

## AGM Chairman's address and CEO's presentation

**Melbourne, Australia; 29 November 2018:** Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting of Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY), to be held at 3.00pm today.

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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® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

**VivaGel®:** Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodimer sodium, a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application is under Fast Track review by the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to 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® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Australia and Canada under the Lifestyles® Dual Protect™ brand.

**DEP® - Dendrimer Enhanced Product®:** Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more.

[Starpharma.com](http://Starpharma.com) | [Twitter](https://twitter.com/Starpharma) | [LinkedIn](https://www.linkedin.com/company/starpharma)

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### 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.



**Chairman's Address**  
**Starpharma Holdings Limited**  
**Annual General Meeting**  
**29 November 2018**

Good afternoon,

On behalf of the Starpharma Board, it is with great pleasure that I welcome you to the 2018 Annual General Meeting.

This was another very positive year for Starpharma in which we achieved many significant milestones across our VivaGel<sup>®</sup> and DEP<sup>®</sup> drug delivery portfolios, including successful clinical trial results, international licences, submission of a New Drug Application (NDA) to the US FDA and a string of further achievements and commercial milestones.

Our successes are made possible through the strategic utilisation of our proprietary dendrimer platform technology, which allows Starpharma to develop both novel therapies, such as our VivaGel<sup>®</sup> products, and separately to develop a valuable and highly versatile delivery platform for enhancing the performance of drugs. This strategy has allowed Starpharma to build a deep and diverse pipeline of products (internal and partnered), which have the potential to generate significant revenues, create and extend patents and provide life-changing improvements for patients worldwide. The leverage and optionality that the platform affords us is quite remarkable.

Monetising and commercialising our products at the ideal stage to optimise their value is one of our strategic priorities. Doing so ensures we have the benefit of multiple late-stage and clinical products in our portfolio but we do not carry the cost-burden of funding the full development for all of them. Starpharma's strategy is to licence at the optimal stage to maximise value, with proceeds to be reinvested into our pipeline, predominantly in our high-potential DEP<sup>®</sup> drug delivery portfolio.

Regulatory activities and commercialisation have been a significant focus for us over these past 12 months, with considerable effort dedicated to licensing VivaGel<sup>®</sup> BV around the world and completing the enormous task of an NDA filing. Starpharma is one of a handful of Australian companies to have ever achieved this.

Starpharma's NDA for VivaGel<sup>®</sup> BV was submitted to the FDA, comprising a clinical and regulatory data package with more than 110,000 pages. This was a tremendous achievement for a company of our size to submit an NDA - and be accepted for filing first time and without issues. The FDA confirmation of this important milestone reflects the completeness of the package. It's a significant milestone for any company to pursue a new drug FDA approval and more so for a relatively small Australian company. Importantly, the FDA has also confirmed that the VivaGel<sup>®</sup> BV NDA will be the subject of a Fast-Track priority review, which has a target review period of approximately six months from acceptance.



In regard to licensing VivaGel® BV, a critical factor in Starpharma's partner selection involves an assessment of each potential partner's sales and marketing expertise and resources to successfully market a novel, specialty women's health product, as well as obtaining the best deal terms. The competitive process we undertake with input from a US healthcare bank typically involves negotiating with several parties simultaneously to enable Starpharma to achieve the best deal terms possible – and find the most suitable partner.

This year we were delighted to sign a multi-region licence for VivaGel® BV with leading pharmaceutical company, Mundipharma, which covers the majority of the globe including Europe, Russia, Commonwealth of Independent States, Asia, the Middle East, Africa and Latin America. Mundipharma has an impressive sales network across these areas, leading brands and significant expertise in marketing feminine care products. The deal terms for this licence are very attractive for Starpharma. The Company is eligible to receive a share of sales revenue from the product as well as up to US\$24.7 million in milestone payments. Since execution we have been impressed with the speed at which Mundipharma is progressing with its registration and launch plans for a number of launches, which include Europe in 2019.

There is significant preparation and work that goes into these launches and the timing for each market is ultimately controlled by our partners. Launch schedules often involve strategic decisions taking into account in-market factors, such as new product or sales cycles in the relevant outlets, in addition to product preparations such as manufacturing and supply chain activities, and marketing and promotion. These activities are now well underway for a number of regions with both Mundipharma – for larger regions, like Europe, the Middle East and Asia and also with Aspen, for the smaller Australian market.

The US is the highest value BV market with approximately 125 million adult females and a high prevalence of BV (1 in 3 women). We are well advanced with negotiations for a US deal and as mentioned earlier, we are running a competitive process involving multiple parties with negotiations progressed to an advanced stage.

Advancing the commercialisation of our VivaGel® assets means that Starpharma is now set to move to a new phase as a company and generate recurrent revenue. Revenue growth is expected to occur over time, as the product is rolled out globally with initial launches in the first half of 2019. In addition to royalties or revenue share, Starpharma is also eligible for multiple milestone payments upon certain events, such as regulatory approvals, market launches and sales thresholds. Revenue is expected to build over the medium-term as more territories come on stream. This expected revenue, and our existing healthy cash balance, are expected to enable Starpharma to unlock significant new portfolio and pipeline opportunities from within its DEP® platform and selected other areas.



In our internal DEP® portfolio, we reported excellent clinical trial results for DEP® docetaxel, which transitioned seamlessly into phase 2, and in parallel we advanced the clinical development of two other lead products – DEP® cabazitaxel and DEP® irinotecan. With the phase 1 data for DEP® docetaxel in hand and phase 2 advancing, we now have a set of human clinical data to add to the extensive body of preclinical data that has reproducibly demonstrated the benefits of our platform in improving drug efficacy and reducing side effects. DEP® docetaxel is currently in phase 2, and we now have four large UK sites recruiting patients with lung or prostate cancer. I'm pleased to report that recruitment is proceeding well, there have been no cases of neutropenia and we continue to see early efficacy signals in a number of patients. We also continue to explore the potential to add value through DEP® docetaxel's use in combination with other oncology agents, and the potential to include additional indications, if these would add value commercially.

Starpharma's second internal product, DEP® cabazitaxel, commenced a phase 1 / 2 trial this year for patients with solid tumours and DEP® irinotecan will be our third DEP® product to enter the clinic. The final stages of preclinical work for the DEP® irinotecan phase 1 / 2 trial are almost complete and the trial is planned to commence this financial year. The trial will be open to patients with a range of cancers, including colon and pancreatic, where impressive efficacy has been shown in preclinical models.

What each of our oncology products have in common is that they are all based on cancer drugs with significant markets, that in their current formulation have significant issues such as neutropenia, hair-loss and other serious side-effects. Our DEP® formulations have demonstrated, in a range of preclinical studies, and now in humans, that the DEP® technology can reduce certain toxicities (like bone-marrow toxicity) which can be devastating and life-threatening for patients. As our DEP® formulations are detergent-free, there have been no cases of anaphylaxis, and no steroid pre-treatment is required.

During the year we continued to work closely with our DEP® partners, advancing several programs, including AstraZeneca's AZD0466 - a highly optimised dendrimer formulation of a dual Bcl2/xL inhibitor which has the potential to be a best-in-class, blockbuster cancer drug. While AstraZeneca has been making final preparations for AZD0466 to enter the clinic, their first DEP® patent application was published, featuring compelling efficacy data on their DEP® Bcl2/xL conjugates, both alone and in combination with market-leading anti-cancer treatments, in various human leukemia models.

We're delighted that our DEP® platform has been central to the development of such exciting, novel oncology drugs and our partnership with AstraZeneca is just one example of the commercial value that can be created. The fact that we can apply the DEP® platform many times over for many different drugs ourselves while simultaneously licensing the technology to partners makes it a very powerful and valuable asset. With partnered DEP®, Starpharma has a carried-interest in significant commercial opportunities that someone else funds while we retain a share of any successful program. The interest in DEP® from big pharma around the world is growing and recent results in pancreatic cancer models only serve to strengthen this. We look forward to announcing further partnerships as that momentum builds.



Turning to the year ahead, this is a really exciting and rewarding time for Starpharma. We look forward to the market launch of VivaGel<sup>®</sup> BV in multiple regions, signing a US licence and FDA approval of VivaGel<sup>®</sup> BV as well as multiple value-adding milestones for the DEP<sup>®</sup> portfolio. With the achievement of each of these milestones, we continue to unlock the immense commercial value from our dendrimer technology and deliver life-changing drugs to patients around the world.

I'd like to thank our CEO, Dr Jackie Fairley and every member of her talented staff who work tirelessly to accelerate the development and commercialisation of our products. As a Board, we congratulate the team on all of their achievements. The expertise and dedication of our people are key to our future success and we thank them for their continued commitment and hard work. I'd also like to take this opportunity to acknowledge the contribution and expertise the Board has provided throughout the year.

