

## Starpharma to present at Virtual Life Sciences Investor Forum

**Melbourne, Australia; 24 June 2021:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that a presentation by Dr Jackie Fairley, CEO, will be broadcast on Thursday 24 June 2021 (US ET) as part of OTCQX's Virtual Life Sciences Investor Forum. The Life Sciences Investor Forum is a leading investor conference that is attended by tens of thousands of investors, primarily US-based retail investors, as well as advisors.

Details of the forum are found via this link: [Virtual Life Sciences Investor Forum](#). Starpharma's pre-recorded presentation features a company overview, including the latest updates on the VIRALEZE™ Antiviral Nasal Spray which has shown potent antiviral activity against multiple variants of coronavirus/SARS-CoV-2 in laboratory studies, and has been registered in Europe (launched) and India. The presentation will also include an overview of Starpharma's DEP® clinical-stage and preclinical assets, and corporate partnerships for its DEP® drug delivery platform, including with Merck & Co., Inc (MSD) and AstraZeneca, as well as its VivaGel® products, which are approved in more than 45 countries. 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 COVID-19, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray for COVID-19, which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE™ is registered for sale in the UK/Europe and India, and available in certain markets via [www.viraleze.co](http://www.viraleze.co). VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® BV has been licensed in >160 countries, is approved 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®, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies. DEP® 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® programs have the potential to generate significant future milestones and royalties.

[Starpharma.com](http://Starpharma.com) | [Twitter](#) | [LinkedIn](#)

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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.

## OTCQX Virtual Investor Conference

24 June 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\$1.55
Shares on issue	406M
Market capitalisation	~A\$630M
Daily average volume (shares)	~843k
Cash on hand - as at 31/03/21	\$64.3M
Share register	Institutions ~55% Retail ~40% Staff & other ~5%

Share price & market cap at 21/06/2021

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 (>150 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, available in multiple countries via [www.viraleze.co](http://www.viraleze.co)



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



**VivaGel® BV** – Approved 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® products on market, SPL7013 antivirals and multiple DEP® clinical assets

Extensive & growing pipeline of proprietary assets

Multiple clinical stage assets

Multiple approved products



**INTERNAL & PARTNERED**

**INTERNAL**

**LICENSED**

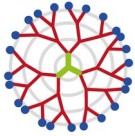
**PARTNERED**

**FURTHER APPROVALS**

**LICENCE AFTER PROOF OF CONCEPT**

**APPROVED PRODUCTS**

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



SPL7013  
Astodimer  
Sodium

- Broad-spectrum antiviral nasal spray containing 1% w/w astodimer sodium (SPL7013), shown in laboratory studies to inactivate respiratory viruses, including >99.9% of coronavirus SARS-CoV-2.<sup>1</sup>
- **Virucidal, irreversibly and rapidly inactivating >99.9% of multiple variants of coronavirus/SARS-CoV-2**
- **Astodimer sodium (SPL7013) irreversibly inactivates a broad spectrum of respiratory viruses**
- **VIRALEZE™ is registered for sale in the UK/Europe & India; partnered with LloydsPharmacy in the UK**

**LloydsPharmacy**



## 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.**<sup>1</sup>
- ✓ **Potent antiviral activity against multiple strains of SARS-CoV-2, including 'Variants of Concern', Alpha, Beta, Gamma.**
- ✓ Ability to inactivate virus either before or after exposure.
- ✓ Contains a well-tolerated, already marketed active, which is not absorbed into the bloodstream.
- ✓ Provides a moisturising and protective barrier to help keep nasal tissue hydrated.
- ✓ Room temperature storage, easy and convenient for regular use.

<sup>1</sup> 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>)

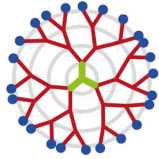
## VIRALEZE™ Clinical study completed

- ✓ Starpharma conducted 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 consecutive days. All participants have completed the study.
- ✓ Finalisation and analysis of some trial data is still underway but VIRALEZE™ nasal spray (and placebo) were both extremely well tolerated by all participants.



# The science behind VIRALEZE™

SPL7013 has demonstrated potent activity in influenza, SARS, MERS and RSV; as well as HIV, HSV, HPV, Adenovirus, HBV, Zika

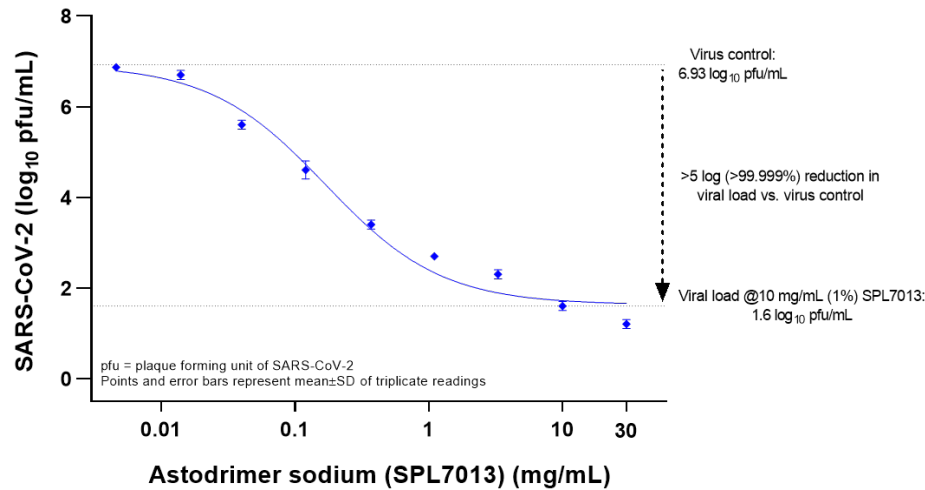


SPL7013  
Astodimer  
Sodium

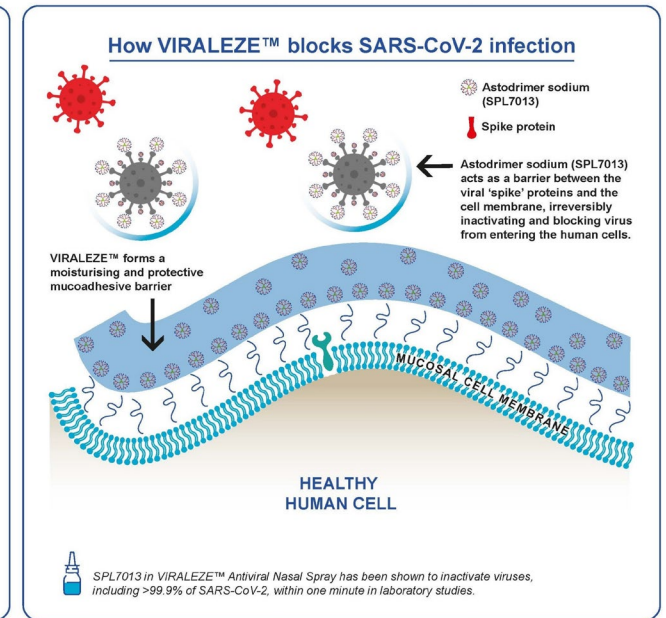
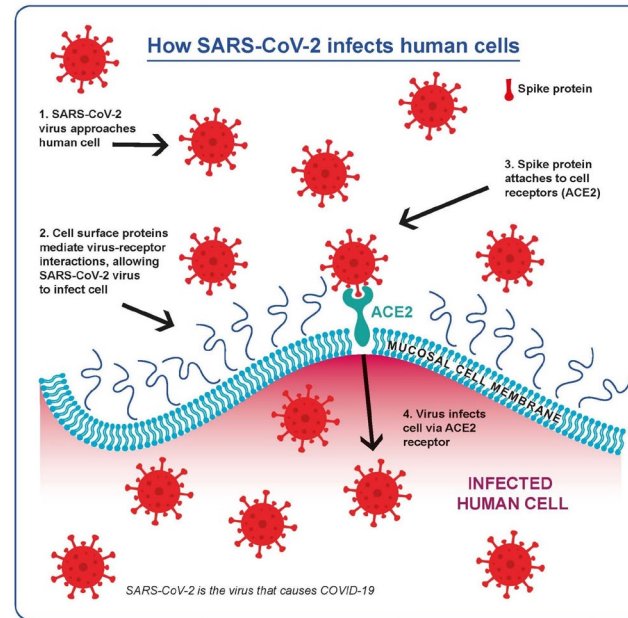
- Extensive research has been conducted at the **Scripps Research Institute** in the US and is published in the prestigious, peer reviewed scientific journal, **Antiviral Research**.
- A 1% w/w concentration of astodimer sodium (the same concentration found in VIRALEZE™) when applied to SARS-CoV-2, has been shown to **inactivate >99.9% of the virus within one minute**<sup>1</sup>.
- The active in VIRALEZE™, astodimer sodium (SPL7013), has a deep pedigree as an antiviral compound, with extensive published data, and is in products that are already approved and on market in more than 45 countries.



