



PHARMACIST ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN
Fleurstat
BVgel

BETADINE BV
VAGINALGEL



MACQUARIE AUSTRALIA CONFERENCE

DR JACKIE FAIRLEY
CEO

5 MAY 2020



Important notice and disclaimer



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 health authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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 presentation 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.

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 VivaGel® Portfolio


3 DEP®

4 Outlook

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

Starpharma is an ASX300 company (market cap ~\$375M) 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\$36.1M cash (31 Mar 2020)



Deep portfolio of high-value products based on novel polymer platform



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



VivaGel® condom – Launched in Japan, Australia and Canada; approved in Europe



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



VivaGel® BV is licensed in more than 160 countries and currently for sale in the UK, Europe, Asia, Australia and New Zealand - further launches and regulatory submissions progressing in multiple regions



The VivaGel® condom has been launched in Japan, Canada & Australia; also approved in Europe



MULTIPLE CLINICAL-STAGE ASSETS



DEP® docetaxel
 DEP® cabazitaxel
 DEP® irinotecan
 DEP® AZD0466



EXTENSIVE & GROWING PIPELINE OF PROPRIETARY ASSETS



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.



Financial summary

Key Financial Data	1H FY20 A\$M	1H FY19 A\$M	FY19 A\$M
Revenue and other income	5.7 ↑	0.7	2.7
Loss for the period	(5.9) ↓	(7.3)	(14.3)
Net operating cash outflows	(5.2) ↓	(7.3)	(10.3)
Net cash burn ¹	(5.4) ↓	(6.9)	(10.1)
Cash as at 31 Dec 2019	\$35.9M		\$41.3M
Cash at 31 March 2020	\$36.1M		



HY20 Result:

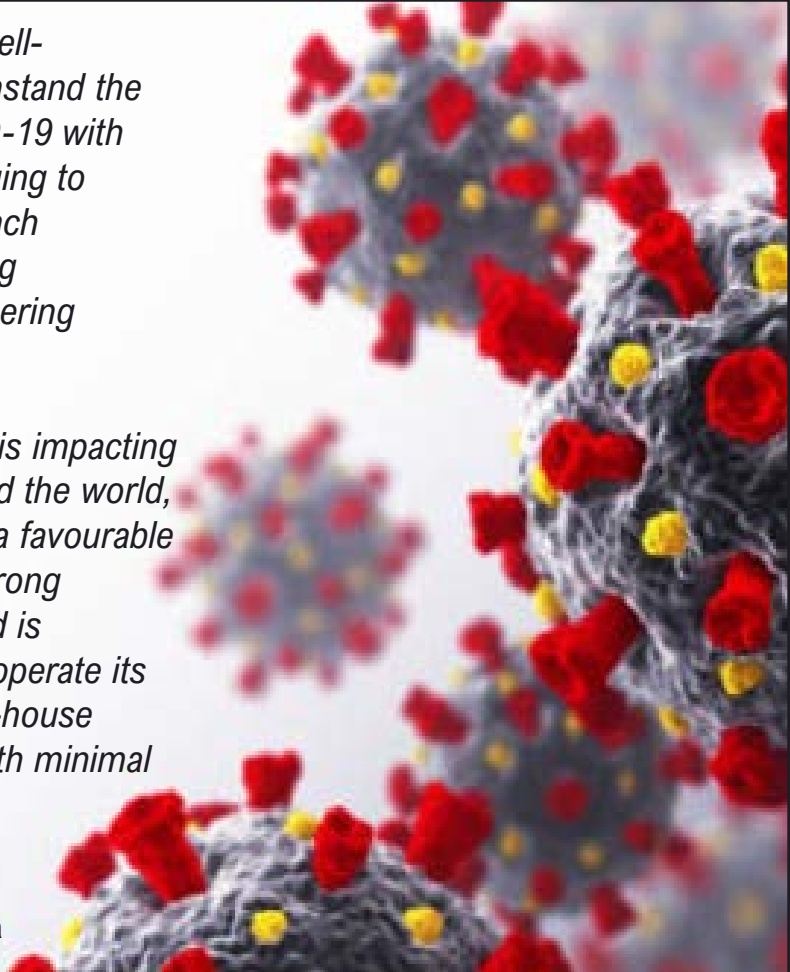
- Total revenue and other income of \$5.7M (pcp: \$0.7M), includes:
 - US\$3M AstraZeneca milestone payment (received in February 2020)
 - VivaGel® product sales and royalties of \$1.1M
- Reported loss for half-year of \$5.9M (pcp: \$7.3M), favourable by 19%
- Expenditure includes spend on the Company's clinical programs including three internal DEP® products
- Net cash burn¹ of \$5.4M for the half year, down 22% on pcp

pcp = prior corresponding period

COVID-19: Starpharma well positioned

Starpharma has a strong balance sheet and has implemented a business continuity plan to mitigate the impacts of COVID-19 including comprehensive measures to protect the health and safety of our staff and trial participants

- Company is well positioned to withstand impacts of COVID-19 with a strong balance sheet, including significant available cash of \$36.1M (at 31-Mar-20)
- Operations continue with minimal disruption: laboratory & in-house GMP manufacturing facilities are currently in full operation. Preclinical programs, other research and clinical trial support continue with minimal disruption.
- Design of the DEP[®] clinical programs is such that COVID-19 is not expected to adversely affect the integrity of trial results but may impact overall timing. Enrolled patients continue DEP[®] treatment, while new patient recruitment is not currently occurring at most sites. AstraZeneca has indicated that dosing in its phase 1 DEP[®] trial for AZD0466 continues.
- At present, no disruption to supply chain activities for VivaGel[®] BV; inventory levels are adequate.
- Formal FDA review is ongoing. Due to the significant disruption to the US healthcare system, activities relating to a potential BV treatment trial in the US are on hold.