Finally, I'd like to thank our shareholders for their ongoing support. Starpharma is in a strong position to leverage its experience, cash resources and, most importantly, its human capital and expanding IP portfolio to drive success and increase shareholder value.

Thank you,

Rob Thomas *AM*, Chairman



# 2018 AGM

## CEO PRESENTATION, DR JACKIE FAIRLEY

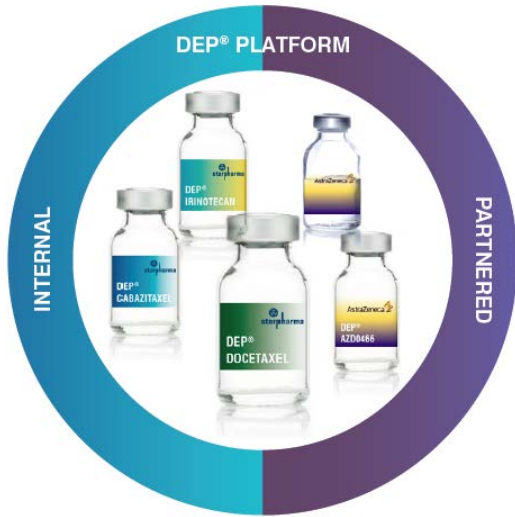
STARPHARMA HOLDINGS LIMITED

ASX:SPL; OTCQX:SPHRY

# Important notice and disclaimer

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# Agenda



- 1 Overview
- 2 Internal DEP®
- 3 Partnered DEP®
- 4 VivaGel®
- 5 Outlook

*Please note: This presentation focuses on recent achievements and upcoming milestones, and is not intended to provide a comprehensive overview of the Company*





Starpharma is an ASX300 company with **a proven record of successful development & commercialisation** including successful partnerships with leading global companies



# Starpharma has a deep portfolio of high-value global products with the potential to significantly improve patient outcomes



Market capitalisation (as at 28 Nov)	~A\$550M	
Issued shares	371.3M	
Share ownership	57% Institutions 41% Retail/Other ~2% Directors/Staff	
Liquidity (average daily volume)	840k	
<b>Annualised Return</b>	<b>SPL</b>	<b>ASX300</b>
1-year	+8.6% p.a.	- 5.3% p.a.
2-year	+63.4% p.a.	+2.0% p.a.
5-year	+17.1% p.a.	+1.3% p.a.
Cash (as at 30 Sep 2018)	A\$49.5M	

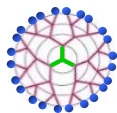
# Starpharma has a deep portfolio of global products with the potential to significantly improve patient outcomes

## VIVAGEL®

### VivaGel® BV



US - ADVANCED  
NEGOTIATION



SPL7013



aspen  
AUSTRALIA



TGA  
APPROVED

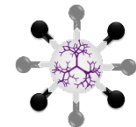


### VivaGel® Condom

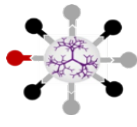


## DEP®

### DEP® Internal Products



DEP®



Targeted  
DEP®

Starpharma's  
proprietary  
dendrimer  
platform

### DEP® Partnered Products

























World-leading  
Antibody Drug  
Conjugate  
Companies

### AstraZeneca

MULTIPLE HIGH VALUE COMMERCIAL OPPORTUNITIES UNDERPINNED BY 100+ PATENTS

# Starpharma's pipeline

	Product	Indication	Preclinical	Clinical/Regulatory	Commercial
VIVAGEL®	VIVAGEL® BV	Bacterial Vaginosis		 	
	VIVAGEL® CONDOM	Anti-viral condom		  	 
	SPL7013 OPTHALMIC	Viral conjunctivitis			
INTERNAL DEP®	DEP® DOCETAXEL	Oncology			Licence after proof-of-concept
	DEP® CABAZITAXEL	Oncology			
	DEP® IRINOTECAN	Oncology			
	OTHER DEP®	Oncology			
	TARGETED DEP®	Oncology			
PARTNERED DEP®	AZ DEP® AZD0466	Oncology			
	AZ #2 DEP® CANDIDATE	Oncology			
	AZ #3 DEP® CANDIDATE	Undisclosed			
	ANTIBODY DRUG CONJUGATE #1	Oncology			Undisclosed Partner
	ANTIBODY DRUG CONJUGATE #2	Oncology			Undisclosed Partner

# Starpharma's strategy provides exceptional optionality underpinned by valuable, late-stage products



## BUILD PORTFOLIO through:

- Strategic investment in high-value, high potential development programs
- Exploring other therapeutic opportunities for dendrimers (e.g. radiopharmaceuticals)

## CREATE VALUE through:

- commercialising or monetising products at the right stage
- developing new IP for Starpharma & for partners



## LEVERAGE platform:

- to add to our deep portfolio of global products for large, high-value markets
- through DEP® partnerships for additional returns

# Starpharma is in a strong financial position to expand & accelerate multiple high-value programs

Key Financial Data	FY 2018 A\$M	FY 2017 A\$M	
Total revenue and income	5.0	3.6	↑ 39%
<b>Loss from continuing operations</b>	<b>(10.3)</b>	<b>(15.2)</b>	↓ 32%
Profit/(loss) from discontinued operation	-	23.4	} Sale of Agrochemicals Business in FY17
Profit/(loss) for the period	(10.3)	8.2	
<b>Net operating cash outflows</b>	<b>(10.2)</b>	<b>(17.0)</b>	↓ 40%
<b>Net cash burn<sup>1</sup></b>	<b>(9.9)</b>	<b>(18.0)<sup>2</sup></b>	↓ 45%
<b>Closing Cash (30 June)</b>	<b>51.3</b>	<b>61.2</b>	

## Outlook - Revenues expected to build with:

- VivaGel<sup>®</sup> BV milestones
- Receipts following VivaGel<sup>®</sup> BV launches
- DEP<sup>®</sup> milestones

## Reduced loss from continuing operations:

- VivaGel<sup>®</sup> BV development now complete
- VivaGel<sup>®</sup> BV licence revenue from Mundipharma for Europe, Russia & CIS, Asia, Middle East, Africa, & Latin America
- R&D spend primarily focused on DEP<sup>®</sup>

<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.

<sup>2</sup> Excludes net proceeds of \$33.3M on the sale of the agrochemicals business in FY17.

# DEP<sup>®</sup> highlights



First patent published for Starpharma's DEP<sup>®</sup> dendrimer with AstraZeneca's Bcl2/xL inhibitors



Commenced DEP<sup>®</sup> docetaxel phase 2 trial following successful phase 1 results



Commenced DEP<sup>®</sup> cabazitaxel phase 1 / 2 trial



DEP<sup>®</sup> irinotecan outperformed standard irinotecan & 5-FU in a human pancreatic cancer model



In-house manufacture of DEP<sup>®</sup> irinotecan for phase 1 / 2 trial



DEP<sup>®</sup> docetaxel & DEP<sup>®</sup> cabazitaxel outperformed standard treatments (Abraxane<sup>®</sup> and gemcitabine) in a human pancreatic cancer model

# VivaGel® BV highlights



VivaGel® BV licensed to Mundipharma for Europe, Russia, CIS and Latin America for an attractive revenue share, in addition to milestones of up to US\$15.5M (A\$20.9M)



VivaGel® BV licensed to Mundipharma for Asia, Middle East, Africa and the majority of Latin America for an attractive revenue share, in addition to milestones of up to US\$9.2M (A\$12.2M)



Completed & submitted New Drug Application (NDA) for VivaGel® BV; FDA accepted the VivaGel® BV NDA and confirmed Priority Fast Track review



VivaGel® BV received Australian marketing approval from the TGA



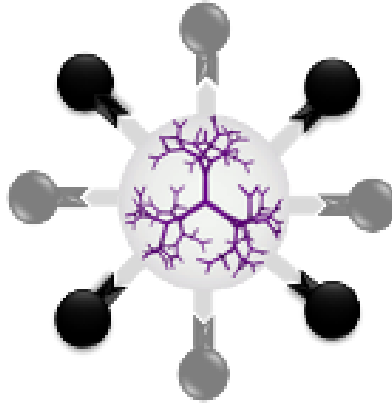
Successful VivaGel® BV phase 3 results for prevention of recurrent BV

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



## Improved

**efficacy<sup>1</sup>:** DEP<sup>®</sup> improves anti-cancer efficacy through better drug targeting & improved pharmacokinetics.



## Reduced

**side-effects<sup>1</sup>:** DEP<sup>®</sup> reduces important side effects such as bone marrow toxicity / low white blood cells (neutropenia) and alopecia (hair loss). Also removes need for steroid pre-treatment.