SPL7013 vs SARS-CoV-2 Virucidal Assay



**Figure 1 (above):** Dose-response analysis of SARS-CoV-2 (2019-nCoV/USA-WA1/2020) antiviral activity of astodimer sodium in Vero E6 cells as measured by infectious virus release. Astodimer sodium was added to cell cultures 1-hour prior to or 1-hour post-infection.



<sup>1</sup> 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>)

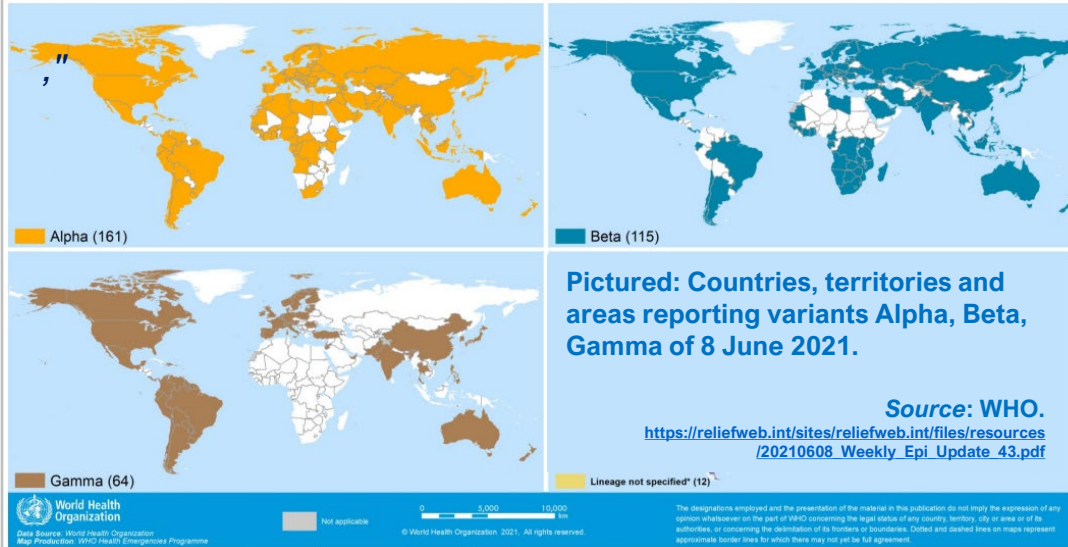


# VIRALEZE™ active (SPL7013) has been shown to have potent virucidal activity (>99%) against multiple SARS-CoV-2 ‘Variants of Concern’



*“We know this virus knows no geographic borders and **addressing this reality is more pressing than ever before, given the rapid proliferation of Covid-19 variants that stand to reverse the progress that has been made to control this pandemic.**”*

*CDC Director Dr. Rochelle Walensky*



*“We are impressed with the **rapid and potent virucidal and antiviral activity of SPL7013, and that it is highly active against the Alpha, Beta, and Gamma variants. 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.**”*

Professor Philippe Gallay, US Scripps Research Institute

- Antiviral testing has confirmed SPL7013 (VIRALEZE™ active) has potent (>99%) virucidal activity against the **Alpha (UK), Beta (South Africa) and Gamma (Japan/Brazil)** variant strains of SARS-CoV-2 coronavirus in laboratory studies
- The 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**<sup>1</sup>
- 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
<b>30 seconds</b>	>99.9%	>99.9%	>99%	>99%
<b>1 minute</b>	>99.9%	>99.9%	>99%	>99%
<b>5 minutes</b>	>99.9%	>99.99%	>99.9%	>99.9%
<b>30 minutes</b>	>99.99%	>99.99%	>99.99%	>99.99%

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

<sup>1</sup> <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern>

# VIRALEZE™ Harlequins partnership illustrates potential sporting and occupational opportunities for the product



Given its broad spectrum of activity in SARS CoV-2 strains and variants VIRALEZE™ could prove to be particularly useful in a range of settings



Sporting matches - teams and spectators



International travel



Major international events such as the Tokyo Olympics



Hotel Quarantine

Iconic UK rugby team Harlequins recently partnered with VIRALEZE™



Harlequins

Harlequins' Head of Medical Services, Dr. Mike Lancaster, said the Quins were delighted to add VIRALEZE™ to the range of safety measures already in place to protect players from COVID-19.

*“Player health is paramount in professional sport and now more than ever, we look to maximise the level of protection we can offer our players. The VIRALEZE™ partnership is an important additional level of protection for our Men’s and Women’s players against viruses such as flu and coronavirus/SARS-CoV-2.”*

# VIRALEZE™ - market research shows a high level of consumer interest

***“Of course, I would (be interested in a spray available for prevention), yeah!”***

Consumer research, November 2020

***“...You can use this and feel better about going to work. Not so anxious all the time.”***

Consumer research, November 2020

***“...shopping malls, public transport; you use it because you’re going to at risk areas.... then yes, why not.”***

Consumer research, November 2020

***“It looks really, really useful. It really does. It would reduce the risk of developing Covid-19. Straightaway, that captures you.”***

Consumer research, November 2020



***“So I think wearing gloves and a mask reduces the risk, but not enough... this would reduce it even more just an additional barrier”***

