

## Starpharma to present at OTCQX Life Sciences Investor Forum

**Melbourne, Australia; 17 September 2020:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that a pre-recorded presentation by Dr Jackie Fairley, CEO, will be broadcast on Thursday 17 September 2020 (US ET) as part of OTCQX's Life Sciences Investor Forum. The forum is one of the largest online investor conference series dedicated to the Life Sciences industry, with more than 72,000 attendees registered, including individual and institutional investors, as well as advisors and analysts.

Details of the forum are found via this link: [Virtual Life Sciences Investor Forum - September 17, 2020](#). Starpharma's presentation features an overview of the business for new investors, including the recent development update on the SPL7013 COVID-19 nasal spray, and information on the Company's DEP<sup>®</sup> candidates and partnerships, and commercial progress with the VivaGel<sup>®</sup> portfolio. The presentation is attached and also available on Starpharma's website.

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### About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel<sup>®</sup> portfolio and DEP<sup>®</sup> drug delivery with the Company developing several products internally and others via commercial partnerships.

**VivaGel<sup>®</sup>:** Starpharma's women's health product - VivaGel<sup>®</sup> BV is based on SPL7013, astodimer sodium, a proprietary dendrimer. VivaGel<sup>®</sup> BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem<sup>®</sup> BV Gel (UK), Betadine BV<sup>™</sup> (Europe), Betadine<sup>™</sup> BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel<sup>®</sup> BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel<sup>®</sup> condom (an antiviral condom which includes VivaGel<sup>®</sup> in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel<sup>®</sup> condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect<sup>®</sup> brand. The VivaGel<sup>®</sup> condom is approved in Europe.

**DEP<sup>®</sup> - Dendrimer Enhanced Product<sup>®</sup>:** Starpharma's DEP<sup>®</sup> drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP<sup>®</sup> programs, including improved efficacy, safety and survival. Starpharma has three internal DEP<sup>®</sup> products – DEP<sup>®</sup> docetaxel, DEP<sup>®</sup> cabazitaxel and DEP<sup>®</sup> irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP<sup>®</sup> programs include a multiproduct DEP<sup>®</sup> licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP<sup>®</sup> version of one of AstraZeneca's major marketed oncology medicines.

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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.



# OTCQX LIFE SCIENCES INVESTOR FORUM

17 SEPTEMBER 2020

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DR JACKIE FAIRLEY  
CEO

ASX:SPL OTC:SPHRY



# Important notice and disclaimer



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## ***FLEURSTAT BVGEL (VivaGel® 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).*



# 1 Overview

2 DEP®

3 SPL7013 & VivaGel® Portfolio

4 Outlook

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

Starpharma (ASX:SPL/OTC:SPHRY) is an ASX300 company (market cap ~A\$640M) with a proven record of development & commercialisation including successful partnerships with leading global companies





Unique polymer (dendrimer) platform creating patented high value healthcare products (>100 patents)



Range of internally developed & partnered programs



Well funded, with A\$30.1M cash (30 June 2020)



Deep portfolio of high-value products (on market and clinical-stage) based on novel polymer platform



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



**SPL7013 COVID-19 nasal spray** – expedited product dev. & regulatory pathway



**VivaGel® condom** – Launched in Japan, Australia & Canada; EU approval



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

# Deep portfolio of high-value assets including products on market

PRODUCTS ON MARKET	LATE STAGE DEV'T
 <p>VivaGel® BV is licensed in more than 160 countries &amp; currently for sale in the UK, Europe, Asia, and Aus/NZ - further launches &amp; regulatory submissions progressing in multiple regions</p>  <p>The VivaGel® condom has been launched in Japan, Canada &amp; Australia; also approved for Europe</p>	<p>SPL7013 COVID-19 nasal spray to prevent acquisition &amp; transmission of SARS-CoV-2; expedited product dev. &amp; reg. pathway</p> 

MULTIPLE CLINICAL-STAGE ASSETS	
 <p>DEP® docetaxel DEP® cabazitaxel DEP® irinotecan DEP® AZD0466</p>	 <p>PHASE 2 PHASE 2 PHASE 2 PHASE 1</p> <p>AstraZeneca</p> <p>LICENCE AFTER PROOF OF CONCEPT</p>

EXTENSIVE & GROWING PIPELINE OF PROPRIETARY ASSETS	
	<p>Starpharma expects to add 1-2 new DEP® candidates each year, advancing the candidates with the greatest potential to clinical development. Current preclinical DEP® programs focus on oncology and anti-infectives, including antivirals.</p> 

# SPL7013 COVID-19 nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2 (coronavirus)

SPL7013 has antiviral activity when applied before, or after, exposure of cells to virus

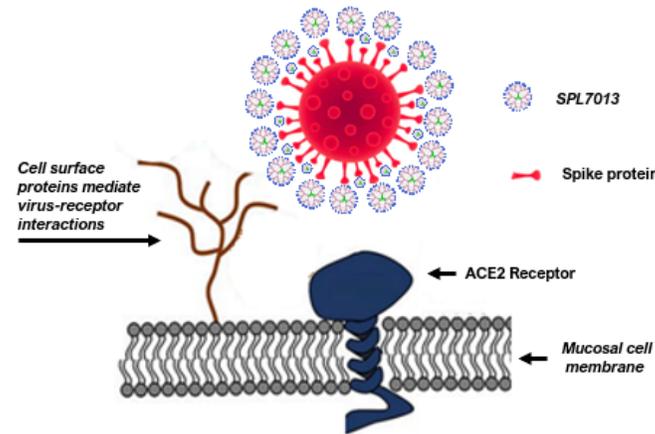
## BROAD SPECTRUM ANTIVIRAL SPRAY

- SPL7013 COVID-19 nasal spray is virucidal
- Has the potential to prevent acquisition and transmission of SARS-CoV-2, and to complement vaccine-based prevention strategies
- Broad spectrum virucidal activity also creates potential in future pandemic preparedness



Above: indicative packaging for the SPL7013 COVID-19 nasal spray

## ANTIVIRAL MECHANISM



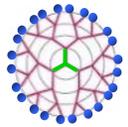
## SPL7013 POSITIVE FEATURES

- SPL7013 has **potent antiviral activity against SARS-CoV-2** if applied **before, or after exposure** of cells to virus
- SPL7013's selectivity index (a measure of relative safety or therapeutic index) is >2000 - this compares very favourably with remdesivir (279) and hydroxychloroquine (55)
- Based on previously established antiviral mechanism of action data, SPL7013 is thought to bind to the SARS-CoV-2 “spike” proteins, blocking the ability of the virus to attach to and enter mucosal (human) cells
- Other SPL7013 products – inhaled, ophthalmic and injection also possible

# Starpharma is expediting the development of the SPL7013 COVID-19 nasal spray & the product is expected to be ready for market 1H CY2021

In addition to coronavirus (SARS-CoV-2), SPL7013 has also demonstrated activity in HIV, HSV, HPV, Adenovirus, HBV, Zika and H1N1 (influenza); SPL7013 is the active included in marketed VivaGel® products