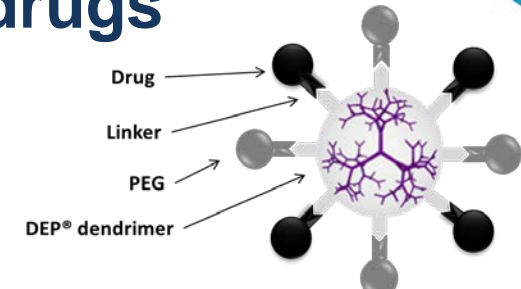


**Patent life:** In addition to the therapeutic and clinical benefits, DEP<sup>®</sup> also provides valuable commercial benefits by creating new intellectual property and extending patent life.

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



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



## DEP<sup>®</sup> BENEFITS

### Improved Efficacy

Reproducible results with many candidates & tumour types

### Improved Safety

Reduced neutropenia/bone marrow toxicities

### Targeting Tumour Tissue

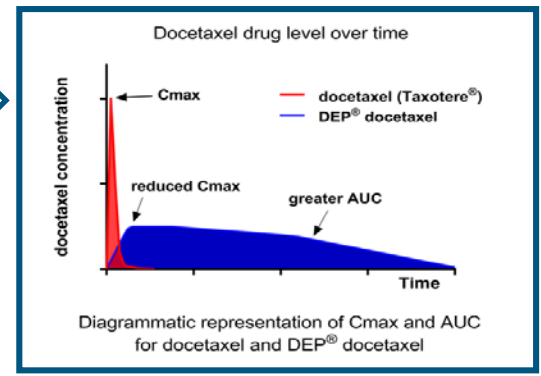
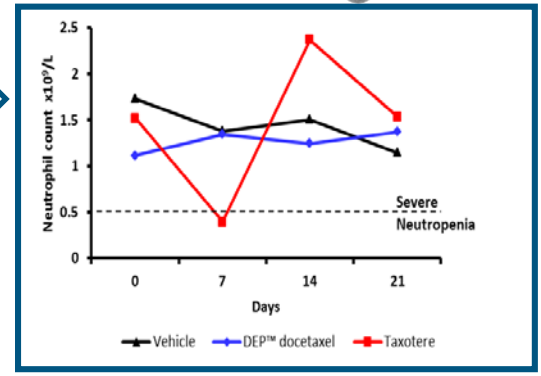
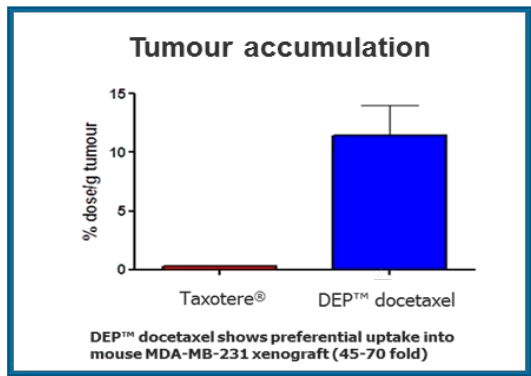
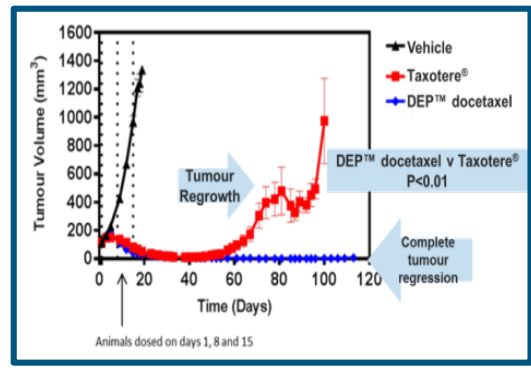
45-70 x more drug in tumour v original drug

### Improved Pharmacokinetics

Longer half life and lower peak (Cmax)

### Improved Solubility

Detergent free DEP<sup>®</sup> formulations for improved safety – 20,000 x solubility increase



# Starpharma's DEP<sup>®</sup> platform has enabled the creation of a deep pipeline of high-value products



DEP<sup>®</sup> docetaxel:  
Starpharma's most advanced DEP<sup>®</sup> product - a detergent-free, enhanced version of widely used anti-cancer drug Taxotere<sup>®</sup>

- ✓ Improved Efficacy
- ✓ Benefit in combination with marketed anti-cancer therapies
- ✓ Improved Safety
- ✓ Improved Survival
- ✓ Patent Life Extension
- ✓ Detergent Free



DEP<sup>®</sup> cabazitaxel:  
Detergent-free, enhanced version of leading prostate cancer drug Jevtana<sup>®</sup>

- ✓ Improved Efficacy
- ✓ Benefit in combination with marketed anti-cancer therapies
- ✓ Improved Safety
- ✓ Improved Survival
- ✓ Patent Life Extension
- ✓ Detergent Free



DEP<sup>®</sup> irinotecan:  
Enhanced version of leading anti-cancer drug Camptosar<sup>®</sup>

- ✓ Improved Efficacy
- ✓ Benefit in combination with marketed anti-cancer therapies
- ✓ Improved Safety
- ✓ Improved Survival
- ✓ Patent Life Extension



Further DEP<sup>®</sup> candidates under development

# DEP<sup>®</sup> docetaxel is an enhanced version of widely used cancer drug, Taxotere<sup>®</sup>



Enhanced version of docetaxel (Taxotere<sup>®</sup>) - one of the most widely used cancer drugs for a range of tumours including breast, lung and prostate



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



DEP<sup>®</sup> patents provide coverage to 2032



## Advantages of DEP<sup>®</sup> docetaxel

- ✓ Elimination of major dose-limiting side effect (neutropenia)
- ✓ Detergent-free formulation (less toxic)
- ✓ Tumour-targeting (~70x more)
- ✓ Improved pharmacokinetics
- ✓ Improved efficacy

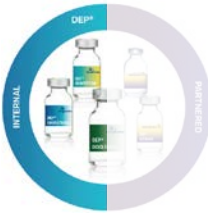
vs



## PHASE 1 RESULTS

- **No steroid pre-treatment required** due to DEP<sup>®</sup> docetaxel’s detergent-free formulation - unlike Taxotere<sup>®</sup>
- **No neutropenia** (compares to >>90% with Taxotere<sup>®</sup>)
- No protocol-defined Dose Limiting Toxicities
- Only one patient (1/27) with mild alopecia/hair loss – compared to ~75% with Taxotere<sup>®</sup>
- No reports of other problematic adverse events observed with docetaxel treatment, including anaphylaxis, fluid retention, diarrhoea and nail disorders
- **Encouraging efficacy signals** in 13/27 DEP<sup>®</sup> docetaxel patients including:
  - Stable disease (SD) in multiple patients with lung, pancreatic (SD>20 weeks), gastro-oesophageal (SD >18 weeks) cancers, and in other patients with glioblastoma (brain) and renal cancers

# DEP<sup>®</sup> docetaxel phase 2 program underway



## PHASE 2

(currently recruiting)

Multi-site trial – 4 sites currently recruiting (Guy's Hospital London, UCLH, Newcastle, Leeds)

1. Open-label, two-stage design (20+20 patients) to allow for exploration of efficacy of DEP<sup>®</sup> docetaxel as a monotherapy
2. In parallel, combination of DEP<sup>®</sup> docetaxel & nintedanib (Vargatef<sup>®</sup>) in lung cancer (4-12 patients)

## TRIAL UPDATE

### Monotherapy arm

- Positive interim trial results for the monotherapy arm show continued lack of neutropenia and encouraging efficacy signals (stable disease, tumour shrinkage) in lung and prostate; 70% of initial cohort recruited.
- Based on investigator interest, also investigating other tumour types including pancreatic.

### Combination arm

- Based on positive interim results in the DEP<sup>®</sup> docetaxel + nintedanib combination arm (no protocol-defined DLTs, efficacy signals, no neutropenia), recruitment is now being expanded; efficacy signals observed include stable disease & tumour shrinkage.