Consumer research, November 2020

***“Wow. I would take that... I'll take it before I go to work”***

Consumer research, November 2020

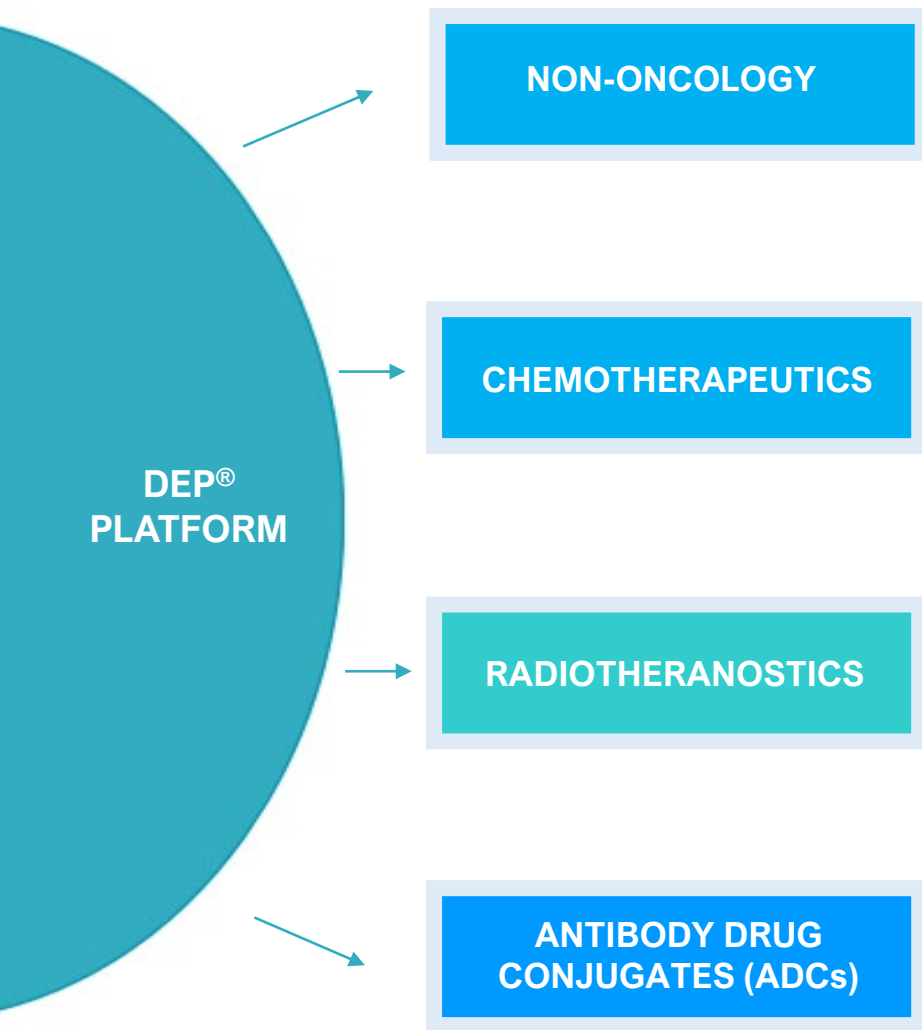
***“Yeah, I would use it definitely. It does make sense”***

Consumer research, November 2020

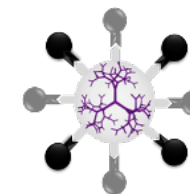
***“Buying online is not a problem for me. I buy virtually everything online”***

Consumer research, November 2020

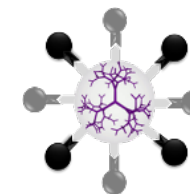
# DEP<sup>®</sup> is a technology platform with multiple commercial opportunities in oncology and beyond



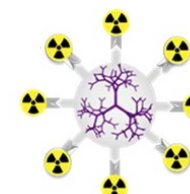
- Antiviral
- Anti-infective
- Endocrinology



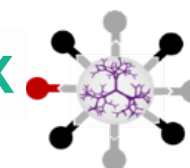
- Franchise extension
- Generic differentiation
- New Chemical Entities
- Combinations including immuno-oncology



- Radiotheranostic applications
- Can use variety of radioisotopes



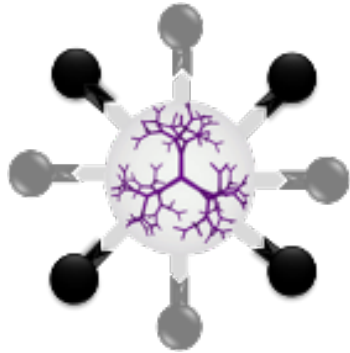
- Flexible technology
- Increased drug antibody ratio
- Targeting group agnostic
- Site selective payload attachment



# DEP<sup>®</sup> benefits

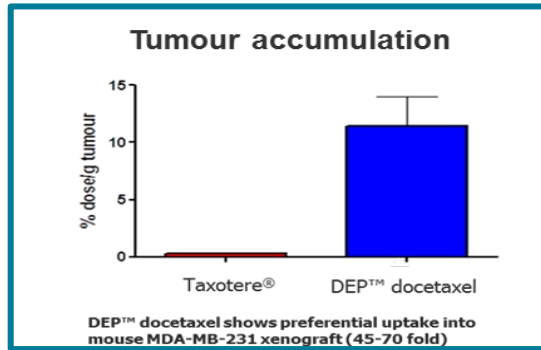
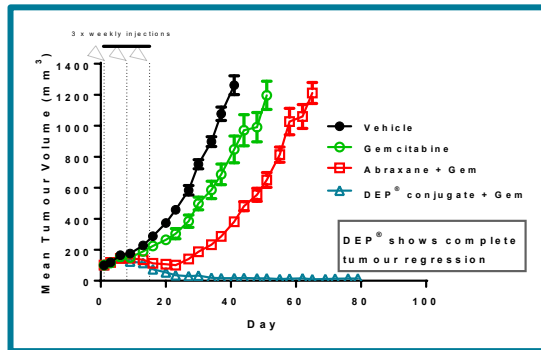
Starpharma's DEP<sup>®</sup> platform conveys product benefits and enhances the commercial value of a wide range of drugs and therapeutic areas

**DEP<sup>®</sup> platform:  
numerous  
reproducible benefits  
across multiple drugs**



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

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



## DEP<sup>®</sup> BENEFITS\*

**Improved Efficacy**  
Reproducible results with many candidates & tumour types

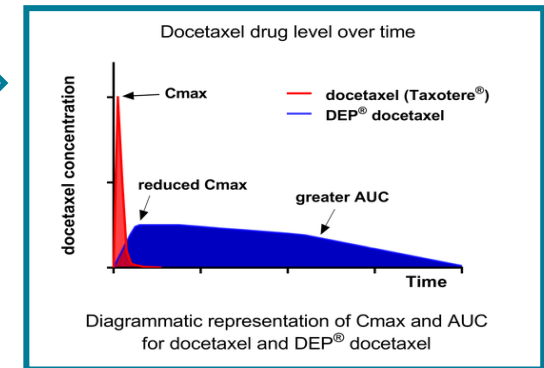
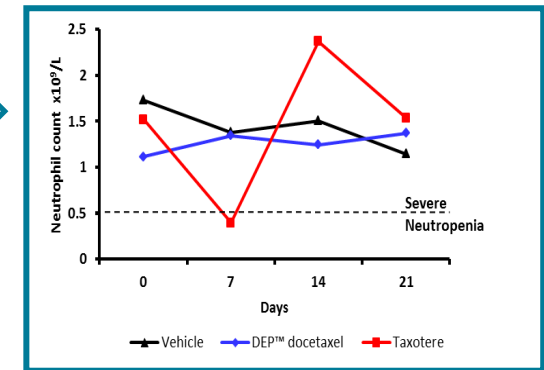
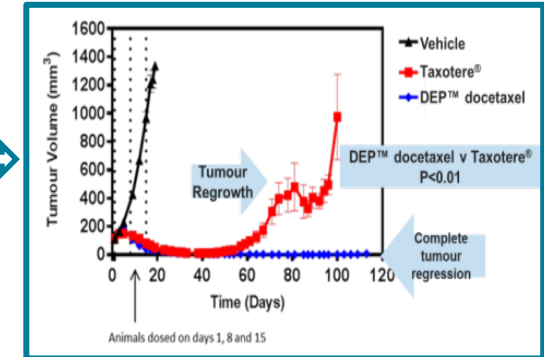
**Benefit in Combination**  
Enhanced efficacy as monotherapy or in combination approaches