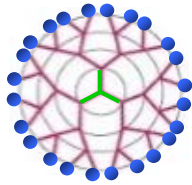
“Starpharma is well-positioned to withstand the impacts of COVID-19 with programs continuing to operate across each portfolio, including commercial partnering activities.

Whilst COVID-19 is impacting companies around the world, Starpharma is in a favourable position with a strong balance sheet and is currently able to operate its laboratory and in-house manufacturing with minimal disruption.”

**Dr Jackie Fairley
CEO, Starpharma**

SPL7013 shows significant antiviral activity against SARS-CoV-2 (coronavirus)

SPL7013 has previously demonstrated potent antiviral activity against a wide range of viruses, including HIV, herpes simplex, hepatitis B, HPV, Zika virus and adenovirus.



SPL7013 is the active included in marketed VivaGel® products

- SPL7013 showed significant antiviral activity blocking infection by SARS-CoV-2 (coronavirus)
- Findings validated by use of positive control, remdesivir (Gilead) (now approved for treatment of COVID-19 by US FDA)
- Several product opportunities are being explored, including nasal/inhaled/other applications to prevent infection, reduce severity of disease, or to treat the infection
- Opportunity to use existing data to fast-track development and commercialisation of SPL7013-based product(s) for COVID-19 – VivaGel® products are already approved and sold in UK, Europe, Canada, Japan, Australia/NZ, and South East Asia
- Discussion with regulators in territories where SPL7013-based products already approved, to confirm regulatory pathways, and ways to expedite approvals
- Starpharma retains global commercial rights to this application of SPL7013; new patent filed April 2020
- Interest from large pharma companies to support development of SPL7013 for coronavirus





1 Overview

2 VivaGel® Portfolio

3 DEP®

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**



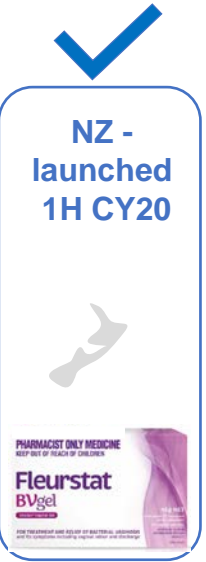
**Asia –
 launched
 1H CY20**

ASIA



On market

AUSTRALIA



**NZ -
 launched
 1H CY20**

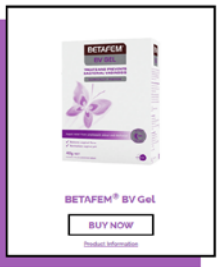




Fleurstat BVgel now available in pharmacies



Fleurstat BVgel ranks as #1 topical BV treatment in Australia

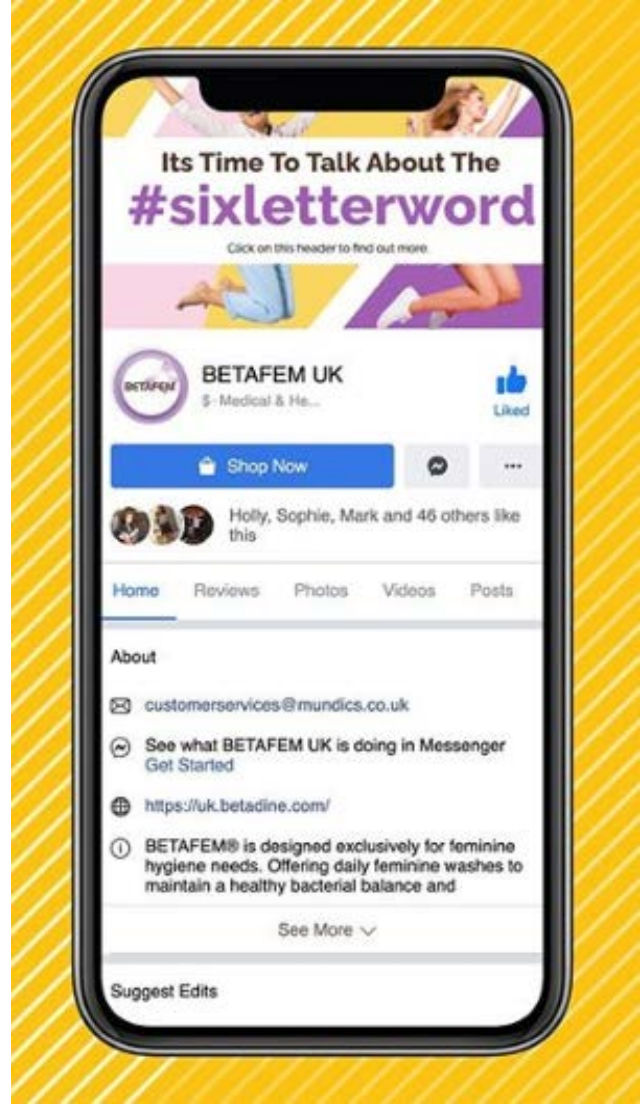


Where can I buy Fleurstat BVgel for bacterial vaginosis?