## Commercial Objective:

- Create value through clinical proof-of-concept in one or more cancer types – both alone and in combination
- License following proof-of-concept clinical data; platform validation
- Utilise accelerated development pathways for optimal ROI

# DEP<sup>®</sup> cabazitaxel is an enhanced version of leading prostate cancer drug, Jevtana<sup>®</sup>



Starpharma's patented DEP<sup>®</sup> cabazitaxel is an enhanced version of cabazitaxel (Jevtana<sup>®</sup>) – primarily used for prostate cancer and in clinical development for other cancers including breast, bladder, head & neck



Cabazitaxel (Jevtana<sup>®</sup>) – estimated global sales of US\$500M for 2018 despite having multiple US FDA “Black Box” warnings (for neutropenia & anaphylaxis – due to polysorbate 80 in formulation)



DEP<sup>®</sup> cabazitaxel patents and applications provide coverage to 2039



vs



## Advantages of DEP<sup>®</sup> cabazitaxel

- ✓ DEP<sup>®</sup> cabazitaxel significantly outperformed Jevtana<sup>®</sup> (cabazitaxel) in a human breast cancer model with respect to efficacy, safety and survival
- ✓ Detergent (polysorbate 80) free formulation
- ✓ Elimination of major dose-limiting side effect (neutropenia)

# DEP<sup>®</sup> cabazitaxel phase 1 / 2 trial program underway



## PHASE 1 / 2 (currently recruiting)

Multi-site trial – currently recruiting at Guy's Hospital London & UCLH (more sites to be added in the expansion phase)

Planning to recruit ~35 patients with solid tumours

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

Phase 1: Open-label, sequential dose-escalation (accelerated) to establish the MTD (Maximum Tolerated Dose) and Dose Limiting Toxicities, RP2D (Recommended Phase 2 Dose) & Pharmacokinetics

Positive interim results:  
no neutropenia and no protocol-defined DLTs

Adaptive phase 1 / 2 trial design enables seamless transition from phase 1 to phase 2, to explore efficacy as early as possible

Phase 2: Dose expansion to establish efficacy



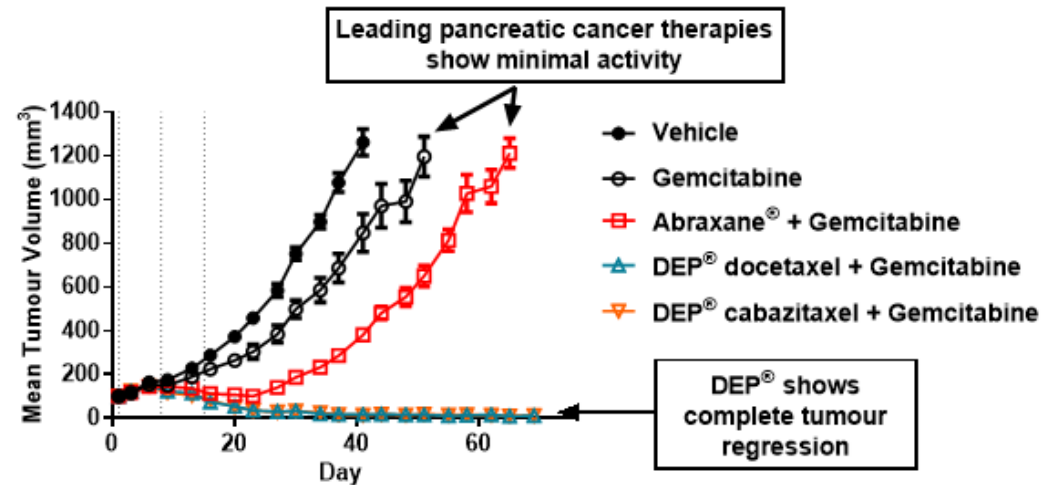
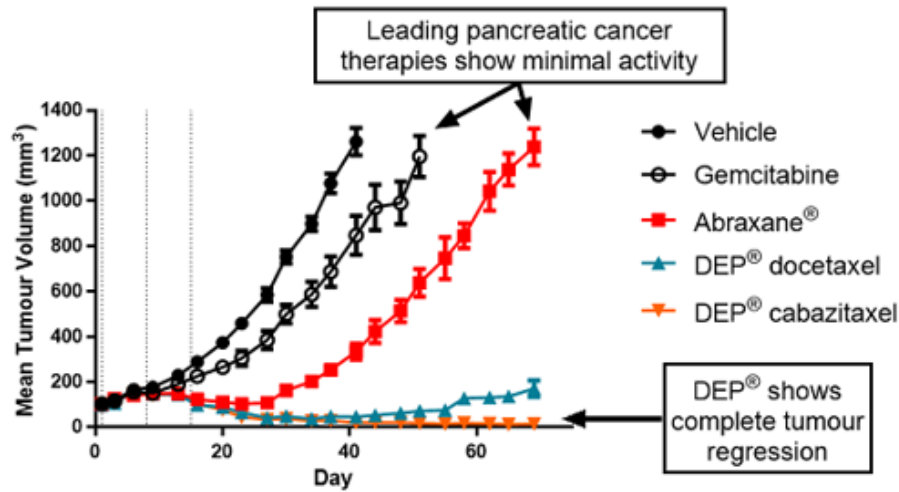
## Commercial Objective:

- Create value through clinical proof-of-concept in one or more cancer types – both alone and in combination
- Potential to commercialise earlier than phase 2

OR

Utilise accelerated development pathways for optimal ROI

# DEP<sup>®</sup> docetaxel & DEP<sup>®</sup> cabazitaxel outperformed both gemcitabine & Abraxane<sup>®</sup> in human pancreatic cancer model



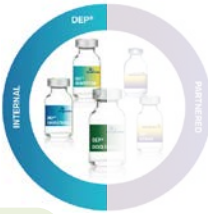
In a human pancreatic cancer model:

- ✓ DEP<sup>®</sup> cabazitaxel, both alone and in combination with gemcitabine, showed complete tumour regression and 100% survival
- ✓ DEP<sup>®</sup> docetaxel, alone, and in combination with gemcitabine significantly outperformed gemcitabine and/or Abraxane<sup>®</sup> and showed 100% survival
- ✓ This data will feed into the clinical development programs for DEP<sup>®</sup> docetaxel and DEP<sup>®</sup> cabazitaxel



- Pancreatic cancer is a leading cause of cancer death, with a 1-yr survival rate of 20%, and a 5-yr survival of only 7%
- Gemcitabine (peak sales US\$1.7B) is frequently used alone and in combination with Abraxane<sup>®</sup> (2017 sales US\$1.2B) in pancreatic cancer as a first line drug treatment

# DEP<sup>®</sup> irinotecan is an enhanced version of widely used cancer drug, Camptosar<sup>®</sup>



An improved version of irinotecan (Camptosar<sup>®</sup>) – used for advanced colorectal cancer (peak sales US\$1.1B).

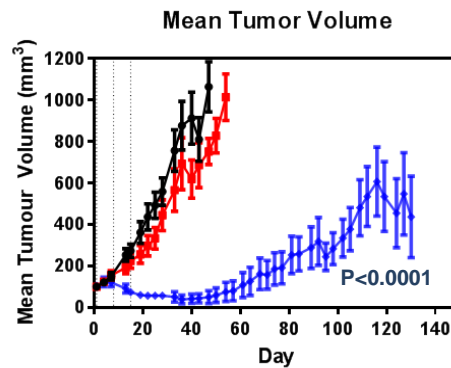


Colorectal cancer is the third most common cancer.

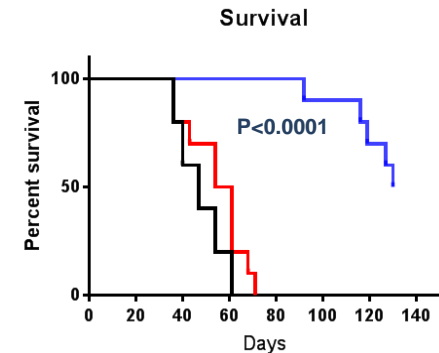
Irinotecan has FDA “Black Box” warnings for severe diarrhoea and neutropenia.

DEP<sup>®</sup> irinotecan demonstrated significantly better anti-tumour activity and increased survival compared with irinotecan (Camptosar<sup>®</sup>) in multiple human colon cancer models

## HT-29 (colon) Xenograft

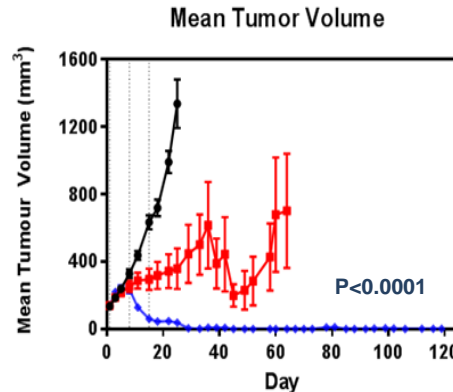


● Vehicle- Control  
 ■ Irinotecan  
 ▲ DEP<sup>®</sup> irinotecan

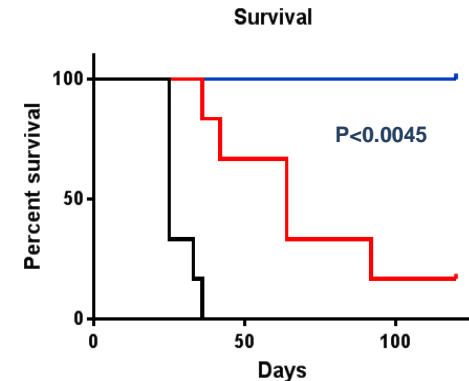


HT-29 (colon cancer) mouse xenograft Balb/c nude mice (n=10 /group). IV dosing with Vehicle, DEP<sup>®</sup> irinotecan or irinotecan on days 1, 8 and 15.