**Improved Safety**  
Reduced neutropenia/BM toxicities

**Tumour Targeting**  
45-70 x more drug in tumour v original drug

**Improved Kinetics**  
Longer half life and lower C<sub>max</sub>

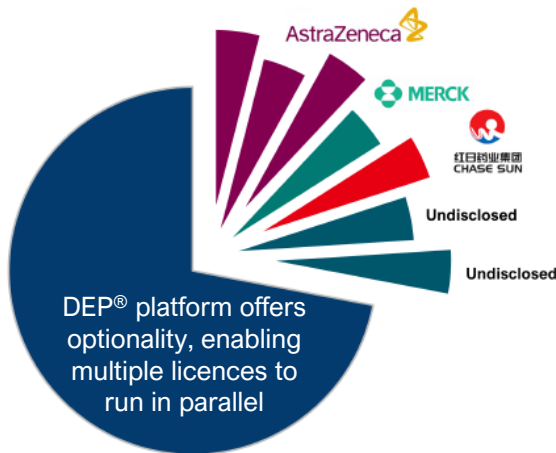
**Improved Solubility**  
Detergent Free Formulations for improved safety; 20,000 x solubility increase for DEP<sup>®</sup> docetaxel



# 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

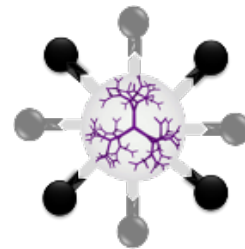


## AstraZeneca's novel DEP<sup>®</sup> nanoparticle AZD0466

- Dual Bcl2/xL inhibitor with DEP<sup>®</sup> significantly improving its therapeutic index
- Phase 1 trial significantly expanded in 2021, to a multi-centre, global clinical trial
- 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)



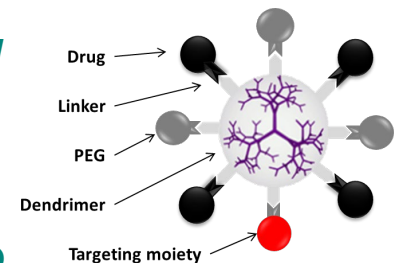
## Starpharma has signed a DEP<sup>®</sup> research agreement with MSD for dendrimer-based ADCs using DEP<sup>®</sup> technology

### 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**



# DEP<sup>®</sup> internal

## 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 2



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

Docetaxel (Taxotere<sup>®</sup>) is 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 2



**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\*:**  
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 2



**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\*:**  
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

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

# DEP<sup>®</sup> docetaxel: phase 2 trial ongoing, encouraging efficacy signals

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



Trial status:	Phase 2 trial ongoing, >44 patients recruited
Efficacy signals seen in:	Lung, pancreatic, oesophageal, cholangiocarcinoma, gastric cancers (and others)
Combinations:	+ gemcitabine, targeting pancreatic cancer + nintedanib (Vargatef <sup>®</sup> ), targeting lung cancer
Interim observations:	<ul style="list-style-type: none"> <li>• <b>Encouraging efficacy signals</b> observed, including prolonged stable disease and tumour shrinkage in patients with pancreatic, oesophageal, and gastric cancer. These impressive tumour responses include stable disease for up to 40 weeks and significant tumour shrinkage in a heavily pre-treated oesophageal cancer patient, maintained for more than 28 weeks.</li> <li>• <b>Notable lack of bone marrow toxicity</b> (e.g. neutropenia) and other common side effects inc. hair-loss, mouth ulcers, anaphylaxis and oedema</li> <li>• Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and 9 different anti-cancer regimens previously)</li> </ul>
Sites:	



The same tumour targeting observed with DEP<sup>®</sup> in animal studies has been replicated in patients treated with DEP<sup>®</sup> docetaxel, **delivering substantially higher levels of drug to the tumour** (> 63x) than in blood

## DEP<sup>®</sup> docetaxel clinical combination studies

### DEP<sup>®</sup> docetaxel + gemcitabine

- Based on compelling DEP<sup>®</sup> preclinical data & investigator interest, combination DEP<sup>®</sup> docetaxel with gemcitabine trial commenced, targeting pancreatic cancer
- Other DEP<sup>®</sup> docetaxel combinations being explored to create value

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

- 13 patients treated
- Encouraging efficacy signals observed
  - prolonged stable disease & tumour shrinkage in non-small cell lung cancer; heavily pre-treated patients
  - Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including mouth ulcers, anaphylaxis and oedema

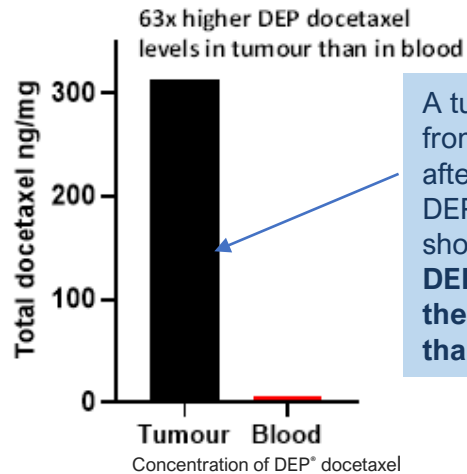


# DEP<sup>®</sup> docetaxel: clinical case studies

**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



A tumour biopsy from the patient after dosing with DEP<sup>®</sup> docetaxel showed **63x more DEP<sup>®</sup> docetaxel in the tumour tissue than in blood**



<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



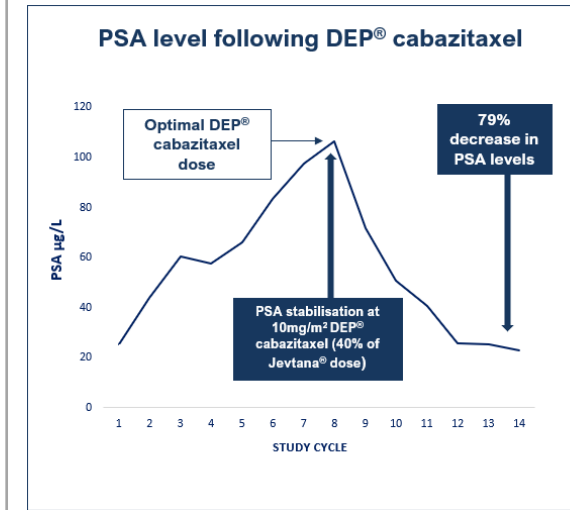
<https://www.cancer.net/cancer-types/esophageal-cancer/view-all>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642056/>

# DEP<sup>®</sup> cabazitaxel: phase 2 trial ongoing, encouraging efficacy signals

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



Trial status:	Phase 2, ongoing, >38 patients recruited
Efficacy signals seen in:	Prostate, ovarian, gastro-oesophageal, cholangiocarcinoma, head & neck, lung and other cancers
Interim observations:	<ul style="list-style-type: none"> <li>• <b>Encouraging efficacy signals</b> have been observed, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g., PSA), in cancers including prostate, ovarian, lung, gastro-oesophageal, head and neck and other cancers.</li> <li>• These impressive tumour responses in heavily pre-treated patients include significant tumour shrinkage including in prostate and ovarian cancer, in patients who have failed multiple other lines of cancer treatment.</li> <li>• Significantly less toxicity than is usually associated with Jevtana<sup>®</sup></li> </ul>
Sites:	



Prostate cancer patient experienced >47 weeks stable disease & 79% reduction in PSA (Prostate Specific Antigen)