## EXISTING APPROVALS & SUPPLY CHAIN FOR SPL7013 ALLOW FAST-TRACK DEVELOPMENT & LAUNCH



SPL7013 is the active included in marketed VivaGel® products

- ✓ Reformulation completed
- ✓ Pilot product manufacture undertaken
- ✓ Device & packaging components selected
- ✓ Manufacturer identified
- ✓ Regulatory documentation compiled in preparation for submission
- ✓ \$1M MRFF grant received



SPL7013 active is **already scaled up for commercial supply**, and the availability of existing stocks of SPL7013 will further expedite development and commercialisation of the nasal spray product



Regulators have confirmed that **minimal re-development is required**, leading to an expedited program & regulatory documentation compiled in preparation for submission



**Starpharma has commenced commercial discussions across a range of distribution channels and customer groups (e.g. B2B, online platforms) and expects that the product will be ready for market in 1H CY2021.**

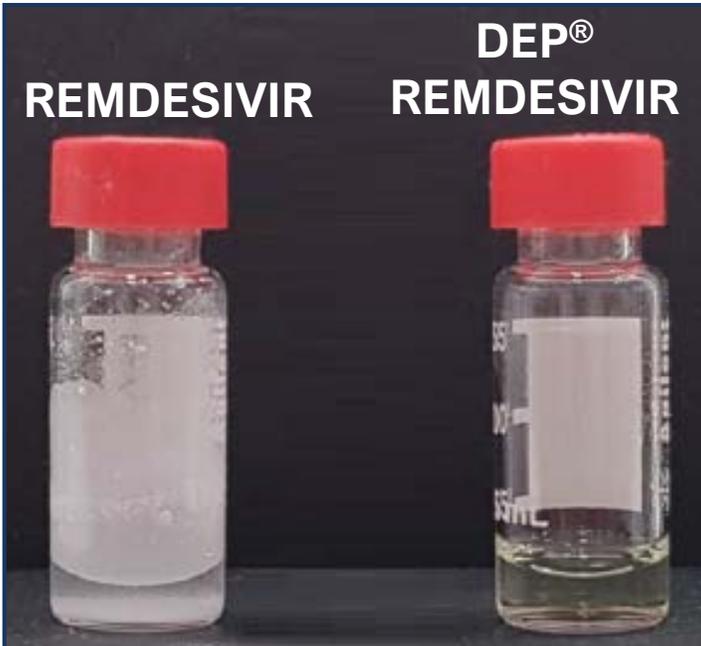


### BROAD USER PROFILE

- Front-line healthcare workers
- Broader population, including airlines and public transport
- Other staff in high-risk environments e.g. aged care, armed forces, abattoirs

# DEP<sup>®</sup> remdesivir: slow release (long-acting) & soluble version of Gilead's remdesivir

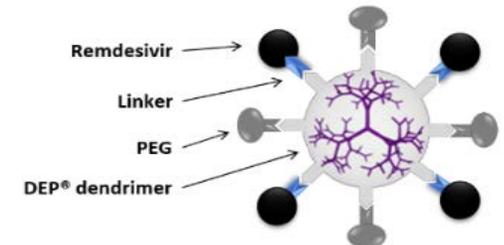
Gilead's antiviral drug, remdesivir, is being utilised for the treatment of COVID-19 under emergency use authorisation from the US Food and Drug Administration for patients with severe disease



DEP<sup>®</sup> remdesivir:  
>100-fold higher solubility  
than remdesivir, no  
cyclodextrin

- Current remdesivir formulations are required to be administered by intravenous infusion due to low solubility, with each infusion taking up to 2 hours and requiring daily administration for 5 -10 days
- Remdesivir is not recommended in patients with renal impairment due to a potentially toxic excipient (a cyclodextrin called SBECD)<sup>1</sup>
- DEP<sup>®</sup> remdesivir expands the potential application of remdesivir, by creating a long-acting version which could be administered subcutaneously rather than by intravenous infusion in hospital

DEP<sup>®</sup> remdesivir is a water-soluble nanoparticle incorporating remdesivir and PEG, providing a controlled release of remdesivir (longer half-life)



# 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



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

PHASE 2

Docetaxel (Taxotere<sup>®</sup>) is a blockbuster cancer drug with peak global sales >US\$3.1B despite having multiple US FDA “**Black Box**” warnings

**Advantages of DEP<sup>®</sup> docetaxel<sup>#</sup>:** Reduction in neutropenia; detergent-free formulation; tumour-targeting (~70x more); improved efficacy; improved pharmacokinetics; patent coverage to 2032 (plus up to an additional ~5 years).



**DEP<sup>®</sup> CABAZITAXEL:**  
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>) – also being developed for other cancers incl. breast and bladder

PHASE 2

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).

**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 must be converted to the active, SN38; this conversion leads to variability between patients and toxicity. DEP<sup>®</sup> solubilises SN38 & allows direct dosing avoiding the need for liver conversion; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



PHASE 2

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

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

# Financial summary

Key Financial Data	FY20 A\$M	FY19 A\$M
Revenue and other income	7.1 <span style="font-size: 1.2em;">↑</span> 162%	2.7
Loss for the period	(14.7)	(14.3)
Net operating cash outflows	(10.8)	(10.3)
Net cash burn <sup>1</sup>	(11.2)	(10.1)
Cash as at 30 June	\$30.1M	\$41.3M

## FY20 Result:

- Total revenue and other income of \$7.1M (pcp: \$2.7M), includes:
  - US\$3M AstraZeneca milestone payment
  - VivaGel® product sales and royalties of \$1.5M
- Reported loss for year of \$14.7M (pcp: \$14.3M), marginally higher by 3%
- Increased research and product development expenses on expanded clinical product portfolio of three phase 2 clinical programs
- Net cash burn<sup>1</sup> of \$11.2M for the year

*pcp = prior corresponding period*



<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.

# Key highlights

▶▶ AstraZeneca's first DEP® product, AZD0466, commenced phase 1, triggering US\$3M milestone



▶▶ DEP® irinotecan phase 1/2 trial commenced and advanced into phase 2 ahead of schedule on positive results



▶▶ DEP® cabazitaxel trial advanced into phase 2 on positive results



▶▶ DEP® docetaxel + gemcitabine combination study commenced



▶▶ SPL7013 shown to be active against SARS-CoV-2 (coronavirus); and significant progress with product development



\$1M MRFF GRANT RECEIVED

▶▶ VivaGel® BV launched in the UK, Eastern Europe, Asia & New Zealand



▶▶ VivaGel® BV approved in multiple countries in Asia, and multiple further regulatory submissions progressed



▶▶ Fleurstat BVgel ranked as #1 topical BV treatment in Australia

▶▶ Okamoto added 11 more Asian countries to its VivaGel® condom licence & EU approval granted



▶▶ DEP® radiotherapeutic candidate, DEP® lutetium, showed significant anti-cancer activity and 100% survival in a human prostate cancer model



▶▶ DEP® irinotecan + immuno-oncology agent resulted in superior anti-tumour activity and significant survival benefit in two human colorectal cancer models



▶▶ DEP® irinotecan, alone and in combination with Lynparza®, showed significant anti-tumour efficacy and synergy in an irinotecan-refractory human colon cancer model