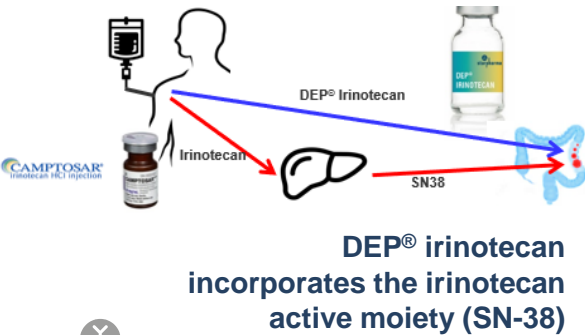
## SW620 (colon) Xenograft



● Vehicle  
 ■ Irinotecan  
 ▲ DEP<sup>®</sup> irinotecan



SW620 (colon cancer) mouse xenograft Balb/c nude mice (n=6 /group). IV dosing with Vehicle, DEP<sup>®</sup> irinotecan or irinotecan on days 1, 8 and 15.



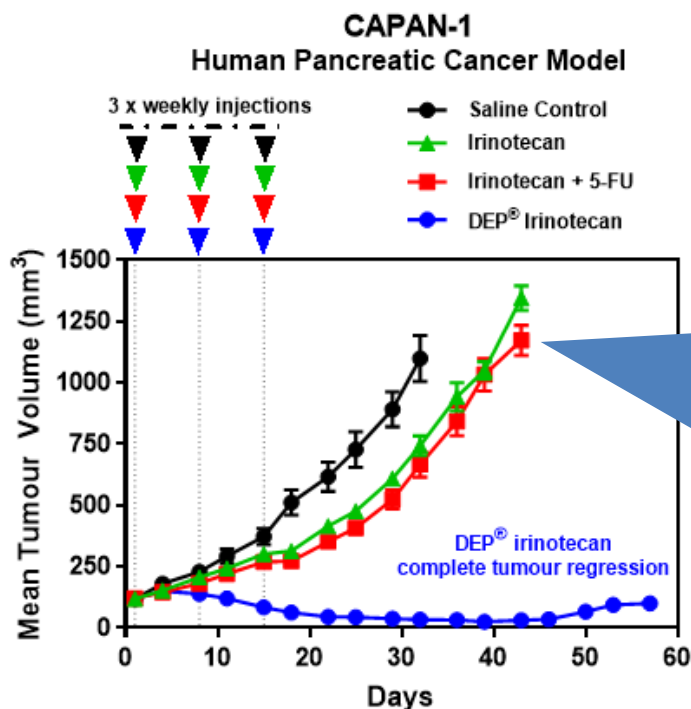


# DEP<sup>®</sup> irinotecan outperformed standard treatments in human pancreatic cancer model



DEP<sup>®</sup> irinotecan alone showed **complete tumour regression** and **100% survival** in a human pancreatic cancer model

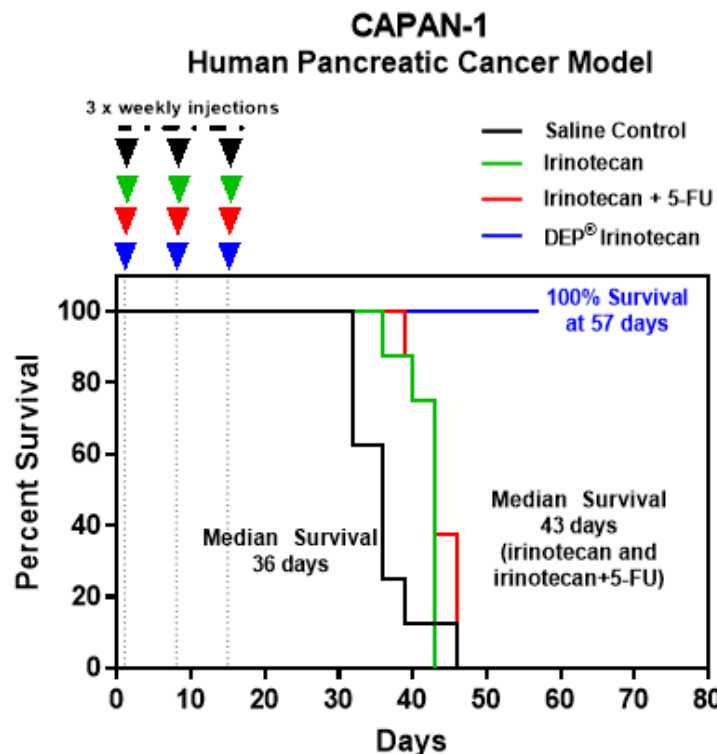
DEP<sup>®</sup> irinotecan is currently in advanced preparations for phase 1 / 2 trial, expected to commence in FY19



Unlike DEP<sup>®</sup> irinotecan, conventional irinotecan +/- 5-FU showed minimal activity in this pancreatic cancer model

**Mean Tumour Volume vs days**

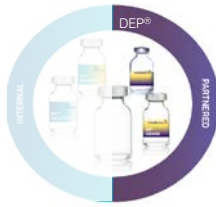
CAPAN-1 (human pancreatic cancer) xenograft in mice (n=8 /group). IV dosing with Vehicle, DEP<sup>®</sup> irinotecan, irinotecan or irinotecan + 5-FU on days 1, 8 and 15



**Kaplan Meier Survival Curve**

DEP<sup>®</sup> irinotecan versus all other groups (P<0.0001 Log-rank Mantel Cox)

# AstraZeneca's DEP<sup>®</sup> programs illustrate the potential returns from DEP<sup>®</sup> partnered programs



## Partnered-DEP<sup>®</sup>



Starpharma produces DEP<sup>®</sup> candidates under research collaboration



Partner selects candidate – either **novel or existing drug** (for life-cycle management)



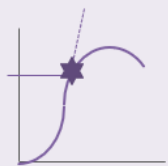
Partner funds development – creates a free carried interest for Starpharma



Starpharma is eligible to receive significant milestone payments & royalties on products

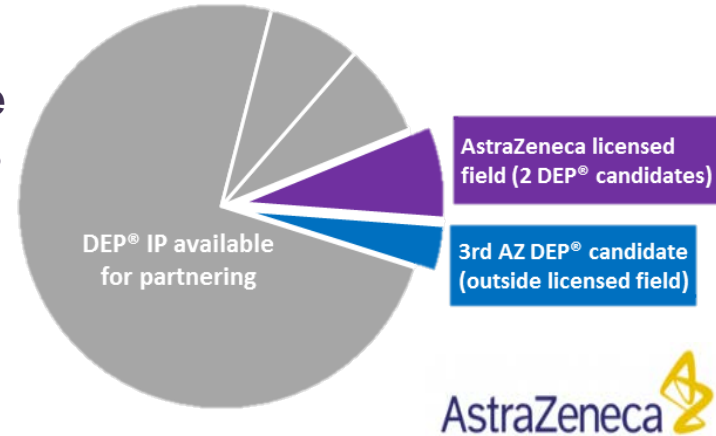


Licences are structured to allow for multiple partnered-DEP<sup>®</sup> programs run in parallel



When DEP<sup>®</sup> is used for life-cycle management, it allows partners to achieve continued sales growth through differentiated product benefits & new IP

## AstraZeneca has three active DEP<sup>®</sup> programs



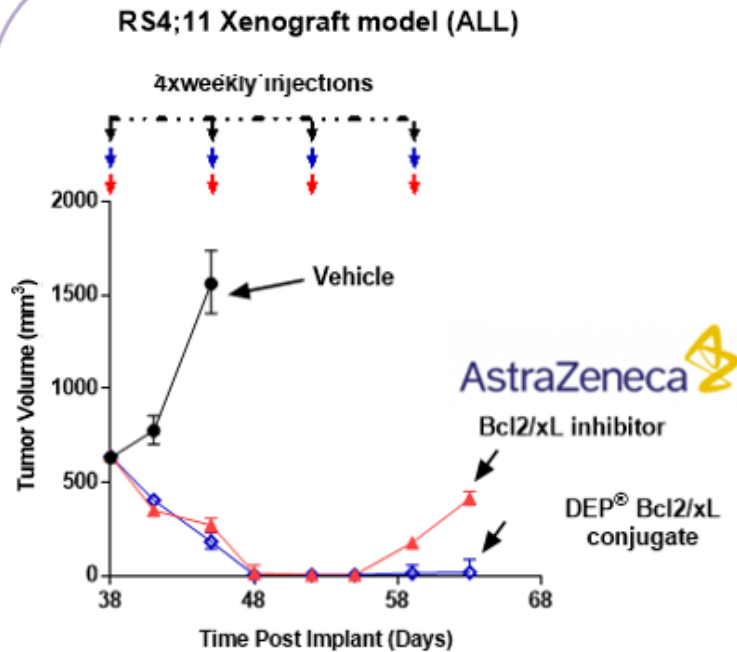
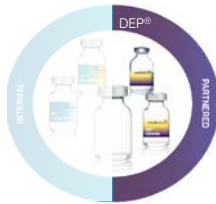
## AstraZeneca's multiproduct DEP<sup>®</sup> licence