## Results from DEP<sup>®</sup> cabazitaxel phase 1 trial

- 14 patients enrolled and received DEP<sup>®</sup> cabazitaxel at doses between 2 mg/m<sup>2</sup> to 25 mg/m<sup>2</sup>
- Up to 15 cycles of DEP<sup>®</sup> cabazitaxel; no steroid, antihistamine or anti-emetic pre-treatment
- Encouraging signs of efficacy were observed in 67% of patients evaluable for treatment response
- Significantly less toxicity than is usually associated with Jevtana<sup>®</sup>

# 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

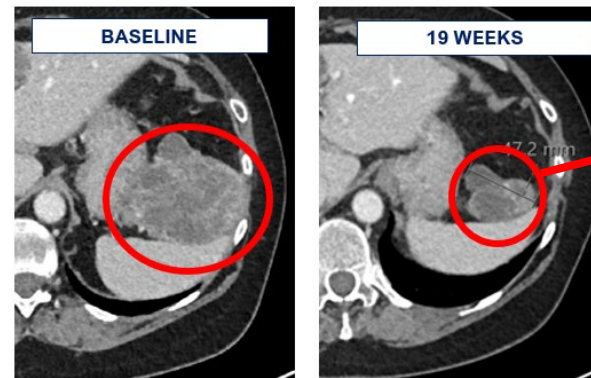


<https://www.cancer.net/cancer-types/esophageal-cancer/view-all>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5642056/>

## 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: phase 2 trial underway, encouraging efficacy signals

Enhanced version of irinotecan (Camptosar<sup>®</sup>) - predominantly used for colorectal cancer



Trial status:	Phase 2, ongoing, >47 patients recruited
Efficacy signals seen in:	Breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer
Interim observations:	<ul style="list-style-type: none"> <li>Encouraging efficacy signals observed include <b>prolonged stable disease, impressive tumour shrinkage and reductions</b> in tumour marker levels for a number of tumour types, <b>including breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer</b></li> </ul>
Combinations:	<ul style="list-style-type: none"> <li>Combinations, based on investigator interest and preclinical studies, being explored with partners to create value</li> </ul>
Sites:	



**DEP<sup>®</sup> irinotecan incorporates the irinotecan active moiety (SN38) and is an improved version of Camptosar<sup>®</sup>**

DEP<sup>®</sup>:

- provides the ability to solubilise the active metabolite, SN38
- removes the need for liver metabolism

DEP<sup>®</sup> irinotecan showed improved efficacy and survival benefit established in preclinical models

## Results from DEP<sup>®</sup> irinotecan phase 1 trial:

- 7 patients were enrolled and received up to 10 cycles of DEP<sup>®</sup> irinotecan up to 12.5 mg/m<sup>2</sup>
- **Encouraging efficacy signals observed in 50% of evaluable patients all of whom were heavily pretreated.**
- Efficacy signals observed included **prolonged stable disease and substantial tumour shrinkage in tumour types including CRC, pancreatic and breast cancer.**
- **No cases of the severe high-grade diarrhoea with DEP<sup>®</sup> irinotecan** – this side effect is experienced by 20-40% of patients with conventional irinotecan and which often requires hospitalisation
- Patients treated with DEP<sup>®</sup> irinotecan **generally experienced less severe side effects than typically associated with Camptosar<sup>®</sup>**; AEs observed included nausea, vomiting, alopecia and neutropenia

*Conventional irinotecan (Camptosar<sup>®</sup>) has two FDA black box warnings (severe diarrhoea and neutropenia) and is associated with a high frequency of adverse events (AEs), including nausea, vomiting, alopecia and neutropenia*

Evaluable patients are those patients who have received ≥1 dose DEP<sup>®</sup> irinotecan and have had a tumour assessment conducted post treatment

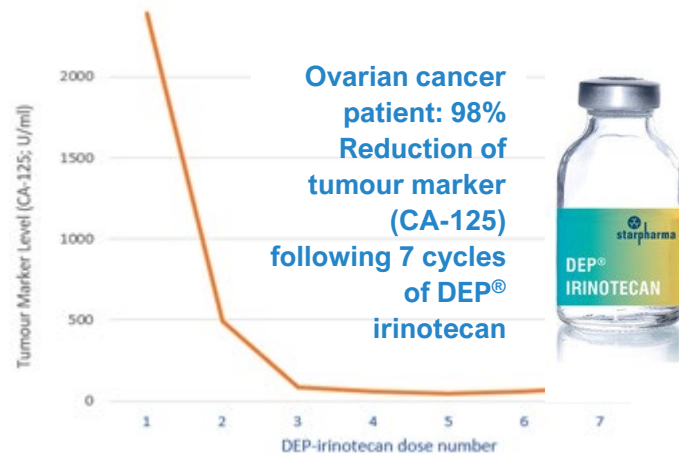
# DEP<sup>®</sup> irinotecan: clinical case studies

**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.

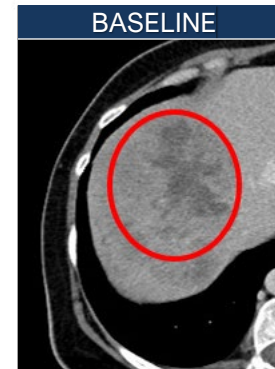


<https://www.cancercenter.com/cancer-types/ovarian-cancer/types>

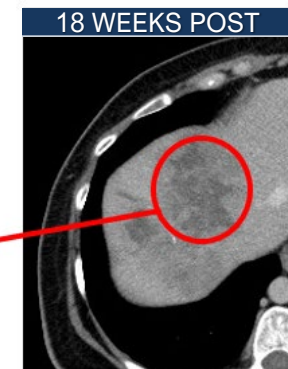
**DEP<sup>®</sup> irinotecan trial case study:** 45-year old woman with **stage IV breast cancer with extensive liver metastases**

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>

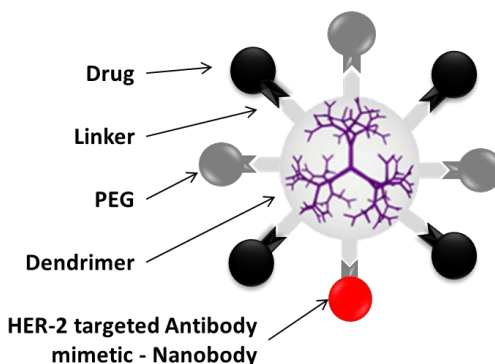
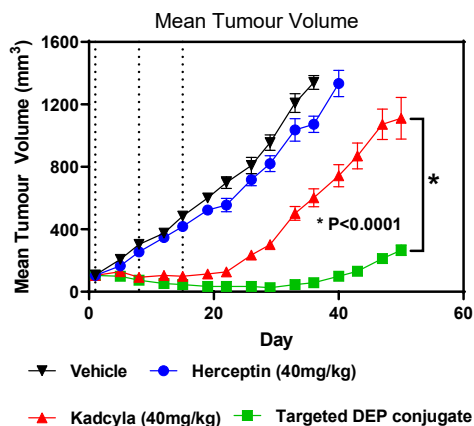
# DEP<sup>®</sup> Antibody Drug Conjugates (ADCs) further build the value of the platform

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 & Kadcyra in a human ovarian cancer model

## DEP<sup>®</sup> HER-2 ADC:



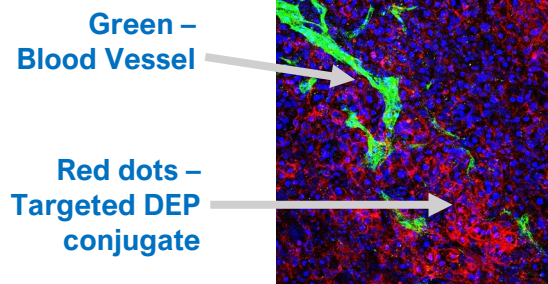
Starpharma has signed a DEP<sup>®</sup> research agreement with MSD for dendrimer-based ADCs using DEP<sup>®</sup> technology