▶▶ New DEP® candidate, DEP® HER-2 ADC, demonstrated significant tumour regression and 100% survival in a preclinical human ovarian cancer model



▶▶ New DEP® candidate, DEP® gemcitabine, demonstrated significantly enhanced anti-tumour activity in a human pancreatic cancer model





1 Overview

**2 DEP<sup>®</sup>**

3 SPL7013 & VivaGel<sup>®</sup> Portfolio

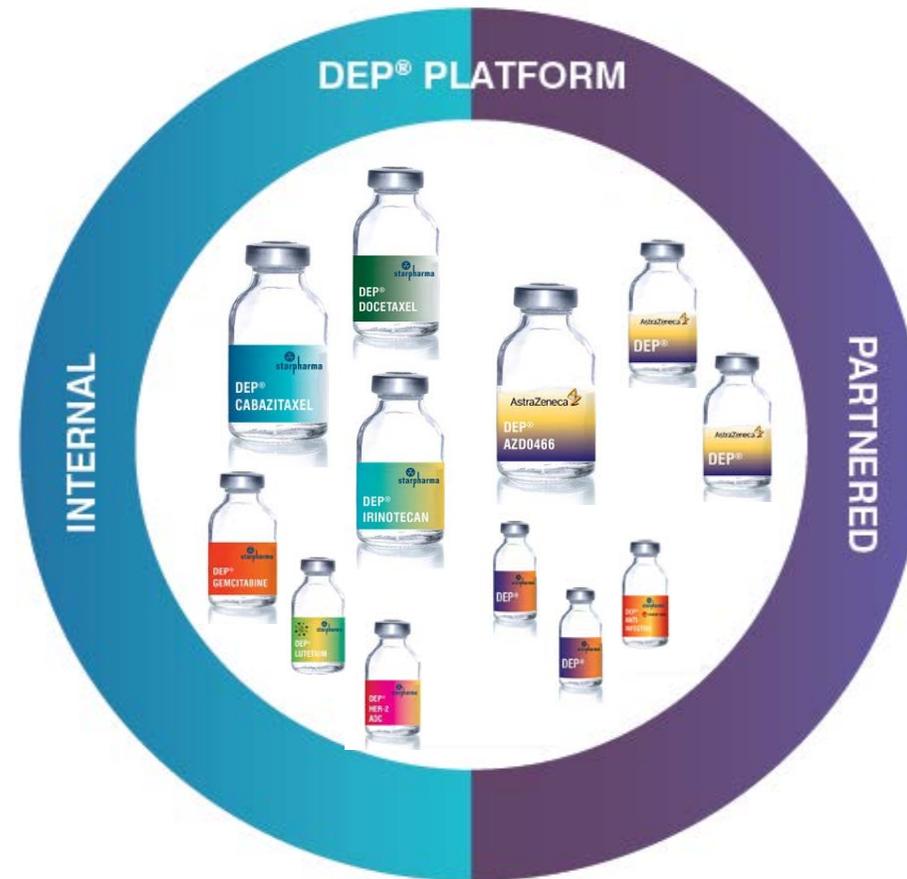
4 Outlook

# Starpharma's DEP<sup>®</sup> platform strategy creates significant optionality and upside

DEP<sup>®</sup> platform strategy provides technical, IP and financial leverage, as well as increasing commercial opportunities, improving ROI and de-risking development

## INTERNAL DEP<sup>®</sup>

- Application to established drugs reduces risk and expedites development
- Multiple therapeutic areas – e.g. oncology and antivirals
- Patent life extension
- Self-funded
- Returns through licensing, milestones and royalties

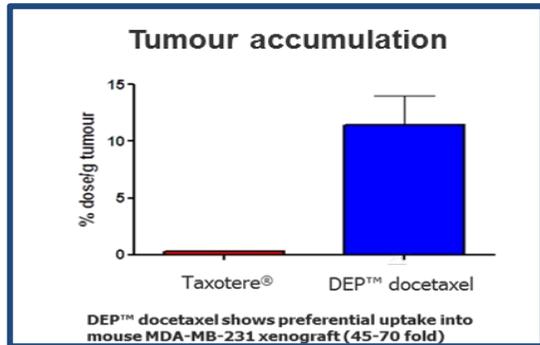
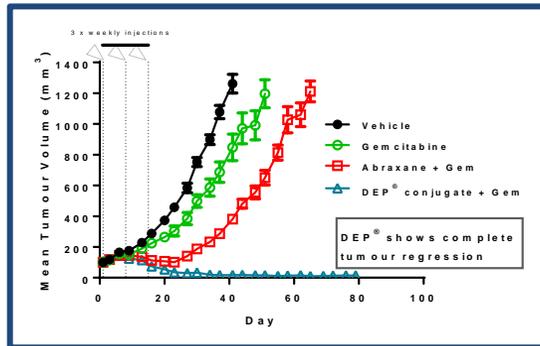
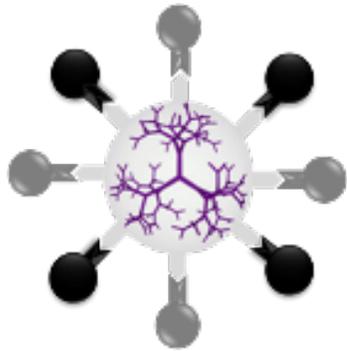


## PARTNERED DEP<sup>®</sup>

- Application to partners' drugs, both novel (e.g. AZD0466) and existing drugs
- Patent life extension
- Partner-funded
- Returns through licensing, milestones and royalties

# 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**



## DEP<sup>®</sup> BENEFITS

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

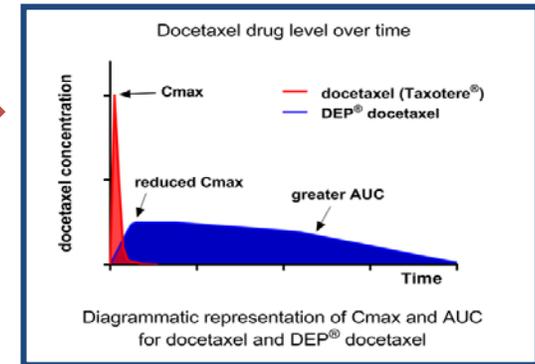
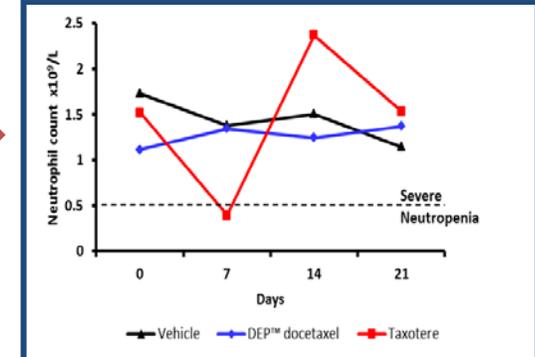
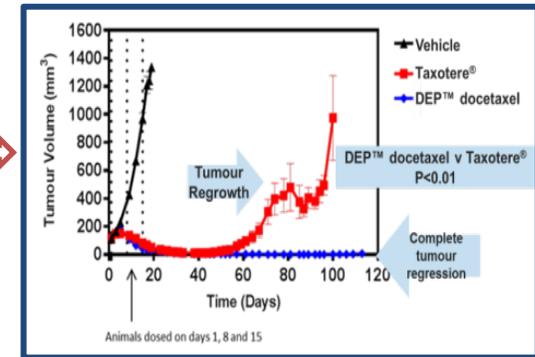
**Benefit in Combination**  
Enhanced efficacy as monotherapy or in combination approaches

