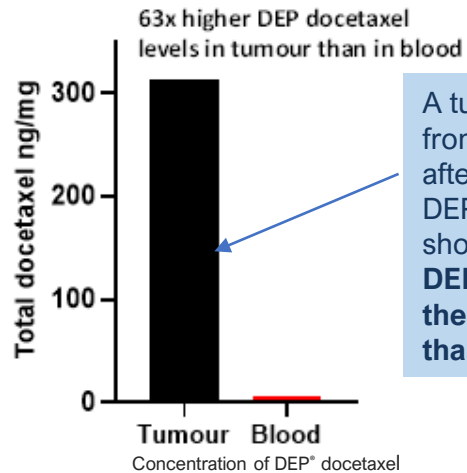
- DEP<sup>®</sup> gemcitabine
- DEP<sup>®</sup> radiotherapeutic candidates
- DEP<sup>®</sup> antibody drug conjugate (ADC) candidates
- Further therapeutic candidates

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

**DEP<sup>®</sup> docetaxel trial case study: 72-year-old woman:** extensive **intrahepatic cholangiocarcinoma**, an often-fatal cancer that affects the bile ducts

Cholangiocarcinoma is a rare but aggressive form of cancer. The 5-year survival rate for intrahepatic cholangiocarcinoma is very low (8%).

- Patient was heavily pre-treated having progressed following 8 cycles of prior anti-cancer therapy
- Patient received 4 cycles of DEP<sup>®</sup> docetaxel and achieved >28 weeks stable disease



<https://www.cancer.net/cancer-types/bile-duct-cancer-cholangiocarcinoma/statistics>

**DEP<sup>®</sup> docetaxel trial case study: 66-year-old man:** stage IV **oesophageal cancer** with liver metastases

Oesophageal cancer is the seventh most common cause of cancer death among men. The estimated 5-year survival rate for stage IV disease is only 10% -15%.

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



**48%**  
reduction in  
size of  
tumour lesion



<https://www.cancer.net/cancer-types/esophageal-cancer/view-all>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642056/>

# DEP<sup>®</sup> cabazitaxel: clinical case studies

## DEP<sup>®</sup> cabazitaxel trial case study: 65-year-old man with late-stage (metastatic) gastro-oesophageal cancer

Oesophageal cancer is the seventh most common cause of cancer death among men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Heavily pre-treated patient with >15 cycles & three different kinds of anti-cancer treatment and cancer progressed
- Response to DEP<sup>®</sup> cabazitaxel: Patient received 6 cycles of DEP<sup>®</sup> cabazitaxel and achieved a 50% reduction in total tumour size maintained for >27 weeks

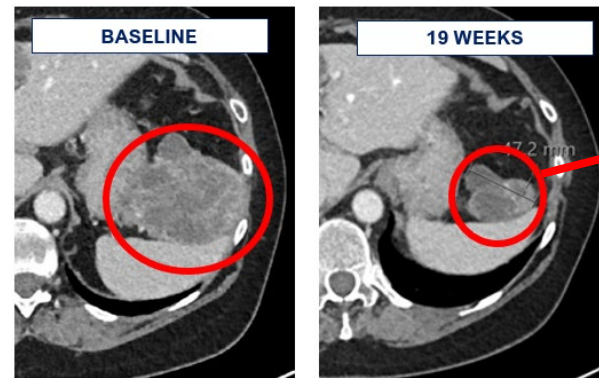


<https://www.cancer.net/cancer-types/esophageal-cancer/view-all>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642056/>

## DEP<sup>®</sup> cabazitaxel trial case study: 60-year-old woman with advanced (metastatic) ovarian cancer

Ovarian cancer has the lowest survival rate of women's cancer and is the eighth most commonly occurring cancer in women.

