

AGM Chairman's address and CEO's presentation

Melbourne, Australia; 21 November 2019: Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting of Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHY), to be held at 4.00pm today.

The AGM will be recorded and available via webcast later today. To access the webcast, participants can register via the following link:

<https://webcasting.boardroom.media/broadcast/5dccc1f06242591605116cb6>

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHY), 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 for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe) and Fleurstat BVgel (Australia) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® 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 Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

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 three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. 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. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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

21 November 2019

Good afternoon,

On behalf of the Starpharma Board, it is with great pleasure that I welcome you to the 2019 Annual General Meeting.

Starpharma's commercial strategy is now yielding a deep portfolio of high value products and partnerships. Each of them has not only great potential for improving patient health but also creating significant value for shareholders. We anticipate further additions to this portfolio of products on a yearly basis. It is remarkable for a company of our size and stage of development to have a portfolio featuring two marketed products and another four exciting clinical stage assets, each of which has the potential to generate significant revenue and transform the company.

Indeed, the next three years should prove to be very exciting for shareholders.

This year we have been delighted with the launches of Starpharma's breakthrough product, VivaGel[®] BV by Aspen and Mundipharma, and to have this product readily available to patients throughout Australia and in Europe. This achievement was a result of significant, sustained effort on the part of Starpharma's team and our partners. We look forward to further launches and regulatory approvals in the coming weeks and months ahead. We also delivered significant value-adding milestones in DEP[®], including the commencement of a new clinical trial and commercial deals, whilst progressing with our existing DEP[®] products. In addition, it has also been very pleasing to see the launch of the VivaGel[®] condom by Okamoto in Japan.

We acknowledge these achievements are being somewhat overshadowed by the FDA's request for confirmatory data for VivaGel[®] BV for the US market and we are progressing with a dual strategy to achieve approval as quickly as possible. The FDA's request is despite the fact that other regulators in Europe, Australia and Asia have already approved the product, and notwithstanding the extensive patient and clinician feedback attesting to the benefits of VivaGel[®] BV.

Working with regulators like the FDA is never a quick or simple process, especially with a novel, 'first in class' compound. There are non-negotiable, complex and systematic protocols we must follow. We remain confident that the process will reap success, and upon US approval, we are looking forward to working with our partner, ITF Pharma, Inc. so that BV sufferers in the US (one in three women) can access this much needed product, alongside the women already benefiting from VivaGel[®] BV in Europe and Australia. The signing of a US license for US\$101 million in milestones, plus royalties was an important achievement during the year.

It is important to note however that VivaGel[®] BV is a genuinely global product which has been licenced in more than 160 countries around the world. The Starpharma team is working assiduously to get VivaGel[®] BV commercialised across the globe.



We look forward to revenues growing from our VivaGel® products, and though it's typical that these revenues will take some time to build, we expect these will play an important role in enabling the Company to underwrite its growing proprietary dendrimer platform.

Starpharma's DEP® platform is unique and by far one of the most innovative and exciting technologies of its kind. The magnitude of possibilities for creating better versions of novel and existing drugs is exceptional when you consider that DEP® is potentially applicable to a large proportion of the top 200 selling pharmaceuticals, including major marketed therapies.

Our internal DEP® assets are being developed to treat a range of cancers with very high-value markets, including lung, prostate and colon cancer. Our strategy is to continue building the value of our DEP® portfolio by adding 1-2 new DEP® candidates each year and advancing the candidates with the greatest potential to clinical proof of concept stage.

Our most advanced DEP® products have demonstrated clear and compelling benefits compared to the original anti-cancer products. And we've seen these benefits not only in our and our partner's preclinical studies, but also in our patient observations in trials that are currently underway. These are exciting and highly promising results, and the potential revenues from licensing any of these DEP® products is substantial in terms of licensing fees, milestones and ultimately the millions in royalties that could flow through each year.

Significant effort has been applied in the past year to demonstrate the synergistic benefits of DEP® products when combined with other anti-cancer agents. An exciting area for combination therapy is to combine DEP® with immuno-oncology agents which require patients to have a functioning immune system. DEP® products lack typical bone marrow toxicities, which make them ideal to combine with this new leading therapy area. You can see the extraordinary results being achieved with DEP® used in combination in some of our recent releases.

One of the most important commercial benefits of our DEP® platform is that it can be licensed to multiple partners, and be applied to multiple products in parallel. This creates remarkable optionality. AstraZeneca's DEP® programs are a prime example of the platform's significant commercial potential and we look forward to AstraZeneca commencing its clinical trial for their potential blockbuster oncology agent, AZD0466, expected later this year.

The FDA's recent IND approval for AZD0466 and its advancement into the clinic is an important milestone for our Company, in terms of the value of the DEP® portfolio - both for the future partnering of our internal DEP® assets, and for future licences for the DEP® platform. As AstraZeneca presents their results to the wider scientific community over the next year, we expect this will also drive further interest in the DEP® platform.

The progression of our multiple clinical DEP® assets to licensing will mark a significant inflection point for Starpharma and the resultant revenue has the potential to be transformative for the company.



The success of Starpharma relies on a small and talented team of 45 people who work diligently and expertly across our diverse portfolio. I commend Jackie Fairley for her determination and leadership and the whole Starpharma team for their tenacity and commitment, in bringing a product all the way from bench to market, achieving multiple approvals and launches of VivaGel BV[®] and for advancing three, and soon to be four, DEP[®] products into human trials.

We're also proud to have a performance-driven culture. Working with a sense of urgency, innovative thinking and collaboration are central to our shared values. Our people have a strong sense of how their work benefits the broader community and Starpharma is focussed on responsible practices regarding the environment, sustainability and governance.

In addition to thanking our employees, I'd like to thank my Board colleagues for their insights and commercial judgement throughout the year. Dick Hazelton having served 13 years on our Board, has advised us that he will retire at next year's AGM. Starpharma has therefore commenced a process of Board renewal to ensure a smooth transition and also provide a handover period between Dick and the new director.

I would also like to express our gratitude to the many clinicians and patients who have spoken clearly in support of our new medicines.

And lastly, to our shareholders, I thank you for your continuing support. I acknowledge that our road to commercial success is not always straight. Today, Starpharma is very well-positioned with innovative technology, financial resources and human capabilities to enable the Company to generate significant value for investors, while delivering better medicines and clinical outcomes to patients around the world.

Thank you

Rob Thomas AO, Chairman

PHARMACIST ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

Fleurstat
BVgel

BETADINE BV
VAGINAL GEL



2019 ANNUAL GENERAL MEETING

CEO PRESENTATION, DR JACKIE FAIRLEY

21 NOVEMBER 2019



Important notice and disclaimer



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FLEURSTAT BVGEL (VivaGel® BV) for the treatment of BV and relief of symptoms

Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. Do not use for more than 7 days unless a doctor has told you to. See your doctor if symptoms persist after 7 days or recur within 2 weeks, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).