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



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



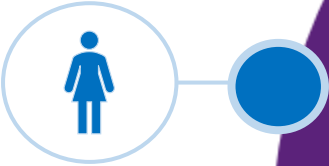
Positive patient experiences about VivaGel® BV benefits



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**”

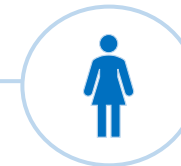
“Almost a total acceptance of Fleurstat BVgel by the detailed doctors as the product that will become the **first choice for the treatment of BV**”

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

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

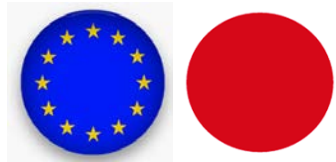
QIDP +5 YEARS EXCLUSIVITY

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



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.



1 Overview

2 VivaGel® Portfolio

3 **DEP®**

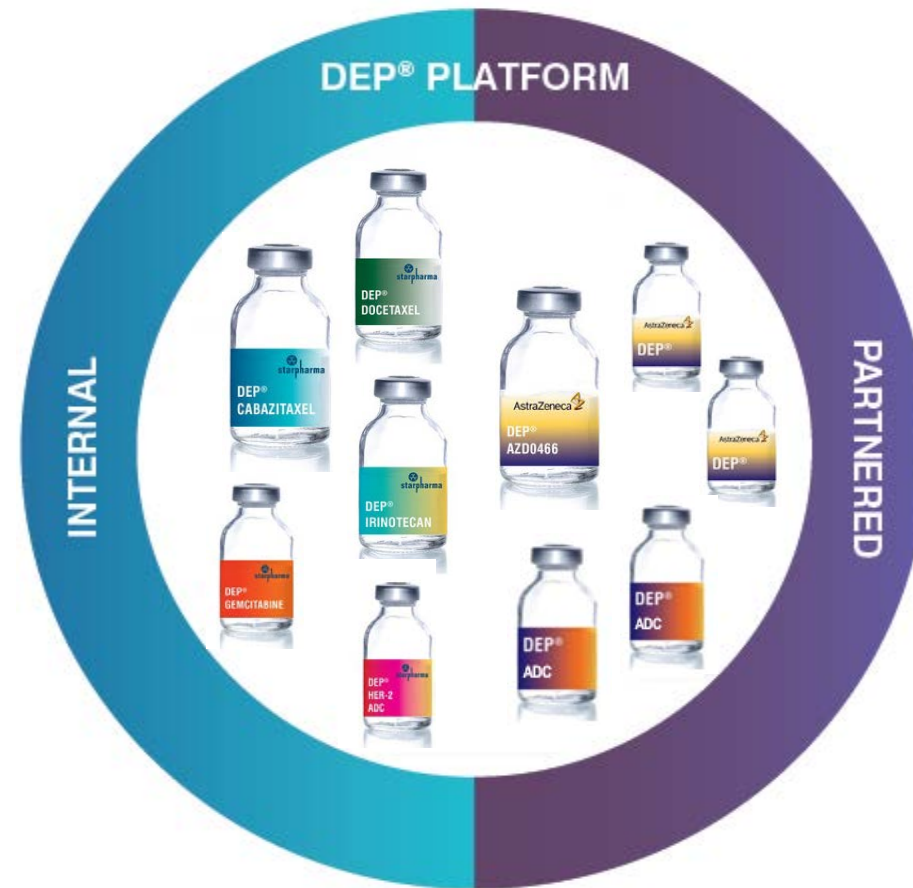
4 Outlook

Starpharma's DEP[®] strategy creates significant optionality and upside

DEP[®] strategy provides technical, IP and financial leverage, as well as increasing commercial opportunities, improving ROI and de-risking development

INTERNAL DEP[®]

- 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

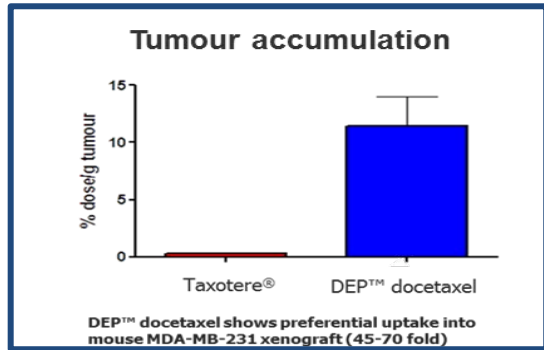
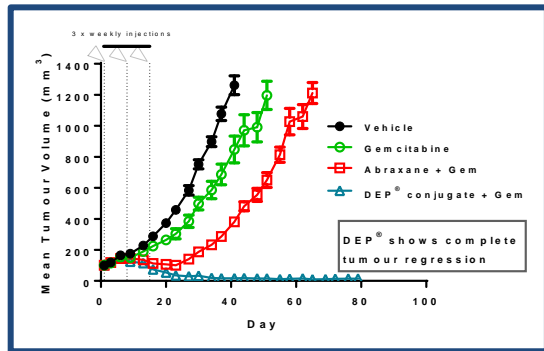
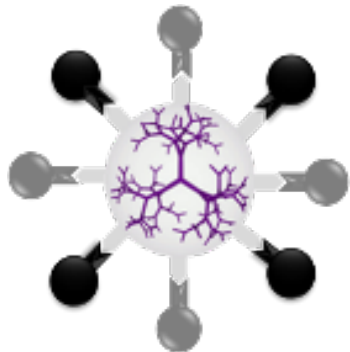


PARTNERED DEP[®]

- 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[®] platform conveys product benefits and enhances the commercial value of a wide range of drugs and therapeutic areas