- Heavily pre-treated; cancer progressed on 3 other anti-cancer therapies including paclitaxel (another taxane); Previously had 14 cycles of treatment and multiple surgeries
- Response to DEP<sup>®</sup> cabazitaxel: Patient received 6 cycles of DEP<sup>®</sup> cabazitaxel - response seen after 3 cycles of treatment with overall response:
  - 40% reduction in total tumour burden for 27 weeks
  - 50% reduction in biomarkers



**43%  
reduction  
in size of  
abdominal  
tumour  
lesion**



<https://www.cancercenter.com/cancer-types/ovarian-cancer/types>

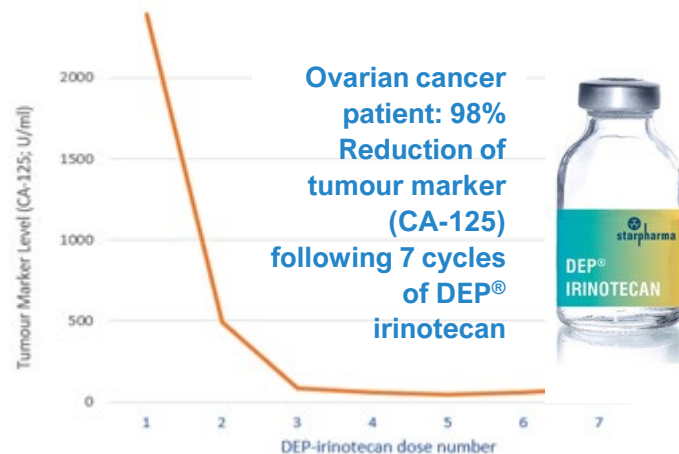
# DEP<sup>®</sup> irinotecan: clinical case studies

**DEP<sup>®</sup> irinotecan trial case study:** 55-year-old woman with heavily pre-treated **metastatic ovarian cancer**, which has a particularly poor prognosis.

Ovarian cancer has the lowest survival rate of women's cancer and is the eighth most commonly occurring cancer in women

- **Heavily pre-treated with > 60 treatment cycles of 6 lines of prior anti-cancer therapy**
- **Received 9 dose cycles of DEP<sup>®</sup> irinotecan to date**
- **Stable disease for >27 weeks (lesion no longer visible) and**
- **Achieved 98% reduction in CA-125 tumour marker from baseline**

CT scans showed a complete disappearance of her ovarian target tumour after 7 cycles of treatment with DEP<sup>®</sup> irinotecan.

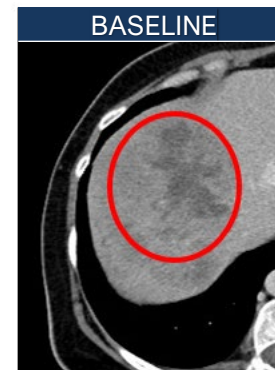


<https://www.cancercenter.com/cancer-types/ovarian-cancer/types>

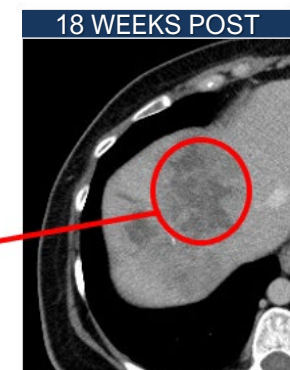
**DEP<sup>®</sup> irinotecan trial case study:** 45-year-old woman with **stage IV breast cancer with extensive liver metastases**

Breast cancer is the most common cancer affecting women and is the second leading cause of cancer-related death in Australian women, accounting for 14.9% of all female cancer deaths

- **Extensive metastases including in the liver**
- **Very heavily pre-treated with >100 cycles of 11 different treatment regimens**
- **Response to DEP<sup>®</sup> irinotecan seen after 3 cycles of treatment**
- **20 cycles of DEP<sup>®</sup> irinotecan treatment to date; well tolerated**
- **Prolonged stable disease >71weeks; 21% reduction in target tumours**