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

Starpharma is an ASX300 company (market cap ~\$480M) with a proven record of development & commercialisation incl. 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\$36.8M cash (30 Sep 2019)



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



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

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 & Australia - further launches and regulatory submissions progressing in multiple regions



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



CLINICAL-STAGE ASSETS



DEP® docetaxel

DEP® cabazitaxel

DEP® irinotecan

DEP® AZD0466

* IND APPROVED

PHASE 1 / 2

PHASE 1 / 2

PHASE 1 / 2

PHASE 1*



LICENCE AFTER PROOF OF CONCEPT

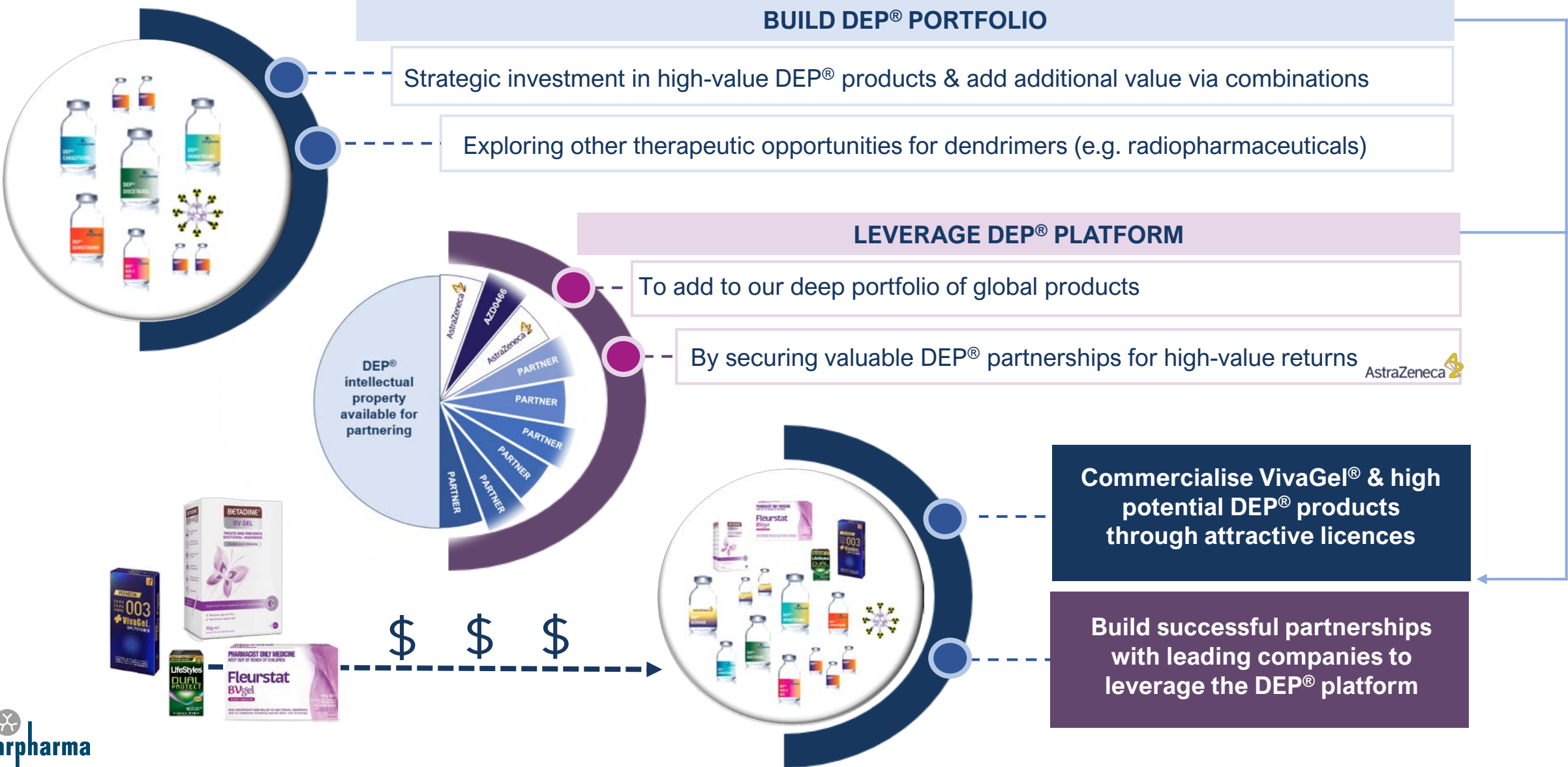
EXTENSIVE & GROWING PIPELINE OF PROPRIETARY ASSETS



Starpharma expects to add 1-2 new DEP® candidates each year, advancing the candidates with the greatest potential to clinical development



Starpharma's strategy provides exceptional optionality from the DEP® platform underpinned by marketed, proprietary products



Recent highlights - significant milestones across DEP® and VivaGel®

Betafem® BV Gel / Betadine BV™ Gel launched in UK/Europe & Fleurstat BVgel launched in Australia



Development and Option Agreement signed to progress development of a DEP® version of one of AstraZeneca's major oncology products

Commenced phase 1 / 2 DEP® irinotecan trial (initial sites include The Christie, the Royal Marsden & Newcastle Freeman Hospital)

Positive interim results observed in patients dosed with DEP® docetaxel and DEP® cabazitaxel in phase 1 / 2 trials; new sites opened and cohorts expanded

DEP® portfolio expanded with new internal DEP® candidate DEP® gemcitabine; outperforms Gemzar® in human pancreatic cancer model

First Asian region regulatory approvals received for Betadine™ BV Gel

VivaGel® BV licensed in the US for up to US\$101M milestones, plus royalties



Okamoto launched VivaGel® condom in Japan



VivaGel® condom approved in Europe



FDA authorised IND - first-in-human clinical trial for AZD0466

US patent granted for AstraZeneca's DEP® Bcl2/xL conjugates, including AZD0466

DEP® irinotecan combinations outperform in both human pancreatic and colon cancer models

DEP® docetaxel & DEP® cabazitaxel alone, and in combination with standard pancreatic cancer treatments, outperform in a human pancreatic cancer model

Positive results with novel DEP® HER-2 ADC using antibody fragment in human ovarian cancer model

Financial summary

Key Financial Data	FY 2019 A\$M	FY 2018 A\$M
Revenue and other income	2.7	5.0
Loss from period	(14.3)	(10.3)
Net operating cash outflows	(10.3)	(10.2)
Net cash burn¹	(10.1)	(9.9)
Cash as at 30 Sep 2019 \$36.8M excludes FY19 \$4.9M R&D tax incentive		