### Recent ADC deals – growing interest

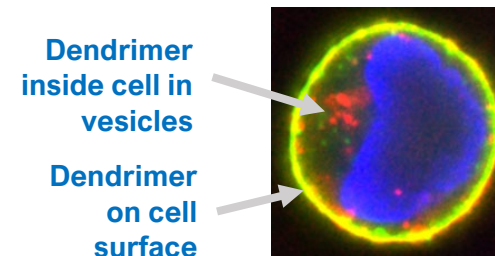
- AstraZeneca & Daiichi Sankyo, **US\$6.9 billion**, July 2020.
- Gilead & Immunomedics, **US\$21 billion**, Sep 2020.
- Seattle Genetics & Merck, **\$6.8 billion**, Sep 2020.
- Merck & VelosBio, **\$2.75B**, Nov 2020.
- Boehringer Ingelheim, **€1.2B (\$1.5B)**, Dec 2020.
- BMS & Eisai, **US\$3.1B**,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



**Kadcyla**® 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

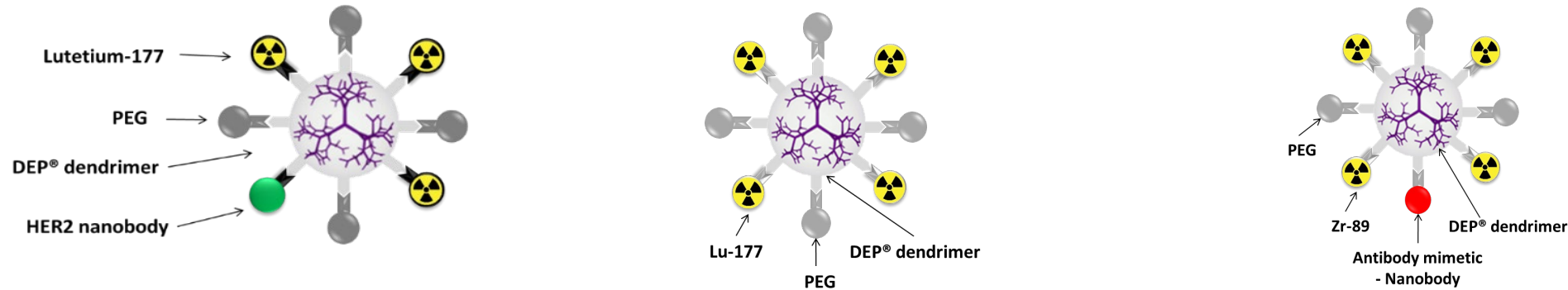


# DEP<sup>®</sup> radiotheranostics

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>



<sup>1</sup> Nuclear medicine world market report & directory, MEDDraysintell, 2016

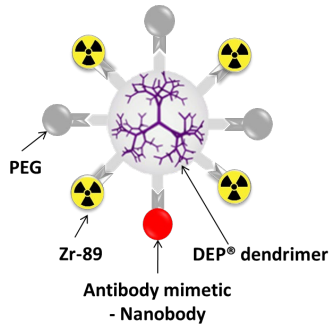
# DEP<sup>®</sup> - a valuable tool for radiodiagnostics and radiotherapeutics

Starpharma has developed multiple novel radiotheranostic candidates

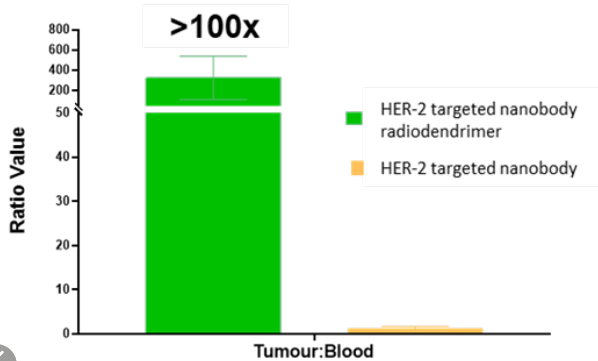
DEP<sup>®</sup> radiopharmaceutical conjugates have the potential to minimise off target toxicity and enhance efficacy when used alone or in combination with other therapeutic approaches

## DEP<sup>®</sup> zirconium

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

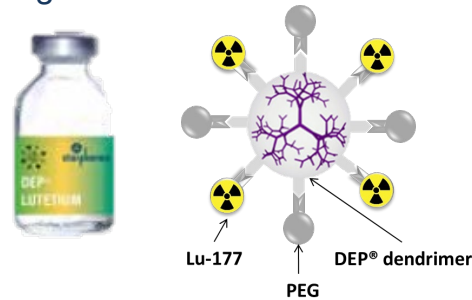


Tumour to Blood Ratio (9 days)

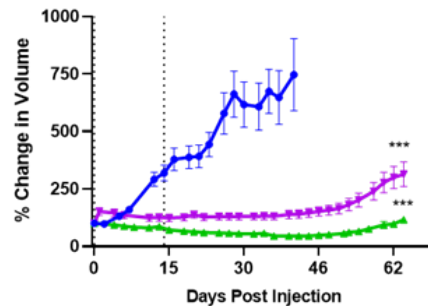


## DEP<sup>®</sup> lutetium

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



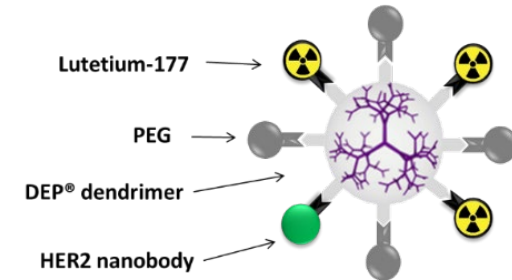
— Vehicle — DEP lutetium 15MBq — DEP lutetium 2 x 9MBq \*\*\* p<0.0001

<sup>1</sup> 100% survival to >66 days

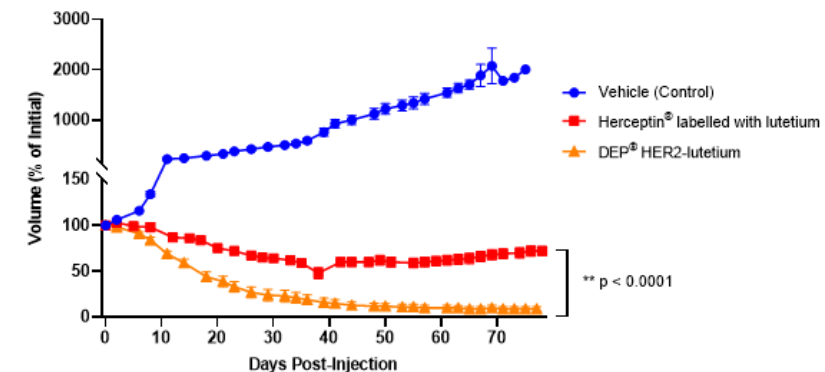
human prostate cancer model (DU-145)

## 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

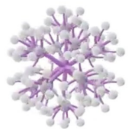
Bacterial vaginosis or BV is caused by an imbalance of naturally occurring normal bacterial vaginal flora (an overgrowth of pathogenic bacteria)

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

## Large market opportunity

BV Treatment: US\$750M (est)  
Prevention of recurrent BV: US\$1B (est)