CT Scan showing 30% reduction in size of liver metastasis



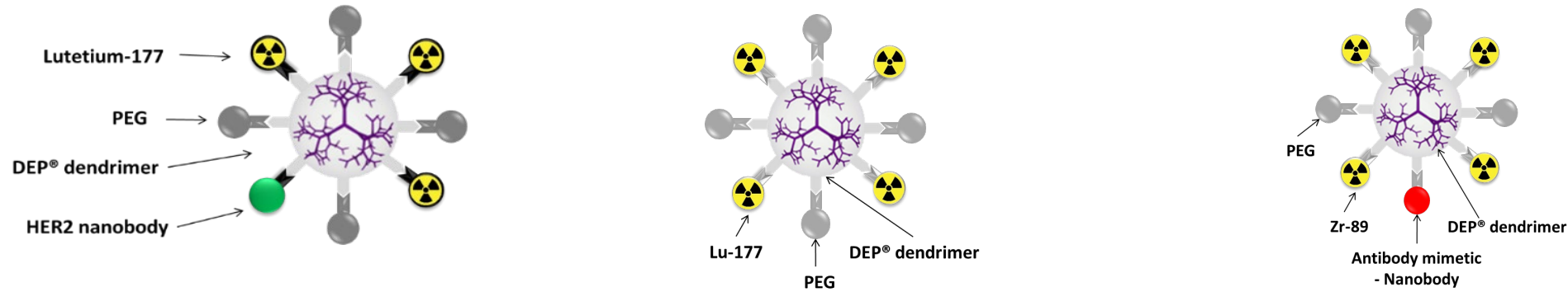
<https://www.cancer.org.au/cancer-information/types-of-cancer/breast-cancer>  
<https://www.bcna.org.au/media/6101/bcna-2018-current-breast-cancer-statistics-in-australia-31jan2018.pdf>

# DEP<sup>®</sup> radiotheranostics

DEP<sup>®</sup> is a valuable tool for radiodiagnostics and radiotherapeutics

## Starpharma has developed multiple novel radiotheranostic candidates

DEP<sup>®</sup> radiopharmaceutical conjugates have the potential to minimise off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches



## Rapidly growing radio-pharmaceuticals market

The radiopharmaceuticals area is a rapidly developing area of cancer treatment and diagnosis, which has recently generated several high-value deals. Sales in this category are estimated to grow to US\$12–15 billion by 2030<sup>1</sup>



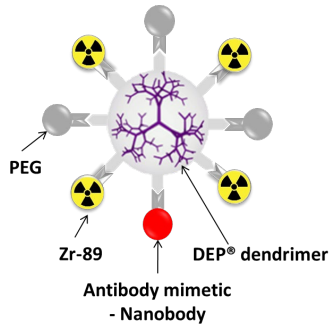
# DEP<sup>®</sup> - a valuable tool for radiodiagnostics and radiotherapeutics

## Starpharma has developed multiple novel radiotheranostic candidates

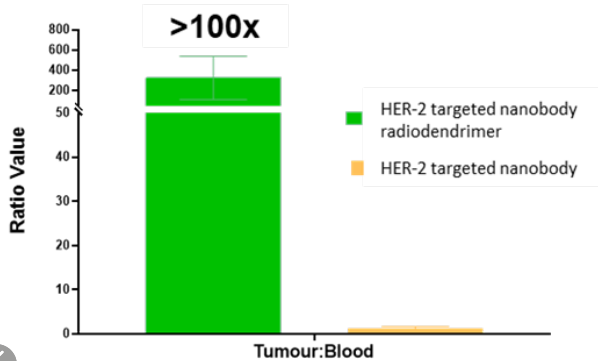
DEP<sup>®</sup> radiopharmaceutical conjugates have the potential to minimise off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches

### DEP<sup>®</sup> zirconium

DEP<sup>®</sup> radiodiagnostic candidate, DEP<sup>®</sup> zirconium, showed significant tumour accumulation: >100x in tumour v blood

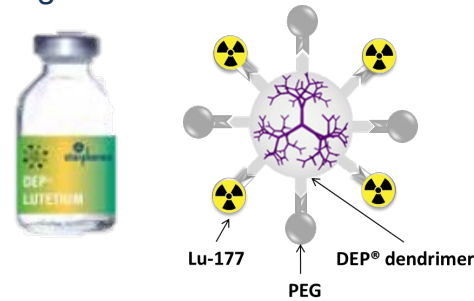


Tumour to Blood Ratio (9 days)