FY19 Result:

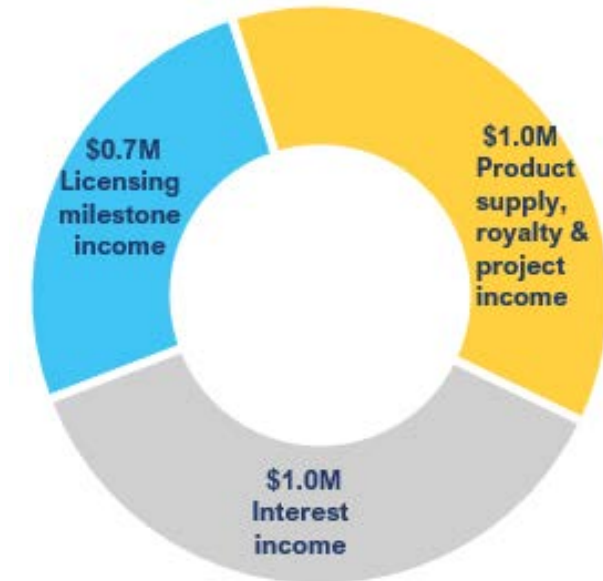
- Lower revenue than FY18 which included VivaGel® BV licence signing milestones (A\$3.0M)
- R&D spend primarily focused on DEP® clinical trials and pipeline
- Commercial and regulatory operating costs higher to support FY19 product registrations and launches of VivaGel® BV in multiple markets



Strong & Clean Balance Sheet:

- No intangibles held on balance sheet
- Expense all R&D expenditure to P&L

FY19 REVENUE - \$2.7M



FY19 Revenue includes:

- Product supply and royalties related to VivaGel® BV and VivaGel® condom:
 - Betadine BV™ Gel launched in Europe
 - Fleurstat BVgel launched in Australia
 - Okamoto Japanese condom
- US\$0.5M milestone for European market launch



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 & Aus

 Approved in South East Asia and New Zealand

 Further launches and regulatory submissions progressing in multiple regions

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



NORTH AMERICA



On market



Approved; FY20 launches



UK VivaGel® BV product



LATAM



AFRICA



MIDDLE EAST

EUROPE



On market

AUSTRALIA

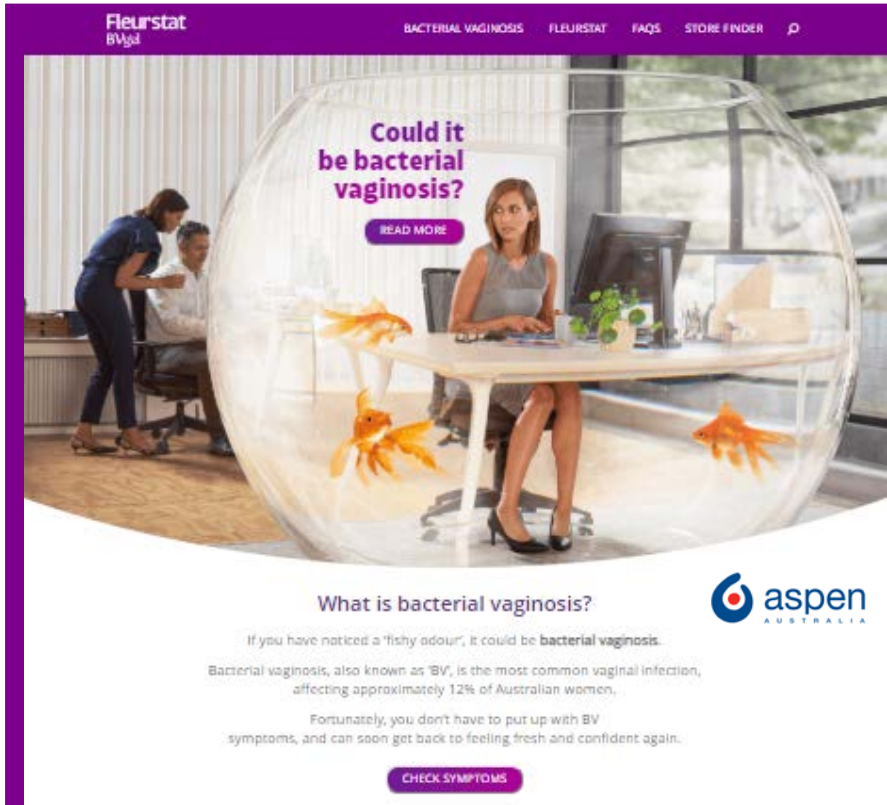


NZ Approved

1H CY20 launch



Fleurstat BVgel successful marketing campaign - highly targeted direct and online initiatives



ONLINE PRESENCE

Fleurstat BVgel website ~20,000 unique users since June

Very high click through rate of >12% (typically 0.5%) – indicating high degree of patient need & interest

More than 2,700 Australian pharmacies currently stock Fleurstat BVgel

Described as one of Aspen's most positively received new product launches, with high pharmacy sell through rates

Now stocked in 100% of Chemist Warehouse, Priceline & Blooms



Fleurstat BVgel was featured in the Oct & Nov issues of the Australian Journal of GP, and on the front cover of the Australian Journal of Pharmacy in May



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).

Fleurstat BVgel - Australian market feedback



“We are very impressed with health care practitioner and consumer feedback on the product, and in the market uptake of Fleurstat BVgel at this early stage of a major launch. We see a great future ahead.”

Rob Barnes, Head of Consumer OTC, Aspen



“I spoke to a trusted 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)



*“Fleurstat BVgel has been the **most positively accepted product ever**. Amazing how much interest and excitement this product has created.”*

Aspen Pharmacy Sales Representative



- *“...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



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

Community Pharmacist



BETADINE® has a market leading position in Feminine Care, trusted by women globally



Launched in Europe by Mundipharma, under the brand name Betadine BV™

Launched in the UK under the brand name Betafem® BV Gel

Next launches: Asia, Eastern Europe & NZ

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

It sits well under the BETADINE® brand, which has emerged as a powerful brand platform ...trusted by women globally.”

Raman Singh
CEO, Mundipharma

VivaGel® BV is part of an established feminine care range under Mundipharma's Betadine® brand



Rapid relief of odour in 24 hours



Targets harmful BV-causing bacteria



Clinically proven to treat BV



Clinically proven to prevent recurrent BV



Restores vaginal flora, normalises pH levels

Embarrassing odour from BV?
Get relief within 24 hours.