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



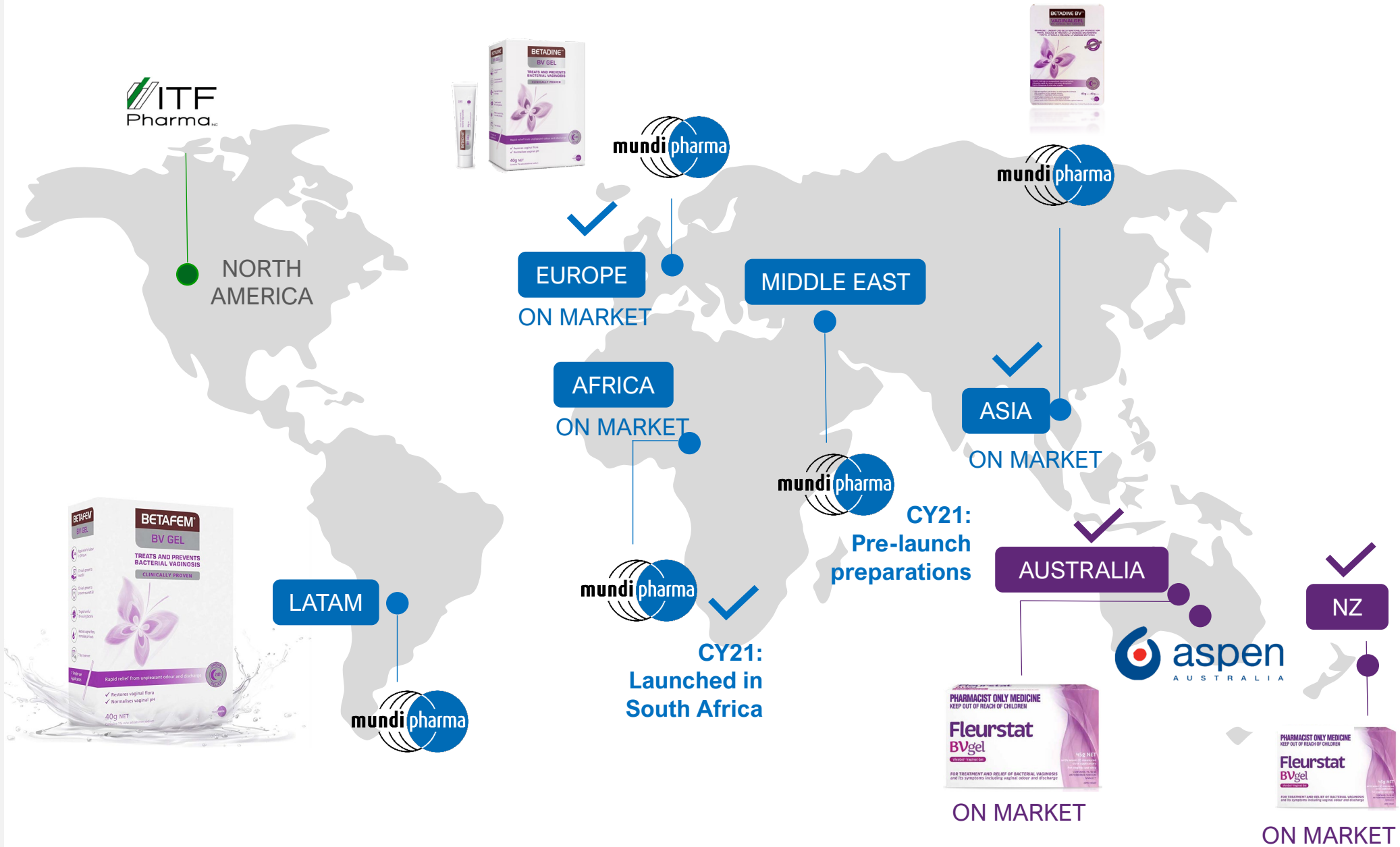
Global market for BV treatment est. to be US\$750M and prevention est. to be US\$1B annually



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



Further launches and regulatory submissions progressing in multiple regions



# Positive experiences with VivaGel® BV - patients and healthcare professionals

*“Amazing, amazing, amazing...within two days I noticed the BV clearing up.”*

UK customer review

*“One of my female GP’s ... calls Fleurstat her ‘Genie in a bottle’ ”*

Aspen Medical Rep feedback

*“Great news re Fleurstat and use in prevention of BV, I had many doctors ask about this”*

Aspen GP Team feedback

*“I used it 12 months ago and BV hasn’t come anywhere nearby me ever since! The med is called Fleurstat.”*

Aspen consumer feedback



## How does Fleurstat BVgel treat bacterial vaginosis?

Fleurstat BVgel is a product for the treatment of bacterial vaginosis and relief of its symptoms. It works to treat BV by disrupting the attachment of BV-causing bacteria to the vaginal lining. It is not an antibiotic.

[READ MORE](#)



“Simple and effective, This pack contains enough treatments to provide 7 days of applications to treat existing BV, or when used every other day to prevent the occurrence of BV. This could happen if you are on antibiotics and are prone to developing it when so”

Iron Maiden 1 Mar 2020



“It’s really easy to use, my itchiness was gone after the first two applications making my life so much more comfortable”

C Foley 3 Jan 2020



“Much better for you than taking repeated courses of antibiotics”

Rochycoo 12 Dec 2019



“I was a bit weary at first if it would work but within 24 hours I saw my symptoms improve especially the fishy smell and the funny colour discharge”