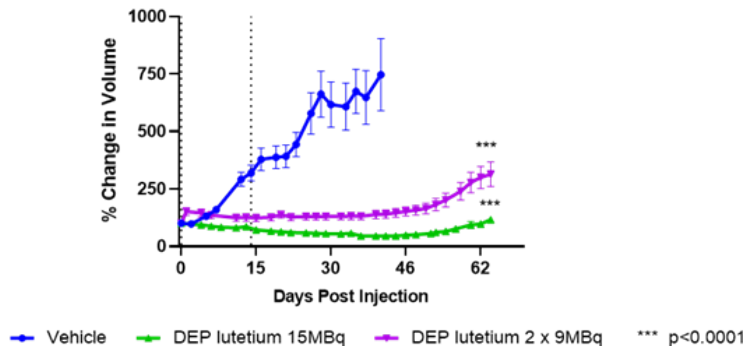


### DEP<sup>®</sup> lutetium

Starpharma's first DEP<sup>®</sup> radiotherapy candidate showed highly statistically significant anticancer activity, tumour regression and 100% survival<sup>1</sup>



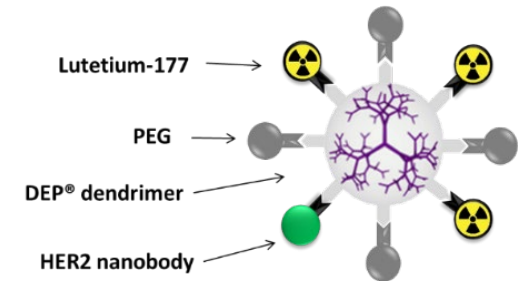
Mean % Change Tumour Volume



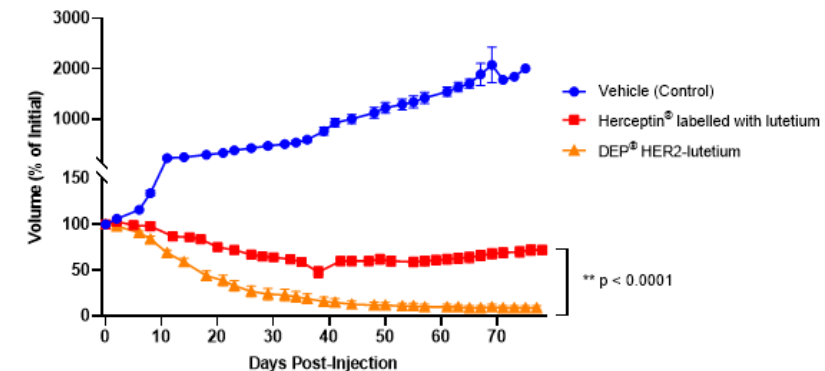
<sup>1</sup> 100% survival to >66 days human prostate cancer model (DU-145)

### DEP<sup>®</sup> HER2-lutetium

Starpharma's second DEP<sup>®</sup> radiopharmaceutical candidate showed complete tumour regression, outperforming Herceptin<sup>®</sup> labelled with lutetium, in a human breast cancer model.



Tumour Volume Change (% of Initial Volume)



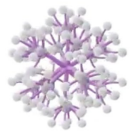
# VivaGel® BV - a breakthrough product for the management of BV – the most common vaginal infection worldwide, affecting 1 in 3 women

Bacterial vaginosis or BV is caused by an imbalance of naturally occurring normal bacterial vaginal flora (an overgrowth of pathogenic bacteria)

BV can lead to a range of medical problems including pelvic inflammatory disease, infertility, premature delivery and miscarriage, low birth weights and uterine infection.

## Current BV therapies are inadequate - and do not prevent BV recurring:

- × Current BV treatment is typically with antibiotics (e.g. metronidazole)
- × Antibiotic resistance is a problem and antibiotics have unpleasant side effects and other issues that limit usage
- × No US approved therapies for prevention of recurrent BV