Be Unstoppable with
BETAFEM

You can put a stop to unpleasant odour and discharge, from BV

Be Unstoppable with
BETAFEM



VivaGel® BV in the US – dual strategy to achieve approval of the NDA

- Options thoroughly explored; ongoing support from a team of expert FDA consultants (regulatory, statistical, clinical, legal; several ex-FDA)
- Additional information and statistical analyses of existing data already provided to FDA
- Productive meetings and dialogue with FDA to address request for confirmatory data and to input into potential treatment trial protocol
- FDA consistently acknowledges potential benefits (e.g. mechanistic and safety) of VivaGel® BV vs. antibiotics
- VivaGel® BV's QIDP and Fast Track status remain on foot based on potential for VivaGel® BV to address significant unmet need in BV



Starpharma is pursuing the following two options in parallel to achieve approval:

1. **Seeking formal review of some of the FDA's initial conclusions via an administrative review process; and**
2. **Preparation for a possible BV treatment trial:**
 - Significant steps already completed and underway, including protocol development, protocol review by FDA, CRO selection & appointment, investigator/site selection
 - Ability to commence a trial in 1-2 months (if required); estimated trial duration 4-6 months

VivaGel® BV opportunity in the US



VivaGel® BV licensed in the US to ITF Pharma for:

- up to US\$101M in milestone payments plus
- escalating double digit royalties on sales

ITF is a US-based specialty pharmaceutical company with a focus on prescription Women's Health products through its Womens Choice Pharmaceuticals Division (www.wcpharma.com)



Significant positive feedback from clinicians & patients in support of VivaGel® BV – confirming BV is an area of significant unmet medical need



72% of US clinicians report that their patients would prefer a non-antibiotic BV treatment



74% of US physicians report that time to resolution of odour is the most important attribute for a BV treatment



Suitable for repeated or long-term use



Dr Belvia Carter, VivaGel® BV Clinical Trial Principal Investigator and Ob-Gyn, US

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

“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 Jack Sobel, ID Physician & KOL Dean, Wayne State Uni School of Medicine



FAST TRACK STATUS

QIDP +5 YEARS EXCLUSIVITY

VivaGel® BV supply

Partners pay for product on standard supply trading terms, with additional royalties paid quarterly in arrears.

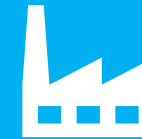


STARPHARMA

Starpharma purchases product based on confirmed partner orders

STARPHARMA'S SUPPLY STRATEGY:

- utilises 3rd parties for manufacture and supply
- modest capital requirements with inventory, mainly API, used across multiple products



3RD PARTY CONTRACT MANUFACTURERS

Manufacture product under licence for Starpharma



PARTNERS

Goods delivered directly to partner for distribution & sale

VivaGel® condom launched in Japan and recently approved in Europe

- VivaGel® condom is being marketed under Okamoto's leading and highly successful Zero Zero Three (003) brand
- Starpharma receives royalties based on sales of the VivaGel® condom and also revenue on supply of SPL7013 active
- First receipts received from Okamoto in April
- Okamoto & Japanese Ministry of Health, Labour & Welfare have developed a joint STI prevention campaign using VivaGel® condoms



厚生労働省
Ministry of Health, Labour and Welfare



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

okamoto



1 Overview

2 VivaGel® Portfolio

3 DEP®

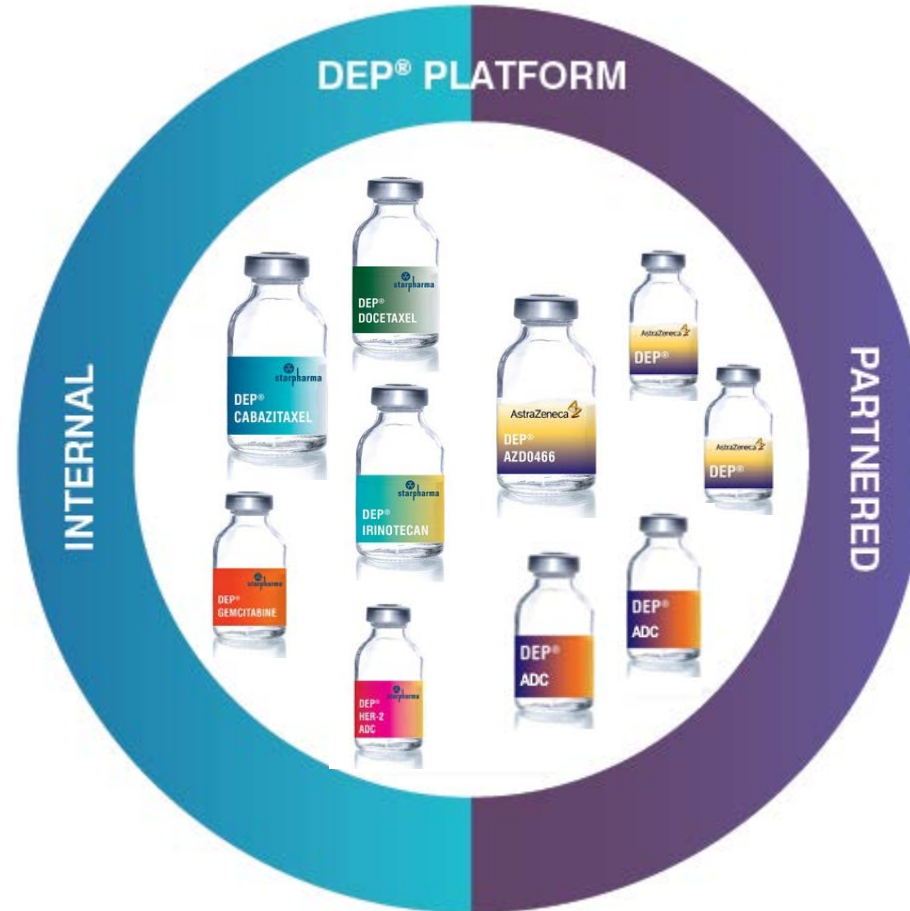
4 Outlook

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
- Patent life extension
- Self-funded
- Returns through licensing, milestones and royalties