**Improved Safety**  
Reduced neutropenia/BM toxicities

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

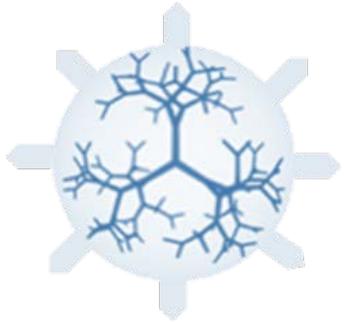
**Improved Kinetics**  
Longer half life and lower C<sub>max</sub>

**Improved Solubility**  
Detergent Free Formulations for improved safety – 20,000 x solubility increase

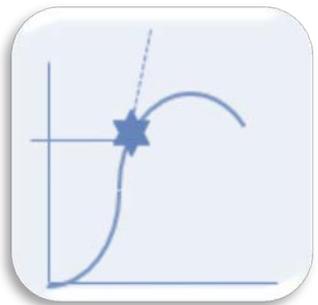


# DEP<sup>®</sup> platform for partnering

## DEP<sup>®</sup> can be used by commercial partners to improve novel drugs *or* life-cycle management

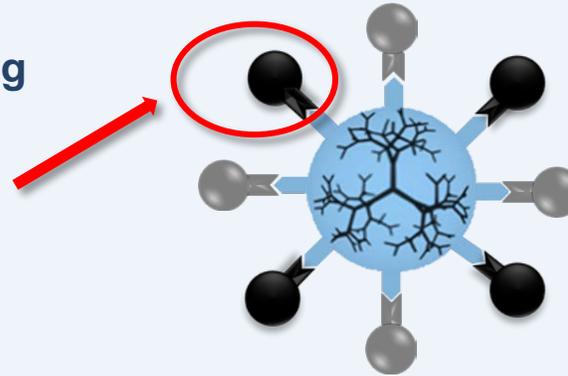


DEP<sup>®</sup> nanoparticles can be used to enhance the features of novel drugs that may otherwise limit clinical use due to issues such as toxicity or insolubility



DEP<sup>®</sup> has utility as a lifecycle management tool to make existing drugs better and create new IP

Starpharma attaches the partner's drug to the dendrimer creating a nanoparticle with key benefits



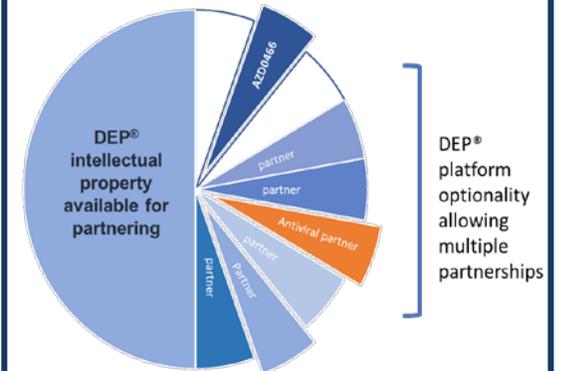
Partner funds development of their DEP<sup>®</sup> product(s)



Starpharma is eligible to receive milestone payments & royalties on DEP<sup>®</sup> products



Licences are structured to allow for multiple DEP<sup>®</sup> programs to run in parallel



Starpharma has multiple partnered DEP<sup>®</sup> programs with large pharma companies incl. AstraZeneca, Chase Sun, and several undisclosed partnerships



# AstraZeneca's DEP<sup>®</sup> programs: novel oncology agent AZD0466 phase 1 underway



## Multiple commercial DEP<sup>®</sup> programs

- US\$7M in milestones received thus far
- Total milestones of up to US\$124M + royalties for AZD0466
- AZ funds development of AZ DEP<sup>®</sup> products including AZD0466

### Multiproduct licence



#### 1<sup>st</sup> AZ DEP<sup>®</sup> candidate (AZD0466)

- Up to US\$124M milestones + escalating royalties
- Est. up to A\$2.4B revenue to SPL



#### 2<sup>nd</sup> AZ DEP<sup>®</sup> candidate (& subsequent candidates)

- Up to US\$93.3M in milestones plus escalating royalties on net sales

### Development & Option Agreement



#### 3<sup>rd</sup> AZ DEP<sup>®</sup> candidate (major existing AZ oncology medicine)

US\$5M on option exercise, industry standard milestones, plus escalating royalties



AZD0466 multi-centre phase 1 trial recruiting patients in the US with solid & haematological tumours (including MD Anderson Cancer Center)

AZD0466 a highly optimized DEP<sup>®</sup> nanoparticle formulation of AZ's novel Bcl2/xl inhibitor patented to 2038



Bcl2 is a **clinically validated oncology target** - venetoclax (Venclexta<sup>™</sup> - AbbVie / Genentech) with **estimated sales** projected to be US\$2-3 billion p.a.



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

# DEP<sup>®</sup> docetaxel phase 2 program – ongoing recruitment and positive interim results

## MONOTHERAPY ARM



35 patients treated



Encouraging efficacy signals observed including prolonged stable disease (up to 40 weeks) & tumour shrinkage



Efficacy signals in variety of tumour types including prostate cancer, lung cancer and several hard-to-treat tumours including oesophageal, cholangiocarcinoma (2<sup>nd</sup> most common liver cancer), gastric and pancreatic



Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and nine different anti-cancer regimens previously)



Based on efficacy signals observed & investigator interest, recruitment ongoing including patients with selected hard-to-treat tumour types



Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects inc. hair-loss, mouth ulcers, anaphylaxis and oedema.



## DEP<sup>®</sup> DOCETAXEL

Open-label, two-stage design to allow for exploration of efficacy of DEP<sup>®</sup> docetaxel as a monotherapy.

In parallel, combination of DEP<sup>®</sup> docetaxel & nintedanib (Vargatef<sup>®</sup>) in lung cancer.

Combination of DEP<sup>®</sup> docetaxel & gemcitabine in pancreatic cancer.



The Newcastle upon Tyne Hospitals NHS Foundation Trust



## COMBINATION ARM (+ VARGATEF)



13 patients treated



Encouraging efficacy signals observed - prolonged stable disease & tumour shrinkage in non-small cell lung cancer; heavily pre-treated patients



Based on positive interim results in the DEP<sup>®</sup> docetaxel + nintedanib combination arm, recruitment was expanded



Notable lack of bone marrow toxicity (e.g. neutropenia) and other common side effects including mouth ulcers, anaphylaxis and oedema

### Other DEP<sup>®</sup> docetaxel combinations



Based on compelling DEP<sup>®</sup> preclinical data & investigator interest, DEP<sup>®</sup> docetaxel + gemcitabine combination trial targeting pancreatic cancer commenced



Combinations with immunotherapy also being explored to create value

The phase 2 DEP<sup>®</sup> docetaxel trial continues to progress well, with further observations of encouraging efficacy signals, including prolonged stable disease and tumour shrinkage in patients with cancers including pancreatic and gastric cancer.