- First DEP<sup>®</sup> candidate, AZD0466: Starpharma's total receipts (milestones + royalties) now estimated to be up to A\$2.4B based on increased annual sales projections
- Subsequent DEP<sup>®</sup> candidates US\$93M in milestones + tiered royalties
- AstraZeneca funds all development & commercialisation costs

*"This licence agreement will enable us to further harness the DEP<sup>®</sup> technology and evaluate its potential across novel molecules within our oncology portfolio."*

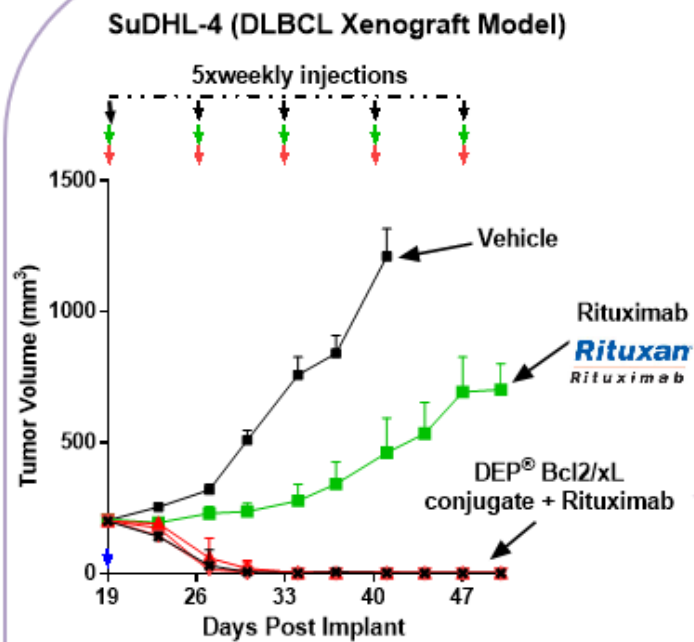
Dr Susan Galbraith, Head of the Oncology Innovative Medicines Unit at AstraZeneca

# AstraZeneca's DEP<sup>®</sup> Bcl2/xL inhibitors show compelling efficacy & synergy in combination



DEP<sup>®</sup> Bcl2/xL conjugates in a human acute lymphoblastic leukemia model

AstraZeneca DEP<sup>®</sup> Bcl2/xL inhibitor conjugates were significantly more efficacious than the Bcl2/xL inhibitor alone, resulting in complete tumour regression in most animals



DEP<sup>®</sup> Bcl2/xL in combination with Rituximab in a human B cell lymphoma model

AstraZeneca DEP<sup>®</sup> Bcl2/xL conjugates in combination with Rituximab performed significantly better than Rituximab alone, resulting in complete tumour regression in most animals



<sup>^</sup>Rituximab sales US\$7.5B (2017)

DEP<sup>®</sup> Bcl2/xL plus Rituximab<sup>^</sup> results in **complete tumour regression**

# VivaGel® portfolio - innovative, late-stage global products



**VivaGel® BV -**  
**A breakthrough product for**  
**BV Treatment & Prevention**  
**of Recurrent BV**



- ✓ Approved in Australia and the EU
- ✓ **US FDA New Drug Application under Fast Track priority review**
- ✓ **Licensed to Mundipharma** for Europe, Russia, CIS, Asia, the Middle East, Africa & Latin America; and to Aspen for Aus/NZ; Advanced commercial negotiations in North America



**VivaGel® condom -**  
**World's first and**  
**only anti-viral**  
**condom – launched**  
in Australia and  
Canada; Licensed to  
Lifestyles; Okamoto  
(Japan); Sky & Land  
(China); & Koushan.



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

## Bacterial Vaginosis (BV):

- affects 1 in 3 women in the US, and recurs in ~50-60% of women; and
- is twice as common as thrush.

## Patient reported impact of BV\* (n=90)

**79%**

reported moderate / severe **overall impact** on their lives

**52%**

reported moderate / severe impact on their **ability to work**

**60%**

reported moderate / severe impact on **relationships**

\*Source: Independent VivaGel® BV Market Research 2018

Starpharma's VivaGel® BV is a patented, non-antibiotic, rapidly acting gel with a novel mechanism of action



Acts rapidly to resolve BV symptoms



Non-antibiotic treatment – avoids side-effects & antibiotic resistance



Selective antimicrobial effect – less candidiasis (thrush)



Local effect, not systemically absorbed – fewer side-effects



Suitable for long-term use (BV prevention)



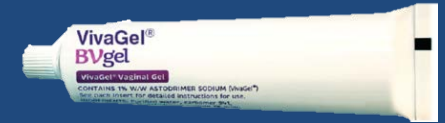
***“Our ability to prevent recurrent BV with current treatment regimes is abysmal. There is an enormous need for a safe and effective treatment to prevent recurrence of BV in women suffering BV.”***

- Professor J Sobel, ID Physician & KOL Dean, Wayne State Uni School of Medicine

# Positive patient experiences from women who have already benefited from VivaGel® BV

*“VivaGel® BV is a wonderful product which specifically targets BV bacteria. My patients have called it a ‘life changing and miraculous treatment’.”*

- Dr Belvia Carter, Principal Investigator & Ob-Gyn, USA



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

*“Yeah, it took care of the discharge and the odor and everything... within two days I seen that it was working.”*

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

*“The next day I noticed a huge difference...”*

*“It did take [the odor] away .... I liked it...”*

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

*“Within two days I seen that it was working. .... I knew it was clearing up.”*



# Positive independent market research for VivaGel® BV - from US physicians and payers alike



*"I would love to try it [VivaGel® BV] because **it is not an antibiotic.**"*



-US GYN #1

*"It [VivaGel® BV] is certainly simple enough and **the side effect profile is minimal**"*



-US GYN #6

*"I think part of the reason why we are seeing **more recurrence** is that there has got to be some kind of **resistance being built up to the antibiotics.**"*



-US GYN #5

*"The good news is **not having an antibiotic hanging around the environment is good.** The more antibiotics you have out there, the more potential for resistance."*



-US Payer #3



*"I like the molecule [VivaGel® BV] ... there's nothing really that treats the recurrent patient."*



-US Payer #2

*"The biggest unmet need is to be able to prescribe a treatment that has **minimal side effects**, does not interfere with the patient's lifestyle and **resolves symptoms quickly.**"*



-US PCP #1

*"It seems like it [VivaGel® BV] would **replace current [off label] prophylactic regimens** that I recommend."*



-US NP #1

# VivaGel® BV has been licensed in most regions around the world to Mundipharma

Mundipharma has licensed VivaGel® BV for more than 160 countries throughout Europe, Russia, CIS, Asia, Middle East, Africa & Latin America; to be marketed as part of the popular BETADINE® Feminine Care portfolio

## Attractive deal terms including revenue share and milestones

- ✓ Starpharma receives returns via an attractive revenue share on VivaGel® BV sales for all territories and up to A\$33.3M (US\$24.7M) in milestones across all territories under licence
- ✓ VivaGel® BV is already approved in Europe, facilitating early market entry
- ✓ Mundipharma is responsible for regulatory activities, market pricing and marketing and promotion
- ✓ Licence agreement term is 15 years & incorporates performance obligations, including minimum annual purchases by Mundipharma

**Mundipharma's registration, product manufacture and launch activities are well advanced for a number of markets, which include Europe in 2019**



Mundipharma is a leading global pharmaceutical company and owns the successful international brand - BETADINE®