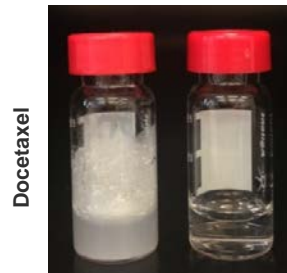
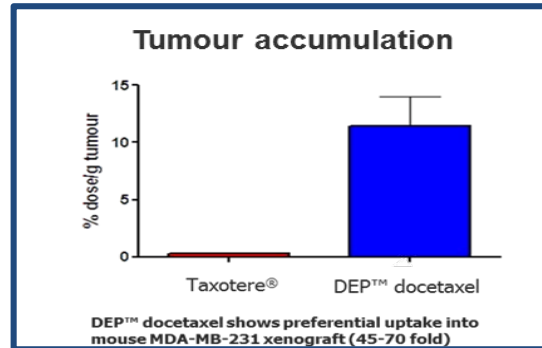
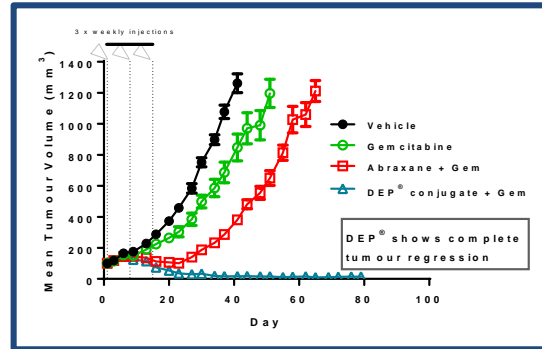
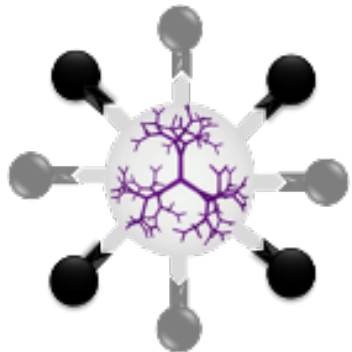


PARTNERED DEP[®]

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

Starpharma's DEP[®] platform enhances the commercial and therapeutic value of a wide range of drugs

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



DEP[®] BENEFITS

Improved Efficacy
Reproducible results with many candidates & tumour types

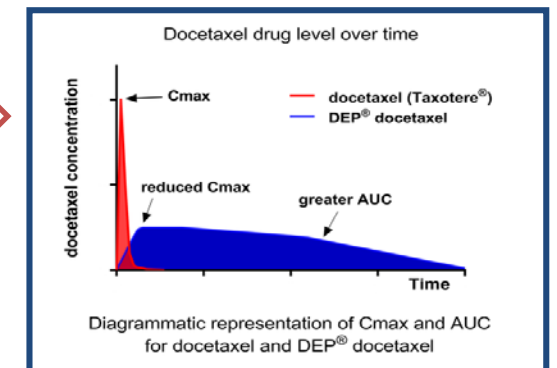
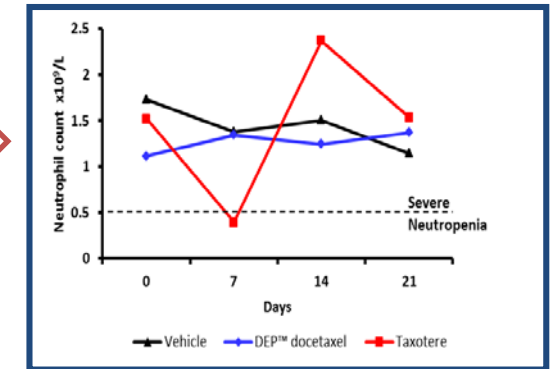
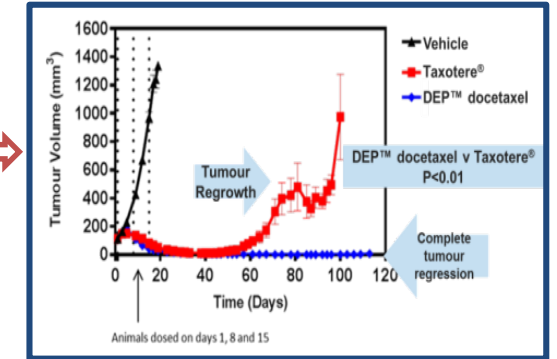
Benefit in Combination
Enhanced efficacy as monotherapy or in combination approaches

Improved Safety
Reduced neutropenia/BM toxicities

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

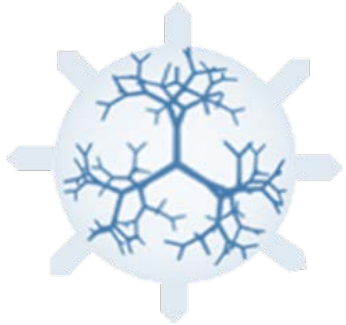
Improved PK and Half-Life
Longer half life and lower C_{max}

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

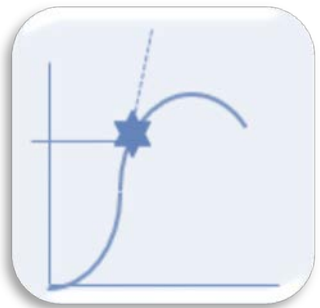


DEP[®] platform for partnering

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

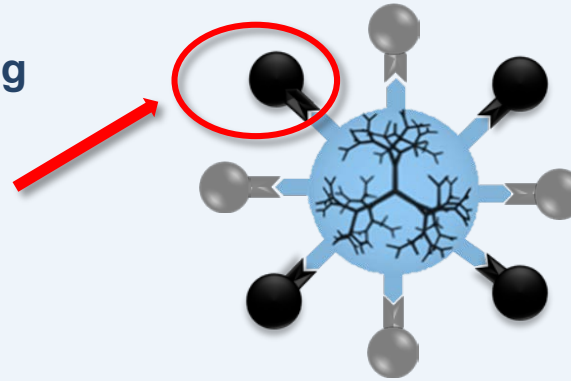


DEP[®] nanoparticles can be used to enhance the features of novel drugs that may otherwise limit clinical use due to issues such as toxicity or insolubility



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



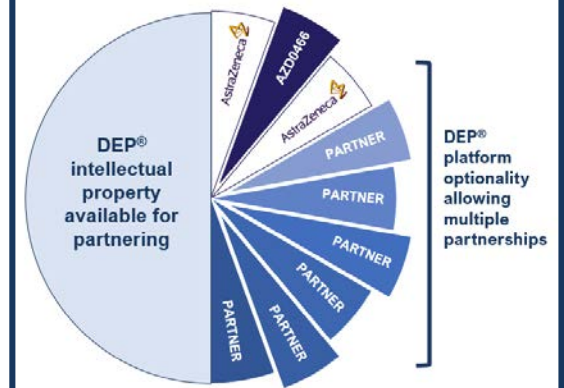
Partner funds development of their DEP[®] product(s)



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: AZD0466 IND approved by FDA; clinical trial start expected CY19 & new DEP[®] agreement signed

AstraZeneca 

Multiple commercial
DEP[®] programs

Multiproduct licence

- US\$4M in milestones received thus far
- US\$3M milestone payable on AZD0466 Phase 1 first dose
- 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 (June '19 – ASCO)



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

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



IND approved by FDA & AstraZeneca expects to commence phase 1 later this year



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.