# Case study: DEP<sup>®</sup> docetaxel in advanced lung cancer



Stage IV metastatic lung cancer (NSCLC) patient:



- Lung cancer is the most common cancer globally
- Non-Small Cell Lung Cancer (NSCLC) accounting for 84% of all lung cancers
- Stage IV lung cancer patients have a 5 year survival rate of 4.7%<sup>1</sup>

46 year old man with stage IV lung cancer (NSCLC):

- genetic profile limited treatment options (he didn't qualify for 1<sup>st</sup> line immunotherapy)
- cancer had progressed after 7 cycles platinum-based chemo + immunotherapy & an investigational enzyme inhibitor
- received x2 cycles of DEP<sup>®</sup> docetaxel + nintedanib

Response:

- reduction in size of tumour lesions of up to 45%
- stable disease > 9 weeks
- improvement in tumour-related pain

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

CT scans of lung: right middle lobe

BASELINE

9 WEEKS POST Rx



41% reduction in size of tumour lesion

# DEP<sup>®</sup> cabazitaxel – positive phase 1 results & phase 2 underway

## PHASE 1 RESULTS

### Positive phase 1 results (dose-escalation)

- 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, including:**
  - prolonged stable disease in multiple patients and in a variety of cancer types, including prostate, gastro-oesophageal, breast, ovarian, cholangiocarcinoma and pancreatic (& at doses several-fold lower than usually used for cabazitaxel).
    - One prostate cancer patient experienced >47 weeks stable disease & a reduction in PSA of 79%
    - One stage IV ovarian cancer patient achieved a reduction in tumour biomarker (CA-125) of 56%
    - One stage III cholangiocarcinoma cancer patient achieved a 82% decrease in a tumour biomarker after two cycles
- **Significantly less toxicity than is usually associated with Jevtana<sup>®</sup>**, including less bone marrow toxicity (neutropenia, anaemia, thrombocytopenia), anorexia and vomiting. No cases of hypersensitivity; **no cases of hair-loss**; no need for anti-nausea medications



Open-label trial, with the objective of establishing anti-tumour activity (efficacy) & safety at the RP2D of 20 mg/m<sup>2</sup>



## PHASE 2



First stage will enrol ~20 patients with a variety of cancers, including prostate cancer; final numbers may be adjusted based on results in certain patient cohorts



Patient recruitment progressing well with 13 patients treated with up to 6 cycles of treatment



The phase 2 DEP<sup>®</sup> cabazitaxel trial continues to progress with encouraging efficacy signals, including stable disease, significant target tumour shrinkage and substantial tumour marker reductions (e.g. PSA), in cancers including prostate, ovarian, lung, gastroesophageal and others



Study will further explore efficacy in selected tumour types



Four sites: Guy's & St Thomas', University College London, Velindre Cancer Centre in Cardiff and Imperial College London; Australian site (Kinghorn Cancer Centre).



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

# Clinical case study: DEP<sup>®</sup> cabazitaxel in advanced prostate cancer

Prostate cancer is the second most commonly occurring cancer in men: ~1 in 7 men will be diagnosed with prostate cancer in their lifetime.



## Stage III Prostate Cancer Patient:

- Stable Disease >47 weeks
- 79% decrease in PSA levels

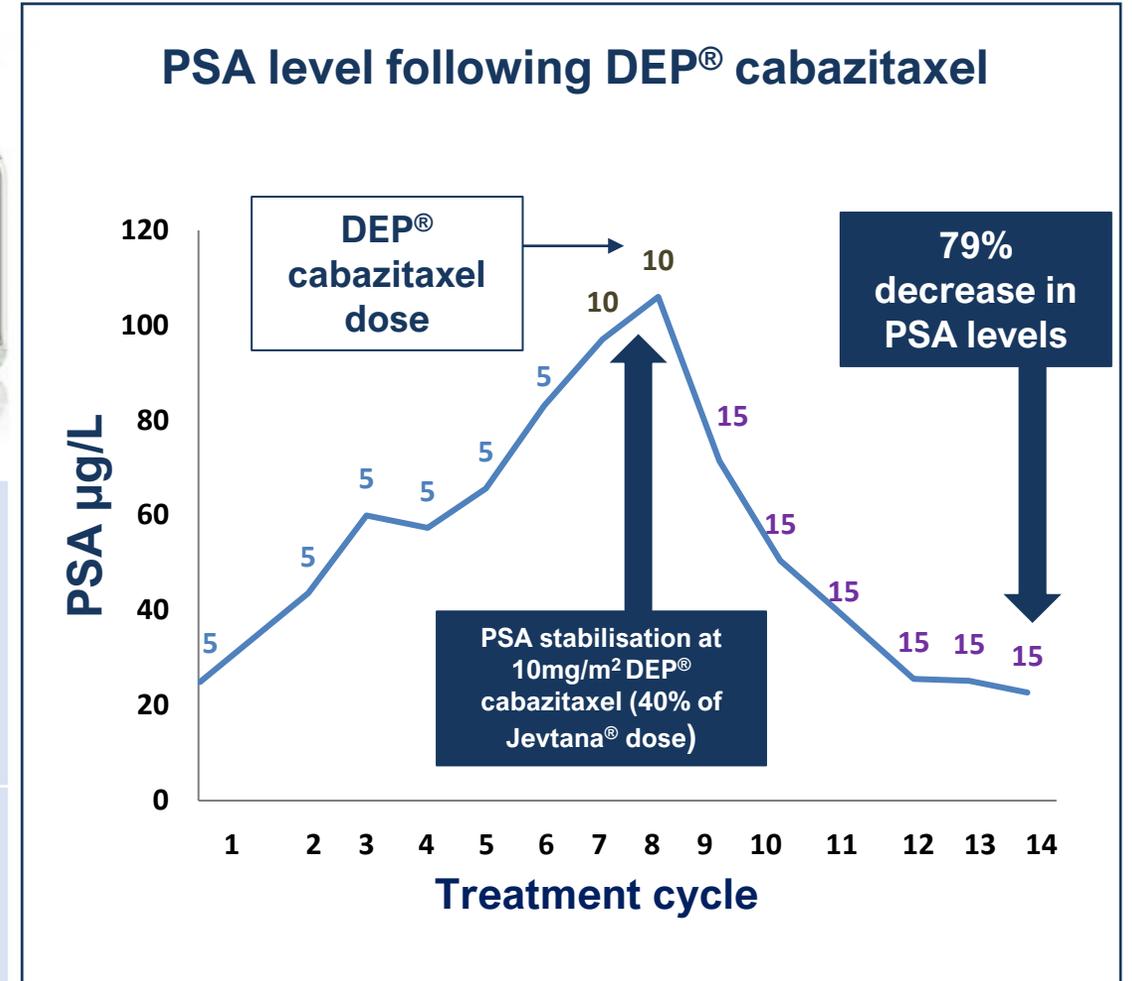


## 70 year old man with stage III prostate cancer:

- Heavily pre-treated; cancer progressed on 4 other anti-cancer therapies
- Was unable to tolerate docetaxel due to toxicity (neutropenia)
- Received 15 cycles of DEP<sup>®</sup> cabazitaxel with no neutropenia
- Response to DEP<sup>®</sup> cabazitaxel began at 40% of the typical dose