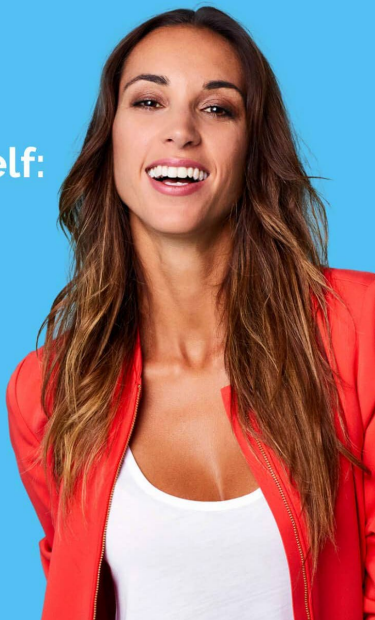
Mummy 30 Dec 2019

AMAZON CUSTOMER REVIEWS



**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 .**

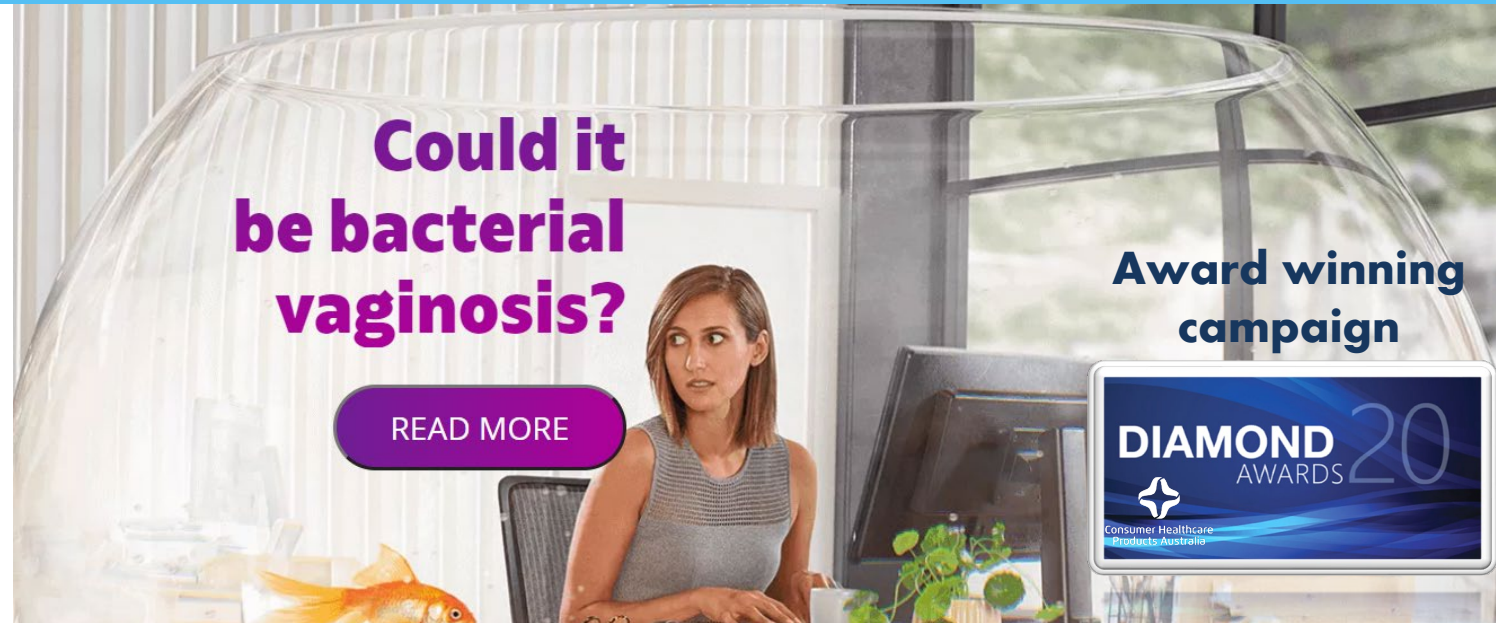


**Marketing campaigns for VivaGel<sup>®</sup> BV in multiple regions**



*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).



# VivaGel® BV regulatory progress

Approved in >45 countries with multiple other submissions underway

Licensed region	Approved	Submitted / submissions underway
UK	✓	
Europe	✓	
Asian countries	✓	✓
Australia & New Zealand	✓	
African & Middle Eastern countries	✓	✓
Latin American countries		✓
US		✓



## US regulatory

- Formal FDA review is ongoing- COVID-19 impact on timing. Due to ongoing disruption to the US healthcare system associated with COVID-19, activities relating to a potential BV treatment trial in the US are on hold
- Regulatory options thoroughly explored; ongoing input from a team of expert FDA consultants - including senior ex-FDA staffers
- FDA consistently acknowledges potential benefits (e.g. mechanistic and safety) of VivaGel® BV vs. antibiotics
- 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

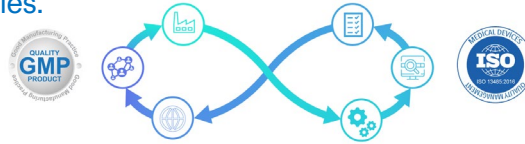
# Starpharma's Commitment to ESG: The very nature of Starpharma's products affords the opportunity of changing lives for the better

- 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.

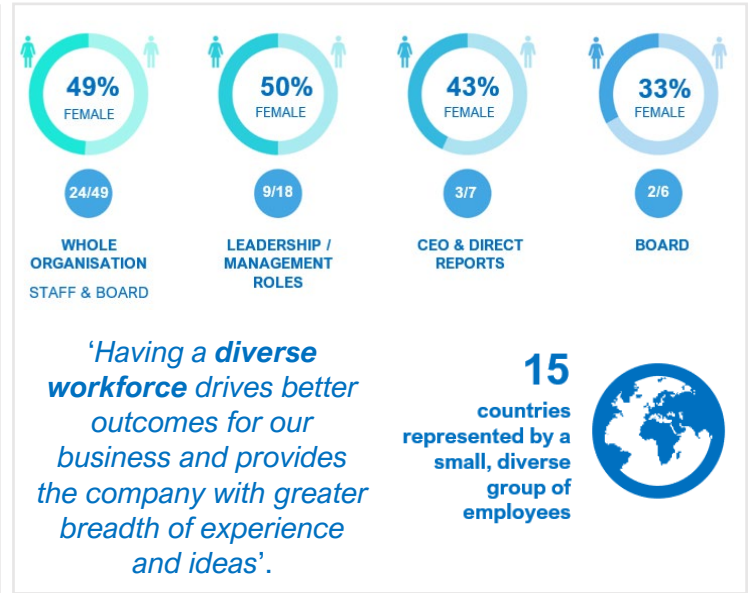
Starpharma is continually reviewing applicable guidance on responsible sourcing and sustainable procurement with the aim of creating greater social and sustainability benefits through its purchasing activities.



Starpharma 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.



Read Starpharma's [Corporate Governance Statement](#)



[Download Report](#)

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



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



Starpharma ensures it has appropriate systems in place to comply with relevant Federal, State and Local regulations, and has adopted documented procedures and processes to ensure all waste products are disposed of strictly in accordance with relevant environmental regulations.



# Financial summary

Strong balance sheet with \$64.3M cash (at 31-Mar-21)

Key Financial Data	1H FY21 A\$M	1H FY20 A\$M	FY20 A\$M
Loss for the period	(10.4)	(5.9)	(14.7)
Net operating cash outflows	(5.4)	(5.2)	(10.8)
Net cash burn (excluding capital raise) <sup>1</sup>	(6.7)	(5.4)	(11.2)

Cash as at 31 March 2021 is \$64.3M

## HY21 Result:

- \$47.0M net proceeds from equity placement and share purchase plan
  - Net operating cash outflows of \$5.4M (pcp: \$5.2M)
  - Receipt of \$5.7M R&D tax incentive
  - Reported loss for half-year of \$10.4M (pcp: \$5.9M\*).
- \*Prior period included US\$3M AstraZeneca DEP® milestone



Customer receipts for VivaGel® BV reflect timing of batch supply and vary according to launch schedule and timing.

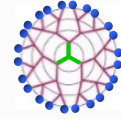
<sup>1</sup> Net cash burn is considered a non-IFRS value and has not been audited in accordance with Australian Accounting Standards. Net cash burn is calculated by the movement in cash and cash equivalents between reporting periods, adjusted for the impact of the capital raising during the period.

# Outlook



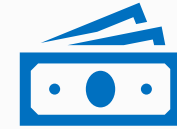
## VIRALEZE™ / VIVAGEL® / SPL7013

- Further roll-out of VIRALEZE™ Antiviral Nasal Spray
- Further VIRALEZE™ registrations and launches; commercial arrangements
- Continued testing of SPL7013 against SARS-CoV-2 variants and other viruses
- Commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Further regulatory approvals and launches for VivaGel® BV; building revenues - milestones and sales/royalties.
- Ongoing formal FDA review process
- Further VivaGel® BV licences
- VivaGel® condom approvals/launch in additional regions
- Further development/co-development of SPL7013, e.g., antiviral ophthalmic drops



## LEVERAGE EXISTING APPROVALS

## COMMERCIAL OUTCOMES



Products on market - milestones, product sales, royalties, revenue share

## DEP®

- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan phase 2 trials; progress value-adding combination studies
- AZD0466 clinical progress, expansion of trial sites recruitment and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and/or deals for further compounds
- Progress with existing partnered DEP® programs, including with Merck & Chase Sun
- Execute/expand new DEP® partnerships/agreements
- Advance DEP® radiopharmaceuticals, DEP® ADCs and DEP® antivirals
- Advance value-adding DEP® combinations in clinic and other DEP® products



Leveraging the DEP® platform to build value



Advancing internal DEP® assets builds value for future licensing



Partnered DEP® - upfront fees, milestones, royalties





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