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

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.



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

Cabazitaxel (Jevtana[®]) – estimated 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.



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

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.

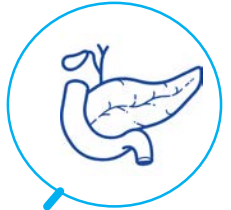
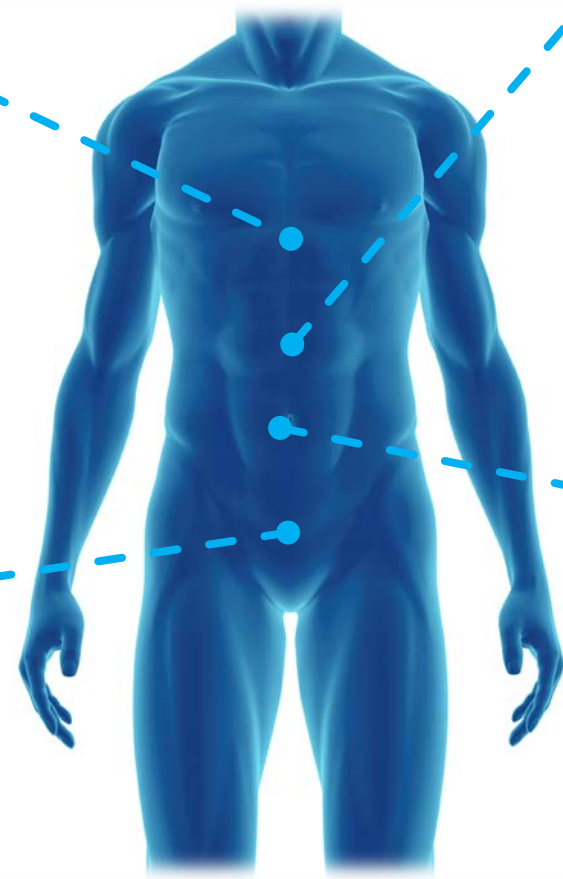
Starpharma's DEP[®] pipeline targets significant needs and opportunities in cancer

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.



NON-SMALL CELL LUNG CANCER (NSCLC)



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.

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.



PROSTATE



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 – positive interim results with two new sites added and Gemzar[®] combination planned

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.



Guy's and St Thomas'
NHS Foundation Trust

The Newcastle upon Tyne Hospitals 
NHS Foundation Trust


The Leeds Teaching Hospitals
NHS Trust


University College London Hospitals
NHS Foundation Trust

2 NEW SITES ADDED:



The Christie
TOWARDS A FUTURE WITHOUT CANCER


WEST OF SCOTLAND CANCER CENTRE

Monotherapy arm

- 27 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, non-small cell lung cancer and several hard-to-treat tumours including cholangiocarcinoma (2nd most common liver cancer which is often fatal)
- Efficacy signals observed in heavily pre-treated patients (up to 40 cycles and 9 different anti-cancers 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 including hair-loss, mouth ulcers, anaphylaxis and oedema.

Combination (DEP[®] docetaxel & Vargatef[®])

- 10 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[®]) commencing in early 2020 targeting pancreatic cancer
- Combinations with immunotherapy also being explored to create value

ESTIMATED PHASE 2 COMPLETION: 1H CY20

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

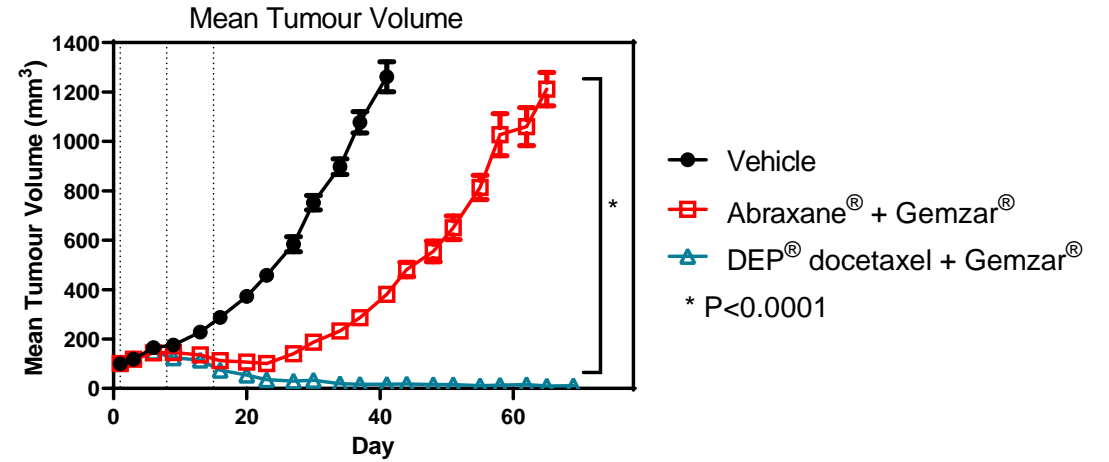


41% reduction in size of tumour lesion

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:

- ✓ DEP[®] cabazitaxel, both alone and in combination with gemcitabine, showed complete tumour regression and 100% survival
- ✓ DEP[®] docetaxel, alone, and in combination with gemcitabine, significantly outperformed gemcitabine and/or Abraxane[®] and showed 100% survival

**Combinations findings feed into clinical development –
DEP[®] docetaxel and gemcitabine combination planned to start in 1Q CY20**

DEP[®] cabazitaxel phase 1 / 2 program – Phase 1 nearing completion with positive interim results

**PHASE 1 / 2
CURRENTLY
RECRUITING**



**2 NEW SITES
BEING ADDED**



**Imperial College Healthcare
NHS Trust**



Multi-site trial (more sites to be added in the expansion phase)

Planning to recruit up to 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 2: Dose expansion to establish efficacy

Phase 1 (dose-escalation) is nearing completion

- 14 patients dosed
- Multiple cycles of DEP[®] cabazitaxel (up to 15 cycles) at 6 dose levels; no steroid pre-treatment
- Encouraging efficacy signals observed including:
 - prolonged stable disease including >47 weeks in prostate cancer
 - in multiple patients - prostate and other tumour types including ovarian, cervix, cholangiocarcinoma and pancreatic cancer
 - tumour shrinkage and decreases in specific tumour biomarkers such as PSA, CA-125 and CA 19-9
 - at doses several-fold lower than usually used for cabazitaxel
- Significantly less toxicity associated with DEP[®] cabazitaxel (including less myelosuppression / low white and red blood cells, diarrhea, vomiting) than expected with Jevtana[®]; no need for anti-nausea medications
- No hair loss observed with DEP[®] cabazitaxel
- Adaptive phase 1 / 2 trial design enables seamless transition from phase 1 to phase 2 - expected in the next 1-2 months
- 2 new sites are being opened in preparation for Phase 2 which is expected to enrol ~20 patients