## Response to DEP<sup>®</sup> cabazitaxel

- Prolonged stable disease >47 weeks
- PSA stabilised following a 79% decrease



# Clinical case study: DEP<sup>®</sup> cabazitaxel in ovarian cancer



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



## Stage IV (metastatic) Ovarian Cancer Patient:

- 7 cycles DEP<sup>®</sup> cabazitaxel
- 56% decrease in CA-125 levels

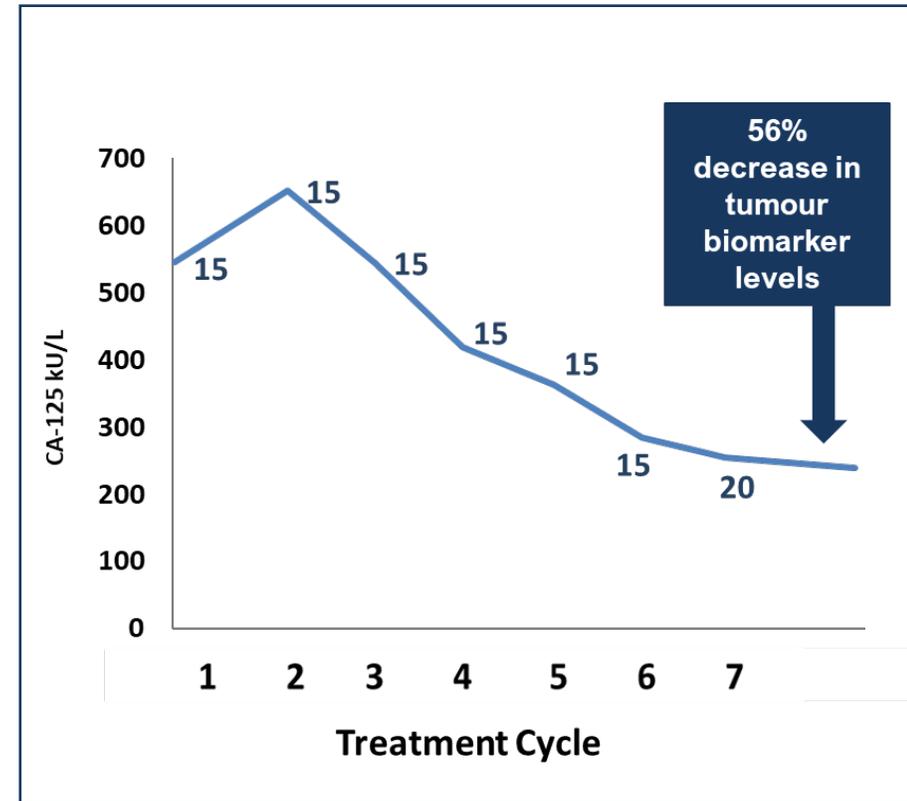


## 73-year old woman with stage IV (metastatic) ovarian cancer

- Heavily pre-treated with 33 cycles of 5 different anti-cancer therapy regimens (including several combinations)
- Patient's cancer progressed on all of these and she was unable to tolerate standard docetaxel due to toxicity (neutropenia)

## Response to DEP<sup>®</sup> cabazitaxel

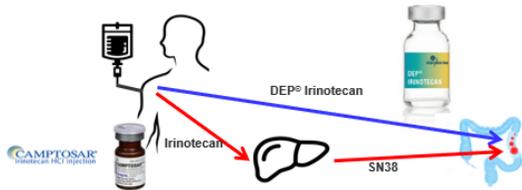
- Received 7 cycles of DEP<sup>®</sup> cabazitaxel (well tolerated)
- Achieved a 56% decrease in tumour biomarker levels
- Tumour response commenced at 60% of the currently recommended Jevtana<sup>®</sup> dose



\* [https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts-\\_2019\\_-FINAL.pdf](https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts-_2019_-FINAL.pdf)

# DEP<sup>®</sup> irinotecan - positive phase 1 results & phase 2 now underway

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



DEP<sup>®</sup> drug delivery:

- provides the ability to solubilise the active metabolite, SN38, which removes the need for liver metabolism
- improves pharmacokinetics
- targets directly into solid tumours
- improved efficacy and survival benefit established in preclinical models

## POSITIVE PHASE 1 RESULTS (DOSE-ESCALATION)

- 7 patients were enrolled and received DEP<sup>®</sup> irinotecan at a range of doses up to 12.5 mg/m<sup>2</sup> and up to 10 cycles of treatment each
- **Encouraging efficacy signals observed in 50% of evaluable patients to date, and in all three tumour types enrolled, despite the fact conventional irinotecan is not approved for breast or pancreatic cancers & that enrolled patients were heavily pre-treated. Efficacy signals observed included:**
  - prolonged stable disease and substantial tumour shrinkage in a range of tumour types including CRC, pancreatic and breast cancer.
- **Patients generally experienced less severe side effects than typically associated with Camptosar<sup>®</sup>, with no cases of the severe high-grade diarrhoea which is experienced by 20-40% of patients with conventional irinotecan and often requires hospitalisation.**
- 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.
  - AEs observed with DEP<sup>®</sup> irinotecan treatment were consistent with those seen in Camptosar<sup>®</sup> and generally less severe and mostly mild (grade 1).
  - AEs observed with DEP<sup>®</sup> irinotecan included nausea, vomiting, alopecia and neutropenia.

## PHASE 2 UNDERWAY



- Dose expansion: open-label trial, with the objective of establishing anti-tumour activity (efficacy) and safety at the RP2D
- ~ 20-30 patients with colorectal cancer and other cancers
- 18 patients already enrolled – high level of interest from clinicians
- Combinations with immunotherapy being explored with partners to create value



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

# Clinical case study: DEP<sup>®</sup> irinotecan in advanced breast cancer



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



**Stage IV breast cancer patient with extensive liver metastases**



**45-year old woman with stage IV breast cancer:**

- Extensive metastases including in the liver
- **Very heavily pre-treated with >100 cycles of 11 different treatments**
- 15 cycles of DEP<sup>®</sup> irinotecan to date

**Response to DEP<sup>®</sup> irinotecan**

- **Response after 3 cycles of treatment**
- **Prolonged stable disease >45 weeks**
- Well tolerated



# DEP<sup>®</sup> irinotecan in combination with immuno-oncology agent (anti PD-1 antibody) boosts efficacy and survival in multiple colon cancer models



DEP<sup>®</sup> irinotecan + anti PD-1 Ab in combination showed significant enhancement of anti PD-1 antibody activity by DEP<sup>®</sup> irinotecan in both CT-26 and MC-38 colon cancer models