*“This product represents a true innovation in the management of BV”.*

CEO, Mundipharma



Rapid relief of odour in 24 hours



Targets harmful BV-causing bacteria



Clinically proven to treat BV



Clinically proven to prevent recurrent BV




Restores vaginal flora, normalises pH levels



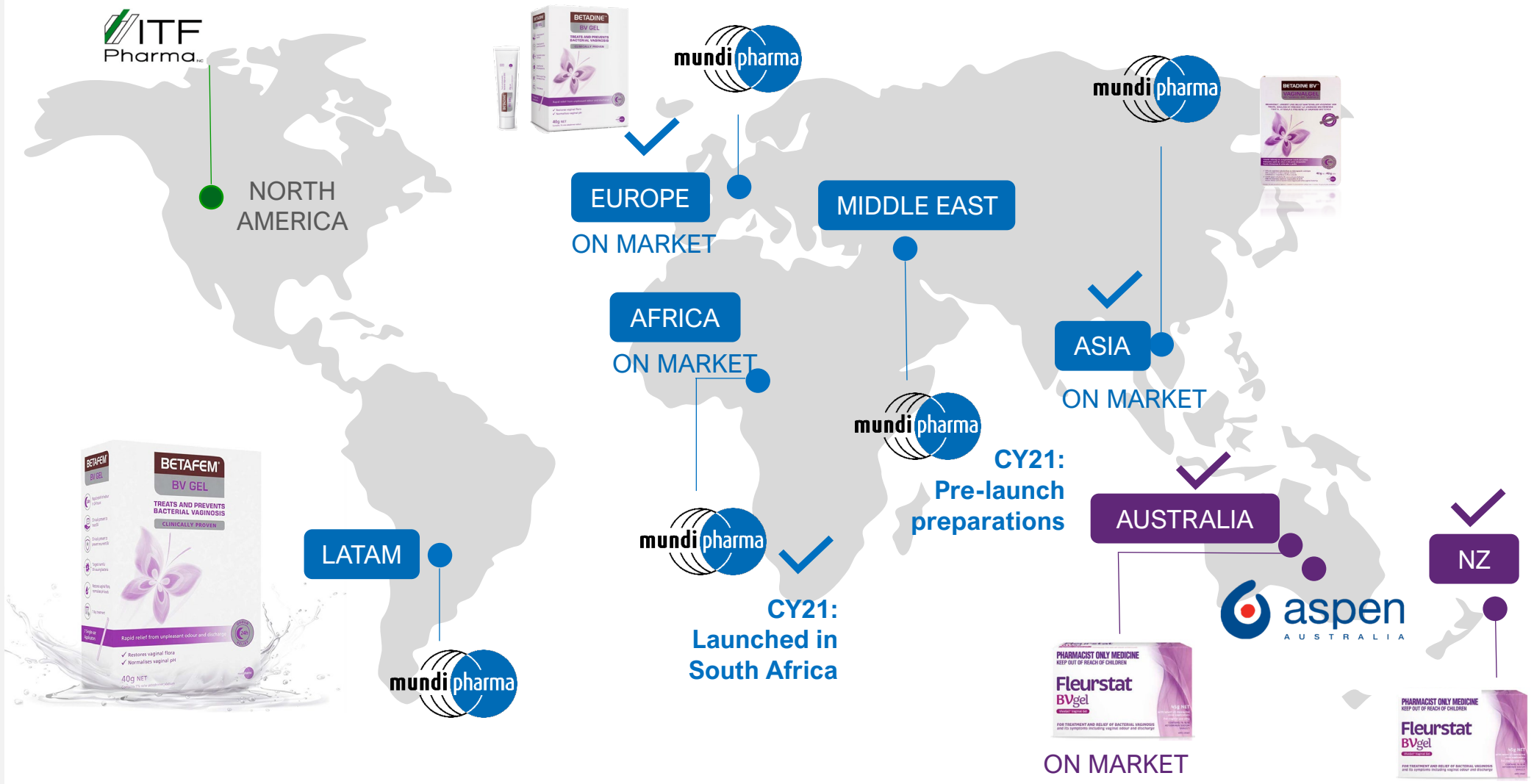
# VivaGel® BV licensed in >160 countries around the world

 Global market for BV treatment est. to be US\$750M and prevention est. to be US\$1B annually

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

 Further launches and regulatory submissions progressing in multiple regions

## Approved in >45 countries with multiple other submissions underway

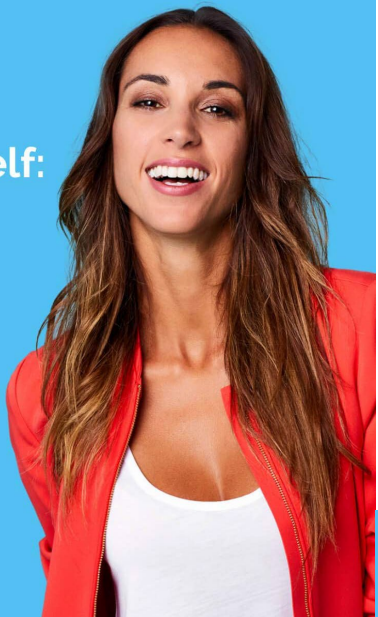


- In the US, a formal dispute resolution process is ongoing with the FDA as part of the regulatory process for VivaGel® BV, and COVID-19 has had an impact on timing.
- VivaGel® BV's Fast Track status & QIDP (qualified infectious disease status) remain on foot based on potential for VivaGel® BV to address a serious infection and significant unmet need in BV.