Active in more than **120 markets worldwide**



Employs more than **8,600 professionals**



Global sales exceeding **US\$3.4 billion**



**Market leading position in Feminine Care,** trusted by women globally



# Launches for VivaGel® BV are expected in most regions during CY 2019



Reg approval > Finalise Claims & Packaging > Manufacture > Distribution > Launch

## Launch Process

- Advanced launch activities underway by both Mundipharma and Aspen in preparation for 2019 launches
- Launch timing is controlled by Starpharma's partners
- Launch strategy and scheduling involves multiple commercial factors including:
  - in-market factors such as specified launch windows mandated by relevant channels
  - extensive product preparations including packaging/label development, manufacturing and supply chain activities
  - comprehensive sales training, advertising/promotional material development and KOL recruitment

US

EUR

ROW

ANZ

~ Relative Market Size

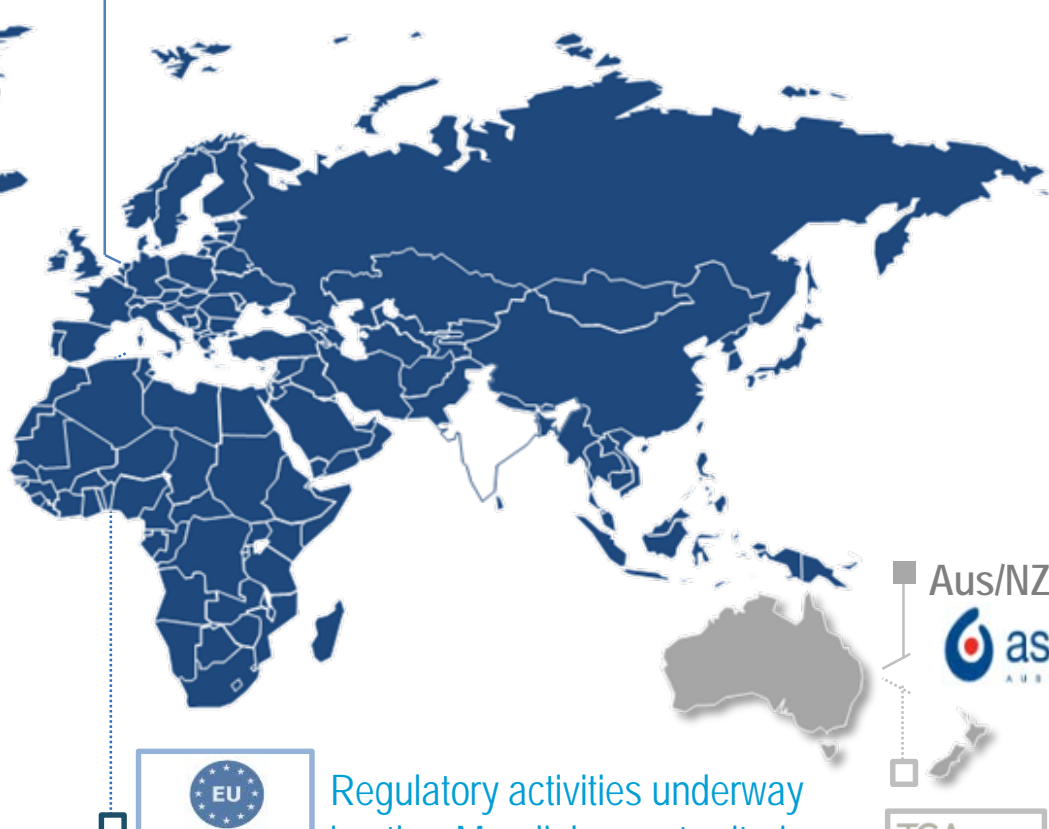
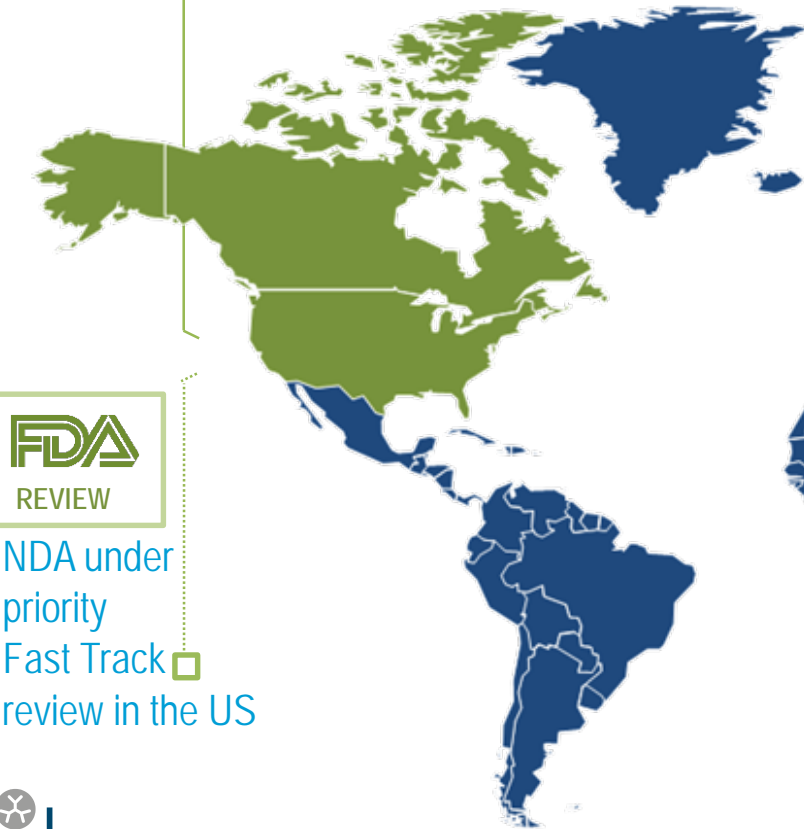
# VivaGel® BV has been licensed in most regions around the world; advanced negotiations in US/North America

The global market is estimated to be ~US\$750M for BV treatment & ~US\$1B annually for BV prevention



**US/North America**  
Advanced negotiations

**Rest of World (RoW)**  
Europe, Russia, CIS, Asia,  
Middle East, Africa, Latin America  
Attractive revenue share + up to US\$24.7M in milestones



NDA under  
priority  
Fast Track  
review in the US



Regulatory activities underway  
in other Mundipharma territories



# Starpharma's dendrimer platform continues to yield further valuable product opportunities



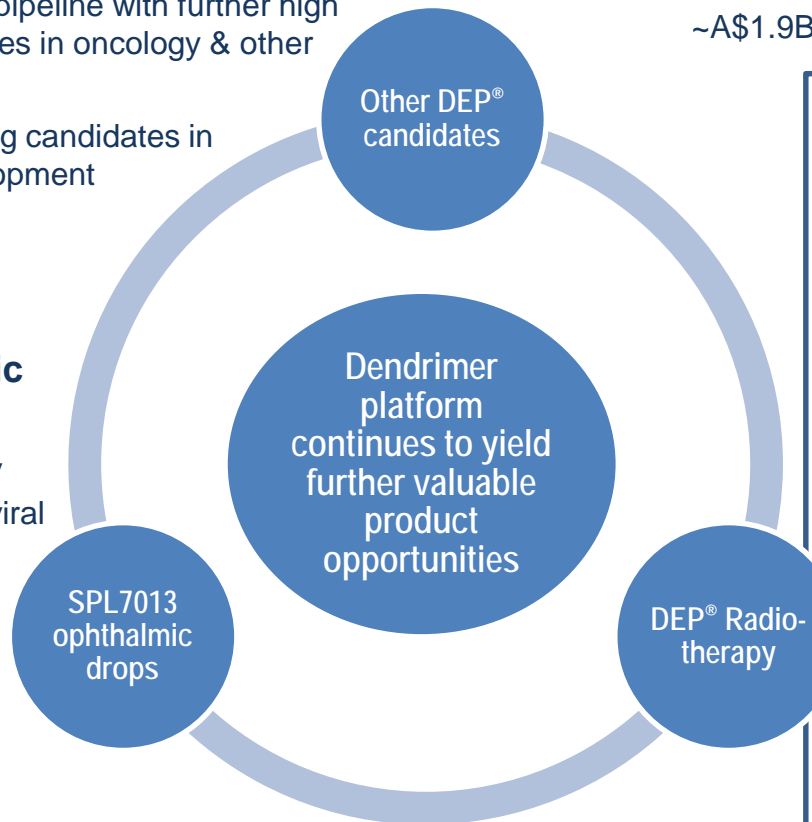
## Leveraging DEP® platform benefits:

- Expand internal pipeline with further high value opportunities in oncology & other areas
- Several promising candidates in preclinical development



## SPL7013 ophthalmic drops:

**SPL7013<sup>1</sup>** has been shown to be highly effective against adenoviral conjunctivitis in animal models

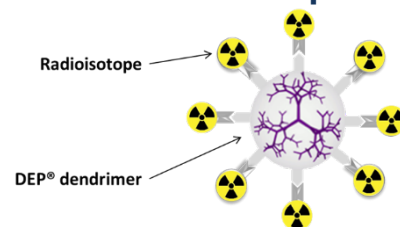


## Radiopharmaceuticals

- Growing category with current sales ~\$750M, & est. \$12–15B by 2030<sup>2</sup>
- Recent deals incl. Sirtex acquisition ~A\$1.9B by CDH Genetech.