DEP[®] has demonstrated numerous reproducible benefits across multiple drugs



DEP[®] BENEFITS

Improved Efficacy
Reproducible results with many candidates & tumour types

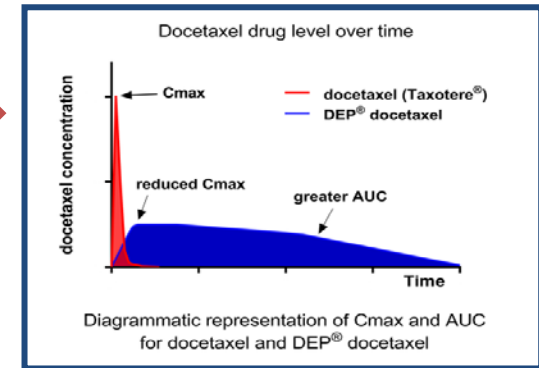
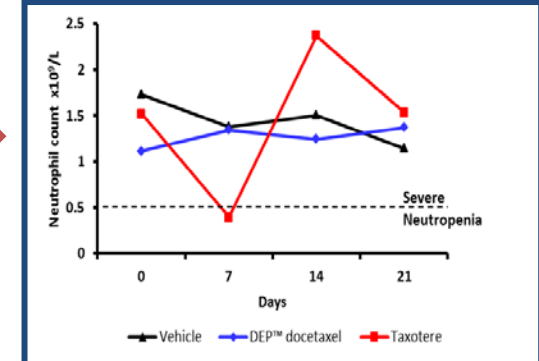
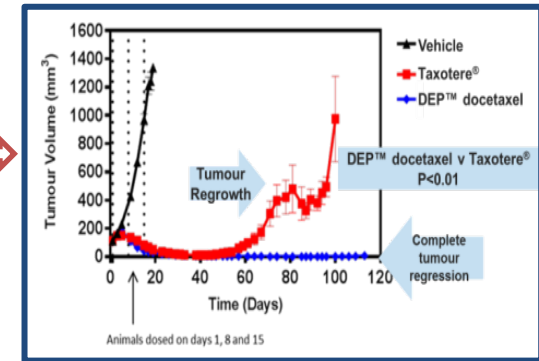
Benefit in Combination
Enhanced efficacy as monotherapy or in combination approaches

Improved Safety
Reduced neutropenia/BM toxicities

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

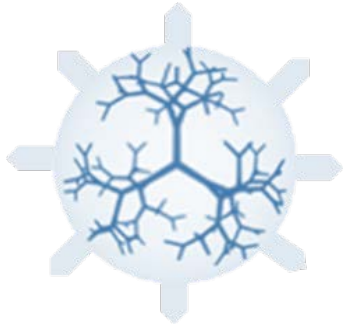
Improved Kinetics
Longer half life and lower C_{max}

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



DEP[®] platform for partnering

DEP[®] can be used by partners to improve novel drugs or life-cycle management

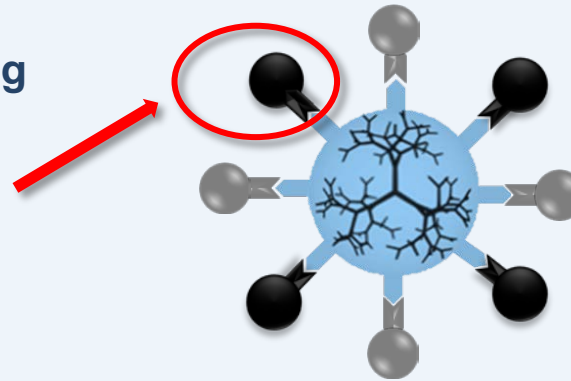


DEP[®] nanoparticles can be used to enhance the features of novel drugs that may otherwise limit clinical use due to issues such as toxicity or insolubility



DEP[®] 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



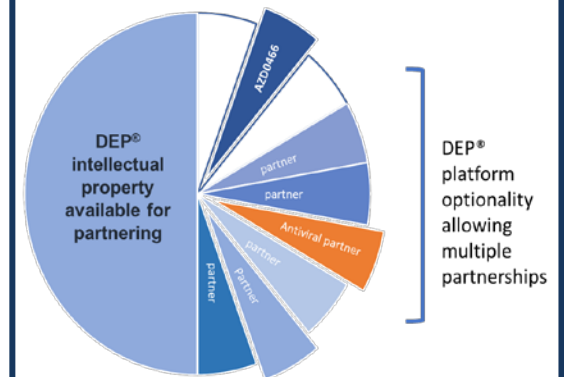
Partner funds development of their DEP[®] product(s)



Starpharma is eligible to receive milestone payments & royalties on DEP[®] products



Licences are structured to allow for multiple DEP[®] programs to run in parallel



AstraZeneca's DEP[®] programs: novel oncology agent AZD0466 phase 1 underway

AstraZeneca 

Multiple commercial
DEP[®] programs

Multiproduct licence

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



1st AZ DEP[®] candidate (AZD0466)

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



2nd AZ DEP[®] candidate (& subsequent candidates)

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

Development & Option Agreement



3rd AZ DEP[®] candidate (major existing AZ oncology medicine)

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



AZD0466 a highly optimized DEP[®] nanoparticle formulation of AZ's novel bcl2/xl inhibitor patented to 2038

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



AZD0466 Phase 1 trial underway in the US in solid & haematological tumours

AstraZeneca 

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[®] 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[®] DOCETAXEL:
Enhanced version of docetaxel (Taxotere[®]) – widely used for breast, lung & prostate cancer

PHASE 2

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

Advantages of DEP[®] docetaxel[#]: 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[®] CABAZITAXEL:
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana[®]) – also being developed for other cancers incl. breast and bladder

PHASE 2

Cabazitaxel (Jevtana[®]) – global sales of ~US\$500M for 2018 despite having multiple US FDA “Black Box” warnings

Advantages of DEP[®] 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).