Figure 1: Mean Tumour Volume Over Time MC-38

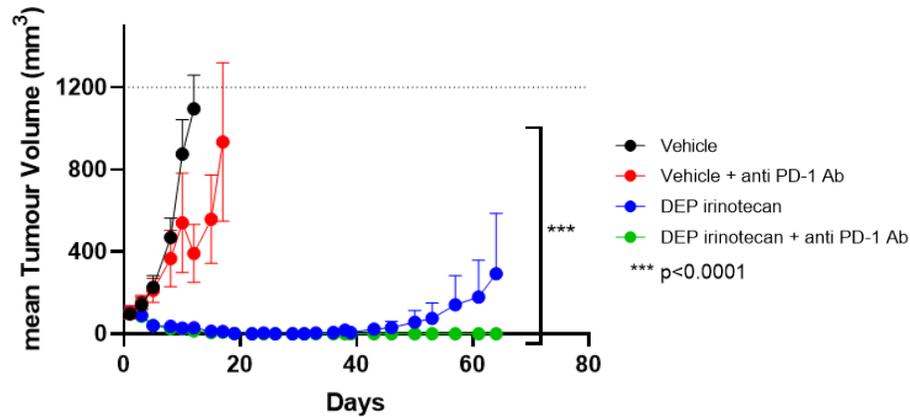
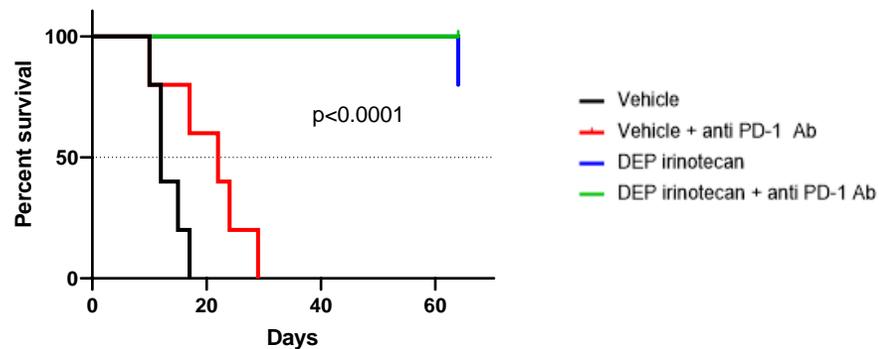


Figure 2: Kaplan-Meier survival curve MC-38



These results indicate that DEP<sup>®</sup> irinotecan in combination with an anti PD-1 antibody could boost the efficacy over anti PD-1 antibody alone, or immuno-oncology (IO) combinations with standard chemotherapeutic agents.

- DEP<sup>®</sup> irinotecan in combination with an IO therapy (anti PD-1 antibody) resulted in superior anti-tumour activity and significant survival benefit compared to the IO therapy alone in two colorectal cancer (CRC) models - this combination benefit did not occur when conventional irinotecan was used together with the same IO therapy



IO agents are now important treatments in several major cancers and **the market for these agents is expected to exceed US\$55 billion by 2025**, and include Merck's Keytruda<sup>®</sup>, BMS' Yervoy<sup>®</sup> and AstraZeneca's Imfinzi<sup>®</sup>



These results provide important information which will assist with the identification of **value-adding clinical combinations and partnering opportunities**

Anti PD-1 antibodies have been a major breakthrough in cancer treatment, but substantial unmet need remains, and non-responders make up more than 75% of all incident cancers, highlighting the need for more effective agents and combinations

(August 2019 IO presentation by Peter F Lebowitz (M.D. PhD), Global Therapeutic Area Head, Oncology, Janssen Oncology, with data sourced from Cancer Incidence from Globocan 2018)

# First DEP<sup>®</sup> radiotherapeutics candidate, DEP<sup>®</sup> Lutetium, shows impressive efficacy in human prostate cancer model

- Starpharma has developed multiple novel radiotherapeutic and radiodiagnostic 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> radiotherapeutics incorporate radioisotopes on to the DEP<sup>®</sup> scaffold and specific patent applications have been filed for DEP<sup>®</sup> radiotherapeutic candidates

## Rapidly growing radiopharmaceuticals market



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



Recent deals including Sirtex acquisition ~A\$1.9B by CDH Genetech

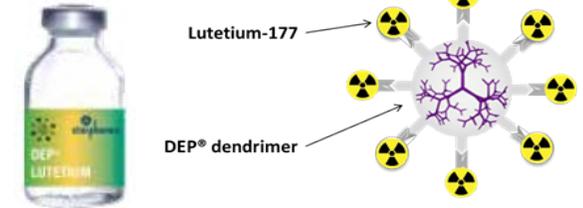


<sup>1</sup> Nuclear medicine world market report & directory, MEDDraysintell, 2016



## DEP<sup>®</sup> Lutetium

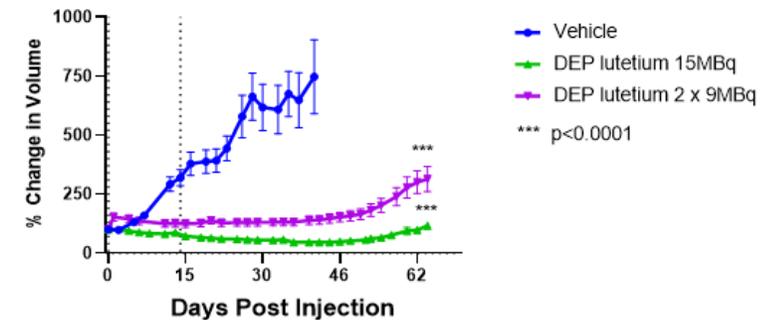
Starpharma's first DEP<sup>®</sup> radiotherapy candidate showed highly statistically significant anticancer activity, tumour and 100% survival in a human prostate cancer model (DU-145)



### % Change Tumour Volume

Figure 1:

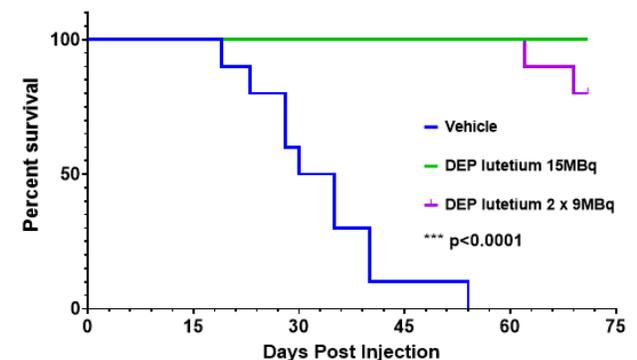
Percentage change in tumour volume over time as measured in the DU-145 human prostate cancer model.



### 100% Survival - Kaplan-Meier curve

Figure 2:

Kaplan-Meier survival curve in the DU-145 human prostate cancer model.