ESTIMATED COMPLETION FOR PHASE 1: 1Q CY20 & PHASE 2: 2H CY20

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

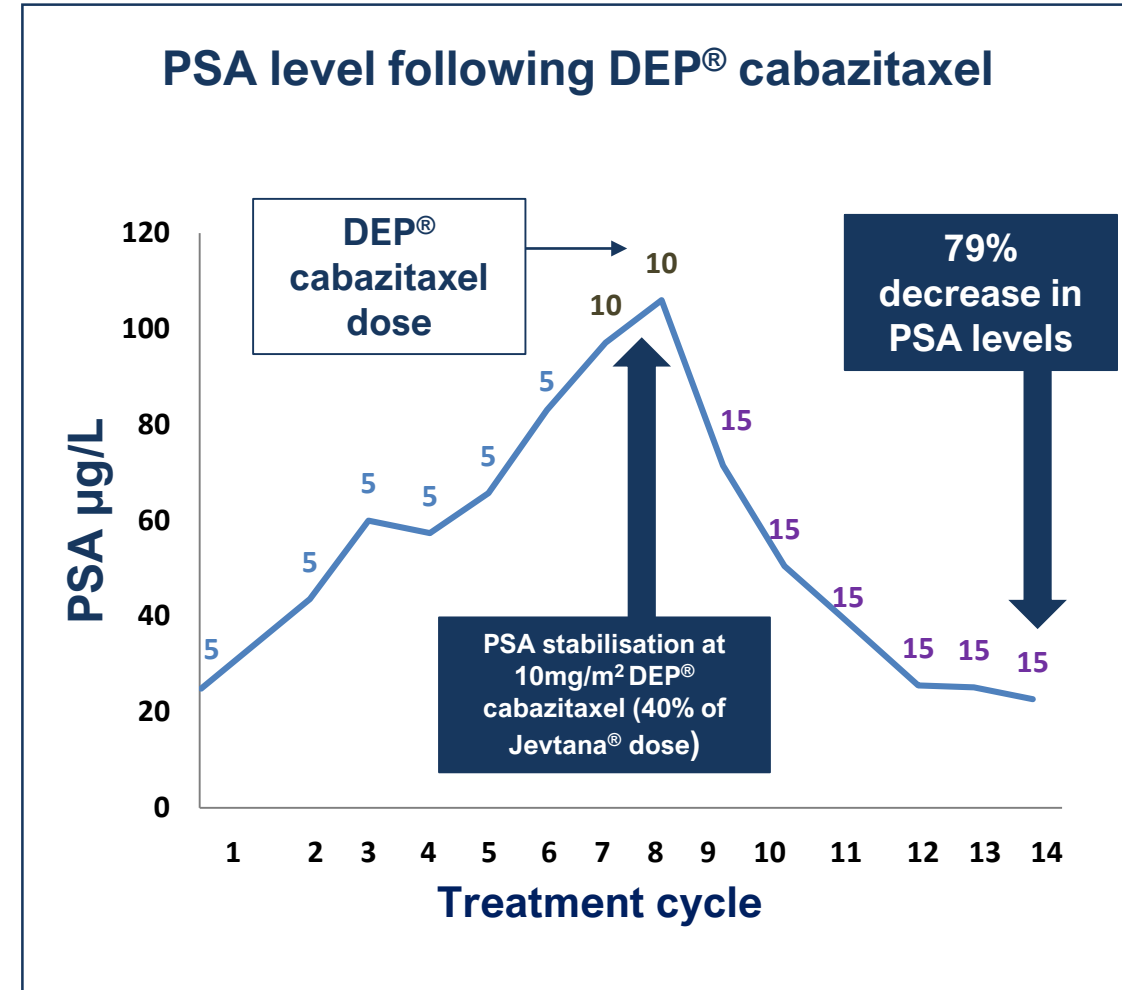


70 year old man with stage III prostate cancer:

- heavily pre-treated; cancer progressed on 4 other anti-cancer therapies
- was unable to tolerate docetaxel due to toxicity (neutropenia)
- received 14 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



DEP[®] irinotecan phase 1 / 2 program underway

PHASE 1 / 2 CURRENTLY RECRUITING

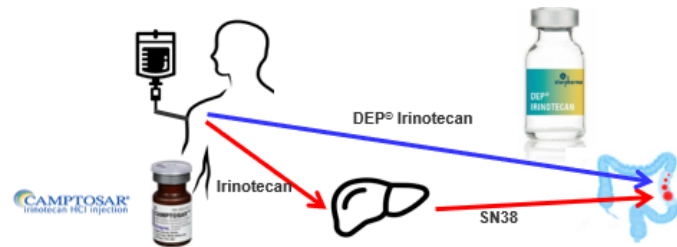


The ROYAL MARSDEN
NHS Foundation Trust



The Newcastle Upon
Tyne Hospitals
NHS Foundation Trust

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
- improves efficacy and survival benefit (pre-clinical)

Phase 1: Open-label dose-escalation

- Several patients dosed, multiple cycles
- No Dose Limiting Toxicities observed to date
- 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