DEP[®] IRINOTECAN:
Improved version of irinotecan (Camptosar[®]) - predominantly used for colorectal cancer



PHASE 1 / 2

Camptosar[®] had peak global sales of US\$1.1B despite having multiple US FDA “Black Box” warnings.

Advantages of DEP[®] irinotecan[#]: Irinotecan is a prodrug that must be converted to the active, SN38; this conversion leads to variability between patients and toxicity. DEP[®] 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).

Multiple preclinical studies have established improved efficacy, survival and safety with DEP[®] with many different drugs

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

Starpharma's DEP[®] pipeline targets significant needs and opportunities in oncology



OVARIAN

Ovarian cancer has the lowest survival rate of any female cancer*.

Market size: US\$1.8B (2018 across the seven major markets*), and it is expected to grow to \$6.7bn in the following ten years



PANCREATIC

Pancreatic cancer is the 4th leading cause of cancer death globally

Median survival is 4.8 months & median 5-year survival is 3%.

Market size: USD 1.9B (2018), expected to reach US\$4.7B by 2026.



LUNG CANCER (NSCLC)

Lung cancer is the most common type of cancer throughout the world NSCLC accounts for 84% of all lung cancers

Market size: US\$6.6B (2018), expected to reach US\$11.9B by 2025.



PROSTATE

Prostate cancer is the most common cancer in men in Australia - 1 in 7 men will be diagnosed with prostate cancer globally

Market size: US\$5.86B (2018), expected to reach US\$11.5B by 2025.



COLORECTAL

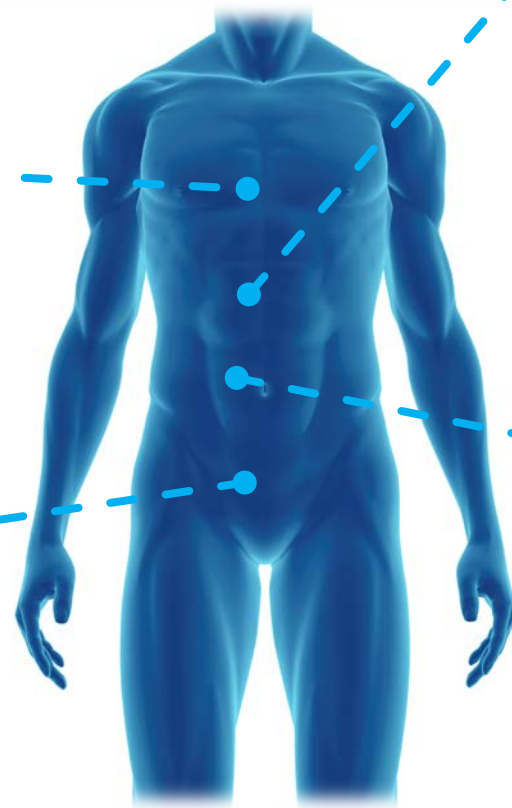
Colon cancer is the 2nd leading cause of cancer death and 3rd most common cancer globally

More than 90% of CRC occurs on people aged 50 years and over

Market size: US\$9.5B (2018), expected to reach US\$11.37B by 2025.



Various hard to treat tumours e.g. cholangiocarcinoma, upper GI (oesophageal), bladder.



DEP[®] docetaxel phase 2 program – ongoing recruitment and positive interim results

MONOTHERAPY ARM



33 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 cholangiocarcinoma (2nd most common liver cancer), gastric and pancreatic



Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and 9 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[®] DOCETAXEL

Open-label, two-stage design to allow for exploration of efficacy of DEP[®] docetaxel as a monotherapy.

In parallel, combination of DEP[®] docetaxel & nintedanib (Vargatef[®]) in lung 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[®] 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[®] docetaxel combinations



Based on compelling DEP[®] preclinical data & investigator interest, combination DEP[®] docetaxel with gemcitabine (Gemzar[®]) trial targeting pancreatic cancer is in final stages of start-up



Combinations with immunotherapy also being explored to create value

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

Case study: DEP[®] 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%¹.

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

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

Response:

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

DEP[®] docetaxel + nintedanib

CT scans of lung: right middle lobe

BASELINE

9 WEEKS POST Rx

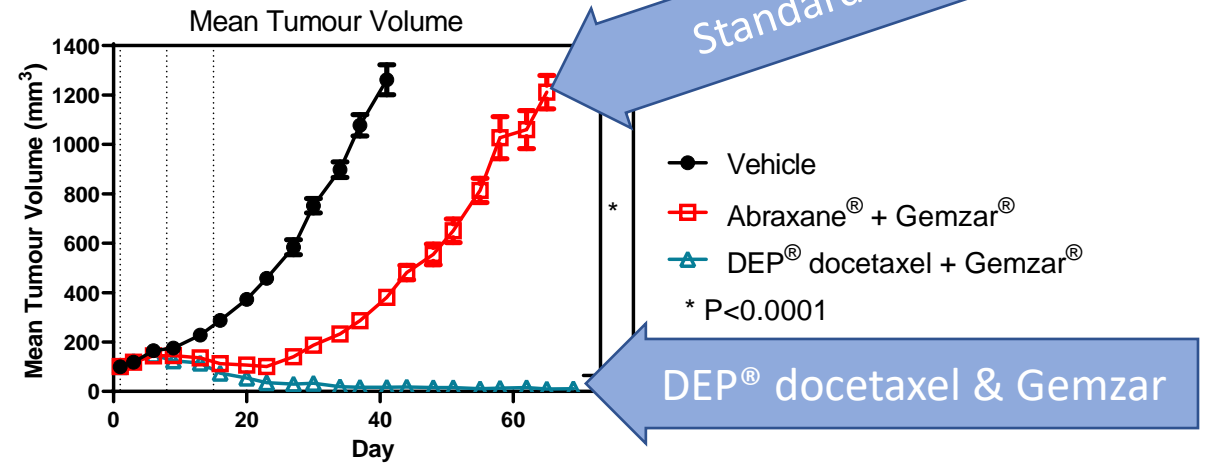


41% reduction in size of tumour lesion

Combination benefit: DEP[®] docetaxel + gemcitabine outperformed standard of care gemcitabine & Abraxane[®] in human pancreatic cancer model



Leading pancreatic cancer therapies, **gemcitabine & Abraxane[®]** are standard of care (SOC) & in combination, show **minimal activity** - this compares to **DEP[®] docetaxel + gemcitabine** which shows **complete tumour regression and 100% survival**



This experiment was conducted in a human pancreatic cancer (CAPAN-1) mouse xenograft model

Pancreatic cancer is a leading cause of cancer death, with a 1-yr survival rate of 20%, and a 5-yr survival rate of only 7%

Gemcitabine (peak sales US\$1.7B) is frequently used alone and in combination with Abraxane[®] (2017 sales US\$1.2B) in pancreatic cancer as a first line drug treatment

In a human pancreatic cancer model:

- ✓ Gemcitabine & Abraxane[®] (standard of care) in combination, show minimal activity
- ✓ DEP[®] docetaxel, alone, and in combination with gemcitabine, significantly outperformed gemcitabine and/or Abraxane[®] and showed 100% survival

Combination findings feed into clinical development with DEP[®] docetaxel + gemcitabine trial planned

DEP[®] cabazitaxel – positive phase 1 results & phase 2 underway

PHASE 1 RESULTS

Positive phase 1 results (dose-escalation)

- 14 patients enrolled and received DEP[®] cabazitaxel at doses between 2 mg/m² to 25 mg/m²
- Up to 15 cycles of DEP[®] cabazitaxel; no steroid, antihistamine or anti-emetic pre-treatment
- **Encouraging signs of efficacy were observed in 67% 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[®]**, 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/m²



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 9 patients treated with up to 5 cycles of treatment



The phase 2 DEP[®] 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 recruiting: Guy's & St Thomas', University College London, Velindre Cancer Centre in Cardiff and Imperial College London; exploring opportunities to initiate further sites including in Australia

Clinical case study: DEP[®] 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