1 Overview

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4 Outlook

# VivaGel® BV - a breakthrough product for the management of BV - the most common vaginal infection worldwide



### Management of BV is an area of significant unmet need:

- Untreated, BV is associated with miscarriage, infertility & PID as well as having a significant impact on quality of life

### Current 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 currently approved therapies for prevention of recurrent BV
- Independent market research indicates a high level of interest in a non-antibiotic BV therapy



**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,  
 Australia & NZ

 Further launches  
 and regulatory  
 submissions  
 progressing in  
 multiple regions

 3 further territories  
 to license (Canada,  
 India, Israel)



**NORTH  
 AMERICA**



UK VivaGel® BV product



**LATAM**



**AFRICA**

**EUROPE**



**On market**



**MIDDLE  
 EAST**



**Asia –  
 launched  
 1H CY20**

**ASIA**



**On market**

**AUSTRALIA**



**NZ -  
 launched  
 1H CY20**



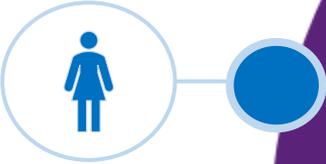
# Positive patient experiences about VivaGel® BV benefits



Comments regarding Fleurstat BVgel



Verbatims from BV sufferers in VivaGel® BV clinical trials



“...the symptoms went away much quicker than the first one that I had (metronidazole)”



“...the female GPs expressed relief that there was a **genuine alternative to antibiotics**”

“Almost a total acceptance of Fleurstat BVgel by the detailed doctors as the product that will become the **first choice for the treatment of BV**”

Aspen GP Sales Representative



“I spoke to a pharmacist and discovered this new product for BV...called Fleurstat BVgel...I cannot express how impressive this is... It's been about 2-3 months now and totally BV free.”

BV Patient (unsolicited comment) trusted



“within the first day I noticed a change already. It was like gone almost overnight. No itching, no discharge.”



“.. it pretty much started to go away right when I started to use it...I could tell it was working.”



“Having access to Fleurstat BVgel over the counter will empower women...to finally take control”

Community Pharmacist

# Be Unstoppable with BETA FEM®

Designed exclusively  
for feminine hygiene  
needs

Fleurstat BVgel now available in pharmacies

**Could it be bacterial vaginosis?**

**NEW Fleurstat BVgel** is for treatment of bacterial vaginosis (BV) and relief from symptoms, including abnormal vaginal odour and discharge, helping to normalise vaginal pH, and restore the normal vaginal flora balance. Fleurstat BVgel is available in pharmacies without prescription.

**PHARMACIST ONLY MEDICINE**  
KEEP OUT OF REACH OF CHILDREN

**Fleurstat BVgel**  
45g NET

FOR TREATMENT AND RELIEF OF BACTERIAL VAGINOSIS AND ITS SYMPTOMS INCLUDING VAGINAL ODOR AND DISCHARGE

betafem\_uk • Follow

betafem\_uk Bacterial Vaginosis is more common than you may think but there's no reason to put up with it. Help fight the infection with clinically proven BETA FEM® BV Gel which treats both the symptoms of BV & the condition itself.

#carefordownthere #femalehealth #Ph-balanced #feelgoodeveryday #feelgoodday #mondaybluesnomore #womenshealthtips #womenshealthcare #bacterialvaginosis #intimatecare #vaginacare

**Fleurstat BVgel ranks as #1 topical BV treatment in Australia**

**BETA FEM® BV Gel**  
BUY NOW

**PHARMACIST ONLY MEDICINE**  
KEEP OUT OF REACH OF CHILDREN

**Fleurstat BVgel**  
45g NET

FOR TREATMENT AND RELIEF OF BACTERIAL VAGINOSIS AND ITS SYMPTOMS INCLUDING VAGINAL ODOR AND DISCHARGE

**Where can I buy Fleurstat BVgel for bacterial vaginosis?**

Fleurstat BVgel is an over the counter BV treatment and is available from most leading pharmacies without prescription. A pharmacist must decide whether Fleurstat BVgel is right for you before you can purchase it.

Your Location:

Search radius: 50 km **FIND STORE**

**Its Time To Talk About The #sixletterword**

Click on this header to find out more.

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Medical & He...

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See what BETA FEM UK is doing in Messenger Get Started

https://uk.betadine.com/

BETA FEM® is designed exclusively for feminine hygiene needs. Offering daily feminine washes to maintain a healthy bacterial balance and

See More

Suggest Edits



FLEURSTAT BVGEL (VivaGel® 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).



## Marketing campaigns for VivaGel® BV in multiple regions



# VivaGel® BV in the US

## Progress with regulatory strategy

- Regulatory options thoroughly explored; ongoing input from a team of expert FDA consultants (regulatory, statistical, clinical, legal - including senior ex-FDA staffers)
- Formal FDA review is ongoing. Due to the significant disruption to the US healthcare system caused by COVID-19, activities relating to a potential BV treatment trial in the US are on hold
- 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



**FAST TRACK STATUS**

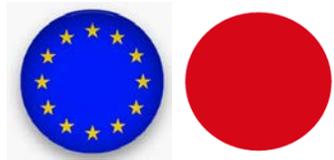
**QIDP** +5 YEARS EXCLUSIVITY

## FDA Administrative review process

Starpharma is continuing to progress the formal review of some of the FDA's initial conclusions via an administrative review process. COVID-19 activities within the FDA may impact on timing.



# VivaGel® antiviral condom launched in Japan and recently approved in Europe



- VivaGel® antiviral condom (HIV, Herpes, HPV) is being marketed under Okamoto's leading and highly successful Zero Zero Three (003) brand
- Okamoto expanded its licence to acquire marketing rights for a further 11 countries in Asia (incl. Sth Korea, Indonesia, Malaysia, Thailand, Singapore and the non-government China market)
- Starpharma receives royalties based on sales of the VivaGel® condom and also revenue on supply of SPL7013 active



Japan's leading marketer of condoms & holds strong market positions in several other Asian markets



Okamoto & Japanese Ministry of Health, Labour & Welfare have developed a joint STI prevention campaign using VivaGel® condoms



Okamoto have manufactured VivaGel® condom samples for Japan Foundation for AIDS Prevention (JFAP) – to increase awareness for health centres nationwide and the LGBT community



Starpharma was recently granted marketing approval for the VivaGel® antiviral condom in Europe.

Starpharma's marketing partner in Europe, LifeStyles, is undertaking marketing preparations ahead of the launch of the VivaGel® condom under the brand name Absolute™ DUAL PROTECTION. LifeStyles also has the marketing rights to the VivaGel® condom in other markets, including Australia and Canada.





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# Outlook



**SPL7013 for Coronavirus** • Expedite development and launch of SPL7013 nasal spray

**LEVERAGE EXISTING APPROVALS**

## VIVAGEL®

- 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 for India, Canada & Israel
- VivaGel® condom approvals/launch in additional regions, such as China/Europe
- Further development / co-development of SPL7013 antiviral ophthalmic drops



**COMMERCIAL OUTCOMES**



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

## DEP®

- Progress and completion of DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan trials; value-adding combination studies
- AZD0466 clinical progress and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and/or deals for further compounds
- Partnered DEP® deals & program developments, including DEP® ADCs
- Advance DEP® radiopharmaceuticals, DEP® ADCs and DEP® antivirals e.g. DEP® remdesivir
- 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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ASX:SPL OTC:SPHRY