**BETAFEM<sup>®</sup>**

Get back to yourself:  
Treat Bacterial  
Vaginosis PLUS  
relieve its  
symptoms\*



**BETAFEM<sup>®</sup> Is Part Of The  
Trusted BETADINE<sup>®</sup>  
Brand .**

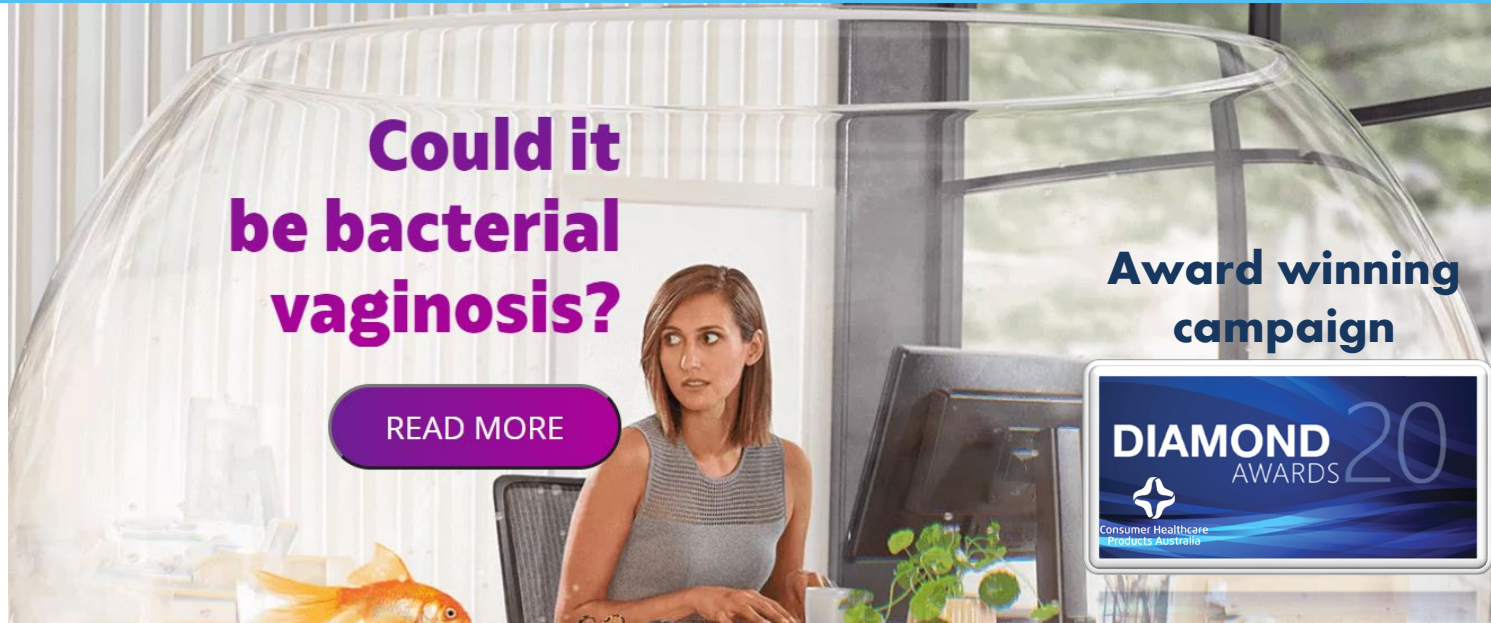


**Marketing campaigns for VivaGel<sup>®</sup> BV in multiple regions**



*After 18 months on market,  
79% of Pharmacists are  
aware & 53% of most often  
recommend Fleurstat.*

**Source:** ACA Research Fleurstat Brand Tracking Study –  
in field Nov 2020, n= 150 Pharmacists.



**FLEURSTAT BVGEL RANKS AS #1 TOPICAL BV TREATMENT IN AUSTRALIA**

**FLEURSTAT BVGEL (VivaGel<sup>®</sup> BV) for the treatment of BV and relief of symptoms:** Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. 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, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).