## DEP® Radiotherapeutic



Incorporation of radioisotope on to DEP® scaffold allows for both radiodiagnostic and radiotherapeutic applications

Tumour accumulation of DEP® radiotherapeutic in prostate cancer model



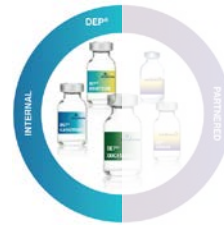
<sup>1</sup>SPL7013 is the active ingredient in Starpharma's VivaGel® products

<sup>2</sup> Nuclear medicine world market report & directory, MEDDraysintell, 2016

# DEP<sup>®</sup> shows significant accumulation in glioblastoma (brain tumour) model

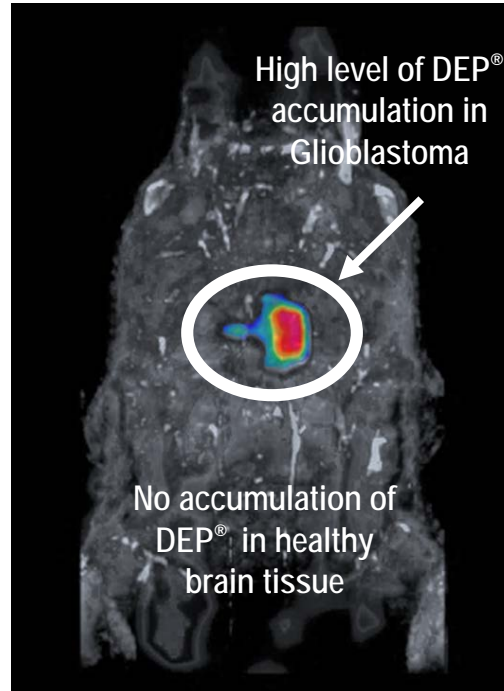


THE UNIVERSITY  
OF QUEENSLAND  
AUSTRALIA



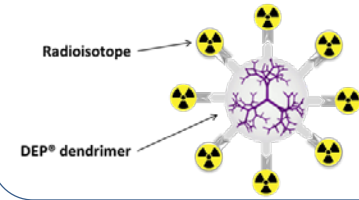
## About Glioblastoma Multiforme (GBM)

- GBM is the most common and aggressive malignant brain tumour
- GBM also has very poor survival rates with fewer than 10% of patients surviving more than 5 years
- GBM is considered to be incurable, with nearly 100% of patients experiencing disease relapse after initial treatment.

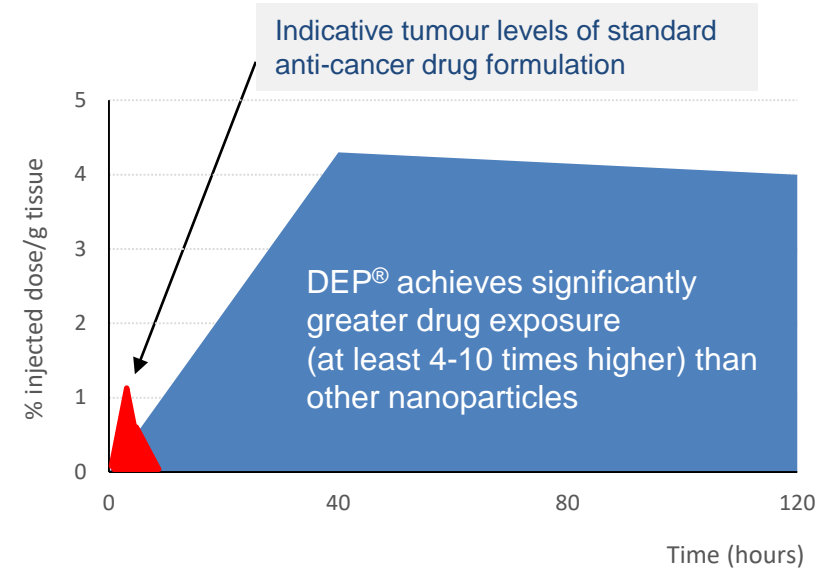


PET-MR image of GBM-bearing mouse 5 days post-injection of DEP<sup>®</sup> conjugate (details not disclosed pending IP filing)

## DEP<sup>®</sup> Radiotherapeutic



## DEP<sup>®</sup> radiotherapeutic accumulation in GBM model



# SPL7013 ophthalmic drops – a potential, novel therapy for adenoviral conjunctivitis



Viral conjunctivitis is the most common cause of infectious conjunctivitis – up to 90% caused by adenoviruses

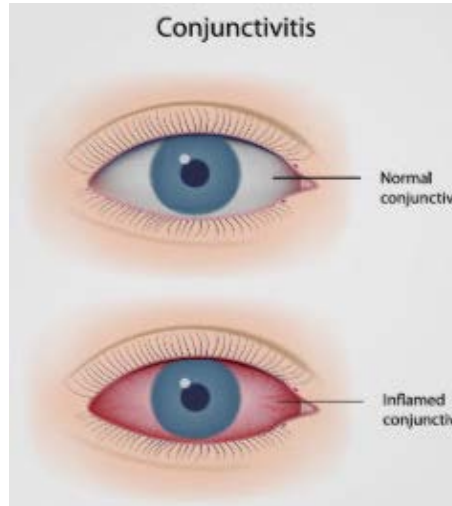


No approved therapies for viral conjunctivitis - remains a significant unmet medical need globally



Viral conjunctivitis affects about 6 million people in the US annually and ~4 million in Europe

Market estimated at US\$700M<sup>1</sup> annually



SPL7013 ophthalmic drops:

- ✓ showed potent anti-viral activity against multiple ophthalmic pathogens
- ✓ significantly decreased duration of shedding (infectivity)
- ✓ significantly decreased viral replication (efficacy)
- ✓ are non-irritating
- ✓ are covered by a US patent (to grant on 11 Dec 2018)



# SPL7013 ophthalmic drops – a valuable novel therapeutic for a significant untapped market (viral conjunctivitis)

*“Treating viral conjunctivitis is a problem. There's no prescribed treatment for viral conjunctivitis - it's all conservative management.”*

- PHYSICIAN

*“... if you can reduce the infectivity then that would be very beneficial.”*

- OPHTHALMOLOGIST

*“The goal of treatment is limiting the spread of the disease.”*

- PAEDIATRICIAN

*“We really need something that is not irritating for the eye.”*

- PHYSICIAN

SPL7013 ophthalmic drops elicited positive responses in 87% of clinicians surveyed<sup>1</sup>

- Clinicians felt that SPL7013 “addresses a major unmet need” for Viral Conjunctivitis
- Clinicians described its novel mechanism of action as “compelling”
- Clinicians were impressed by its ability to inhibit spread of disease



*“I would probably prescribe this [SPL7013 ophthalmic drops] for the majority of viral conjunctivitis cases. There's just nothing but positives in this.”*

- PHYSICIAN

*“Wow, I love what I see. This [SPL7013 ophthalmic drops] is a big unmet need. We have nothing for VC so if this came to market you'd have something.”*

- PHYSICIAN

*“If I thought they had viral conjunctivitis I'd use this [SPL7013 ophthalmic drops] on 100% of patients.”*

- PHYSICIAN

# Outlook

## VIVAGEL® PORTFOLIO



VivaGel® BV US / North American licence and launch



VivaGel® BV launch in Australia, Europe & other Mundipharma regions  



VivaGel® BV US regulatory approval & further approvals in Mundipharma regions



Revenue from VivaGel® BV milestones, product supply & sales



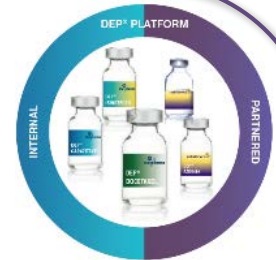
Further VivaGel® condom regulatory approvals



Further VivaGel® condom product launches in multiple regions (e.g. Japan, China, EU)



## DEP® PORTFOLIO



Progress with DEP® docetaxel & DEP® cabazitaxel clinical trials



DEP® irinotecan trial commencement



Other DEP® program developments, including new candidates, DEP® radiotherapeutics



AstraZeneca program developments, e.g. further data published, AZD0466 advanced to the clinic & revenue from milestones; further compounds advanced/nominated



Other partnered DEP® deals and program developments, including for Targeted DEP®



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