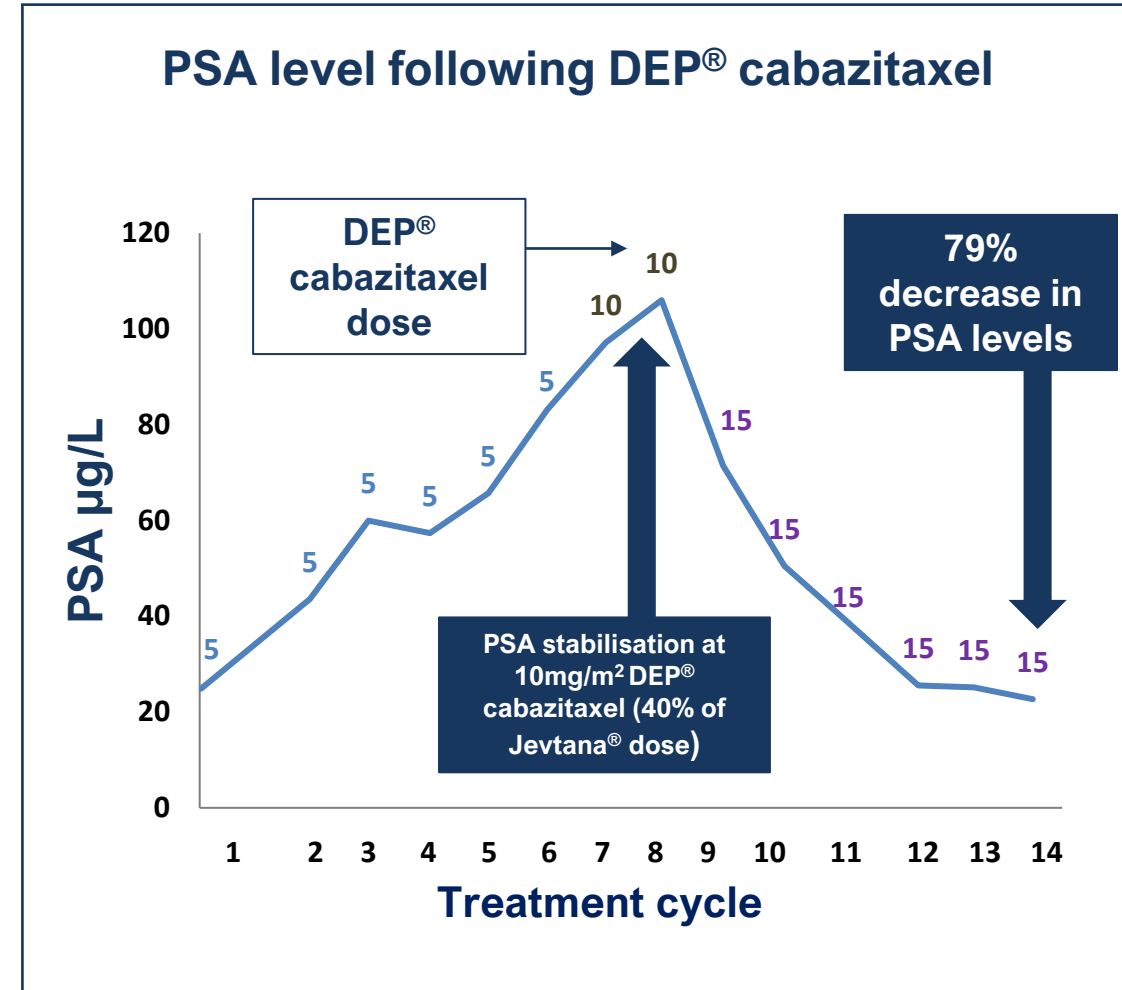


70 year old man with stage III prostate cancer:

- 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[®] cabazitaxel with no neutropenia
- response to DEP[®] cabazitaxel began at 40% of the typical dose

Response to DEP[®] cabazitaxel

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



Clinical case study: DEP[®] 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[®] cabazitaxel
- 56% decrease in CA-125 levels

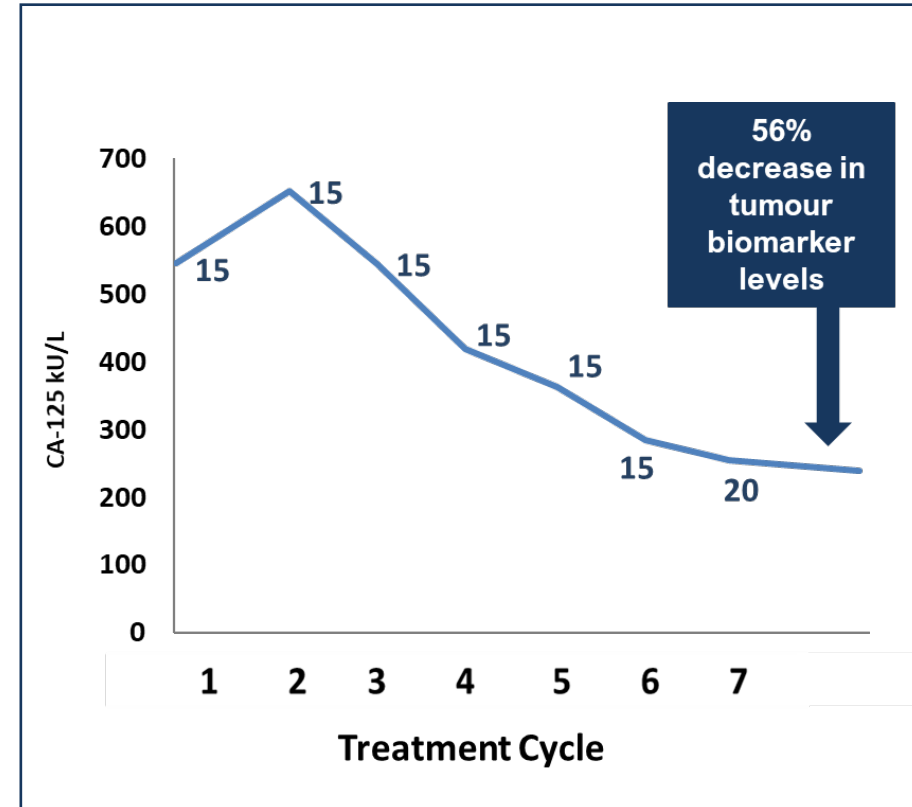


73-year old woman with stage IV (metastatic) ovarian cancer

- 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[®] cabazitaxel

- received 7 cycles of DEP[®] cabazitaxel (well tolerated)
- achieved a 56% decrease in tumour biomarker levels
- tumour response commenced at 60% of the currently recommended Jevtana[®] dose



* https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts-_2019_-FINAL.pdf

Clinical case study: DEP[®] 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.



Advanced ovarian cancer patient with extensive metastases



60 year old woman with advanced (metastatic) ovarian cancer:

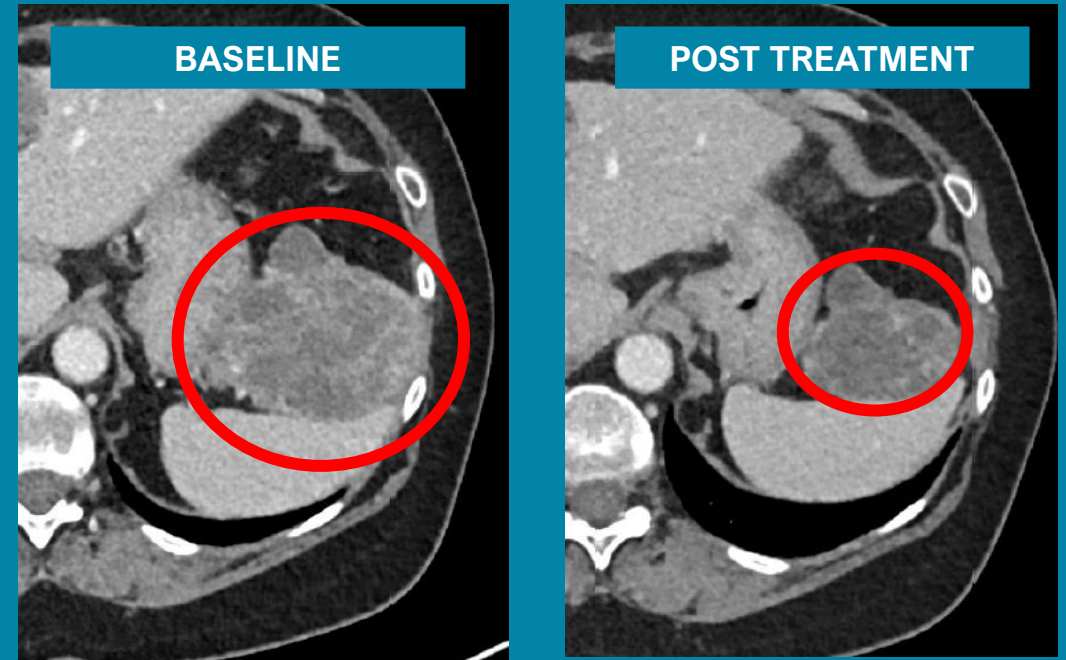
- heavily pre-treated; cancer progressed on 3 other anti-cancer therapies including paclitaxel (another taxane)
- previously had 14 cycles of treatment and multiple surgeries
- received 3 cycles of DEP[®] cabazitaxel to date