# Key value drivers and outlook - DEP®



- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan phase II trials; progress value-adding combination studies



- AZD0466 clinical progress, expansion of trial sites recruitment & receipts from milestones

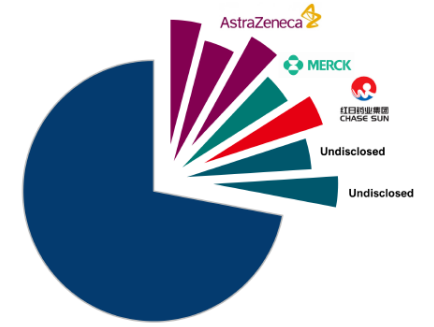
- AstraZeneca: Exercise of Option Agreement &/or deals for further compounds



红日药业集团  
CHASE SUN



- Progress with existing partnered DEP® programs, including with Merck & Co., Inc., & Chase Sun
- Execute/expand new DEP® partnerships/agreements
- Advance DEP® radiopharmaceuticals, DEP® ADCs & DEP® antivirals
- Advance value-adding DEP® combinations in clinic & other DEP® products



# Key value drivers and outlook - VIRALEZE™ and VivaGel® BV



- Further roll-out of VIRALEZE™ Antiviral Nasal Spray
- Further VIRALEZE™ registrations in other regions
- Further VIRALEZE™ launches in other regions



- Further distribution & marketing arrangements with commercial partners
- Continued testing of SPL7013 against SARS-CoV-2 variants & other respiratory viruses

- Commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Further regulatory approvals & launches for VivaGel® BV; building revenues – milestones & sales/royalties
- Ongoing formal FDA review process

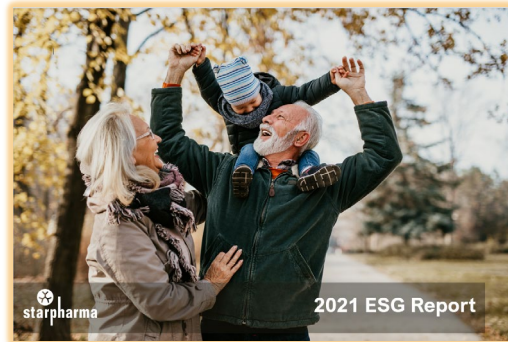


- Further VivaGel® BV licences
- VivaGel® condom approvals/launch in additional regions
- Further development/ co-development of SPL7013



# Starpharma's Commitment to ESG: *The very nature of Starpharma's products affords the opportunity of changing lives for the better*

- Through innovative research and development, Starpharma and its partners are creating therapies which have the potential to profoundly improve patient health worldwide.
- Starpharma remains committed to delivering positive societal outcomes: innovative and life-changing therapies, greater diversity and continued equality in our workforce and a responsible supply chain.
- Starpharma is one of a handful of Australian biotech companies that has successfully developed a product from bench to market.
- Starpharma's supplier code includes a wide range of business practices to provide suppliers with clear expectations regarding their conduct, particularly in relation to employment principles; anti-bribery and fair competition; health and safety; environment; data privacy and information protection; confidentiality and insider trading.
- **Starpharma is continually reviewing applicable guidance on responsible sourcing and sustainable procurement** with the aim of creating greater social and sustainability benefits through its purchasing activities.
- **Starpharma's ESG framework** reflects Starpharma's commitment to ensuring our products are developed safely and ethically, in strict compliance with relevant regulatory requirements, including in the areas of research, commercialisation and supply chain management



[Download Report](#)

## ENVIRONMENT

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






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

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## SOCIAL



>40% of roles, including leadership roles are held by females

**60% of directors are female**

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

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17 countries represented by a small, diverse group of employees



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## GOVERNANCE

Compliance with



No breaches of:

- Code of Conduct
- Anti-bribery
- Whistleblowing

DIRECTOR INDEPENDENCE





Corporate Governance Principles and Recommendations  
4th Edition

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

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

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.



**FOR INVESTOR RELATIONS  
ENQUIRIES CONTACT:**

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ASX:SPL OTC:SPHRY