Response to DEP[®] cabazitaxel

- response seen after 3 cycles of treatment; well tolerated
- 30% reduction in some tumours, 26% overall reduction across all target tumour lesions

DEP[®] CABAZITAXEL

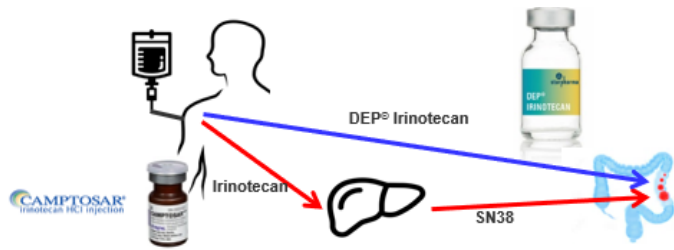
Below: scan of one of the patient's tumour demonstrating reduction in tumour size



30% reduction in size of tumour

DEP[®] irinotecan phase 1 / 2 program progressing well

DEP[®] irinotecan incorporates the irinotecan active moiety (SN38) and is an improved version of Camptosar[®]



DEP[®] 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 pre-clinical models



Phase 1: Open-label dose-escalation

Adaptive phase 1 / 2 trial design enables seamless transition from phase 1 to phase 2

Phase 2: Dose expansion to establish efficacy in 20 - 30 patients

Trial objectives: evaluate the safety, tolerability and pharmacokinetics, to define RP2D) and to determine anti-tumour efficacy of the product in select tumour types.

As the trial progresses, decisions will be made as to which tumour types to focus on and any additional patients will be recruited to explore efficacy in specific tumour types (e.g. colorectal)

The ROYAL MARSDEN
NHS Foundation Trust



The Newcastle Upon Tyne Hospitals
NHS Foundation Trust



PHASE 1 >> PHASE 2



Dose escalation (Phase1) is nearing completion – expect to move to Phase 2 shortly with new sites to be added



7 patients dosed with up to 10 cycles



Heavily pre-treated patients (some with up to 100 prior cycles of other treatments)



Encouraging efficacy signals observed, in patients with colorectal, breast and pancreatic cancer, including in patients previously treated with conventional irinotecan combinations



DEP[®] irinotecan continues to be well-tolerated; No problematic acute or delayed diarrhoea, which is severe and frequently seen with Camptosar[®]



Enthusiastic support from clinicians due to limited treatment options for colorectal cancer

Clinical case study: DEP[®] 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 per cent 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 - more than 100 cycles of 11 different treatment regimens
- received 10 cycles of DEP[®] irinotecan to date

Response to DEP[®] irinotecan

- response seen after 3 cycles of treatment
- prolonged stable disease >27 weeks
- well tolerated





1 Overview

2 VivaGel® Portfolio

3 DEP®

4 Outlook

Outlook



SPL7013 for Coronavirus

- Expedite development & explore regulatory pathways for product concepts e.g. nasal/inhaled/other

EXPLORING PRODUCT OPTIONS

VIVAGEL®

- Commercial roll-out of VivaGel® BV in Europe, Asia & other markets
- Ongoing formal FDA review process
- Further VivaGel® BV licences for India, Canada & Israel
- Further regulatory approvals and launches for VivaGel® BV
- Revenue from VivaGel® BV - milestones and sales/royalties
- VivaGel® condom approvals/launch in additional regions, such as China/Europe
- Further development / co-development of SPL7013 for antiviral ophthalmic drops



COMMERCIAL OUTCOMES



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

DEP®

- Progress DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan clinical trials and additional combination studies, e.g. DEP® docetaxel + gemcitabine; presentations/posters for DEP®
- AZD0466 clinical progress, presentations/posters and receipts from milestones
- AstraZeneca: Exercise of Option Agreement and deals for further compounds
- Progress other partnered DEP® deals & program developments, including DEP® ADCs
- Explore value-adding DEP® combinations & advance other DEP® products, including DEP® gemcitabine, DEP® radiopharmaceuticals, DEP® ADCs
- Continue to explore other DEP® programs including oncology and antivirals



Leveraging the DEP® platform to build value



Advancing internal DEP® assets builds value for future licensing



Partnered DEP® - upfront fees, milestones, royalties



starpharma

WWW.STARPHARMA.COM