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

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

ESTIMATED PHASE 1 COMPLETION: CY20









Multi-site trial

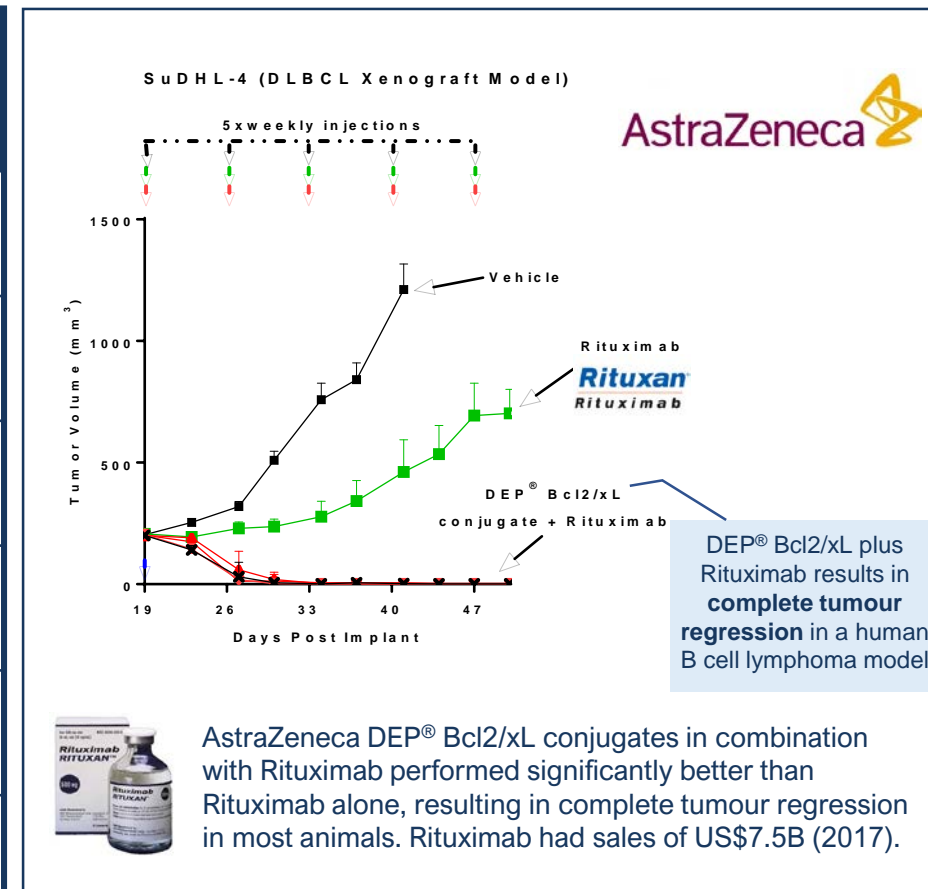
Objectives of the trial are to evaluate the safety, tolerability and pharmacokinetics of DEP[®] irinotecan to define a recommended phase 2 dose (RP2D), and to determine anti-tumour efficacy of the product in select tumour types

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 (with colorectal likely to be included)

DEP[®] combinations with marketed oncology agents add further value

Combination therapies are widely regarded as the future of oncology

DEP [®] combination	Cancer type (human xenograft)	Improved efficacy (compared to current standard of care)
 + DEP [®] docetaxel + gemcitabine (Gemzar [®])	Pancreatic	✓
 + DEP [®] cabazitaxel + gemcitabine (Gemzar [®])	Pancreatic	✓
 + DEP [®] irinotecan + Erbitux [®]	Colon	✓
 + DEP [®] irinotecan + Lynparza [®]	Colon	✓
 + DEP [®] Bcl2/xL + Rituximab	Lymphoma	✓
 + DEP [®] gemcitabine + Abraxane [®]	Pancreatic	✓
Immuno-oncology studies underway		



AZD0466 is highly optimised dendrimer nanoparticle formulation of AstraZeneca's novel Bcl2/xL inhibitor

Data from DEP[®] combination studies will inform clinical development and identify value-adding combinations

Table above: Multiple preclinical studies have established improved efficacy of DEP[®] products in combination with other marketed oncology agents

New Candidate: DEP[®] gemcitabine significantly outperforms alone and in combination in human pancreatic cancer model

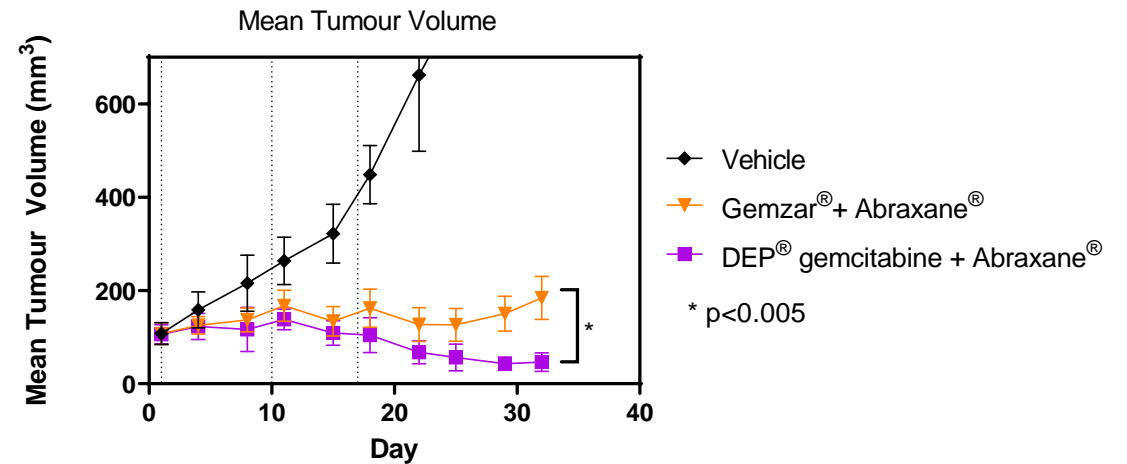
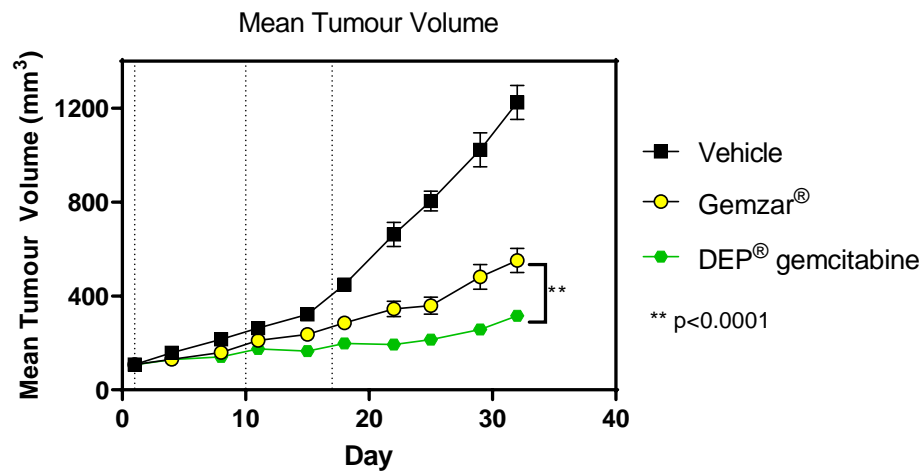


- DEP[®] gemcitabine is a DEP[®] version of Lilly's Gemzar[®] (gemcitabine) - a well-established anti-cancer drug, which had peak sales of US\$1.7 billion.
- Gemzar[®] is a leading chemotherapeutic used to treat pancreatic cancer.
- Gemzar[®] can be administered as a monotherapy or in combination with other therapies such as Abraxane[®].



DEP[®] gemcitabine:

- resulted in significantly greater tumour inhibition than Gemzar[®] (standard gemcitabine); and
- in combination with Abraxane[®], DEP[®] gemcitabine had an additive effect leading to tumour regression; in a human pancreatic cancer model.



This experiment was conducted in a human pancreatic cancer (CAPAN-1) mouse xenograft model. Animals were dosed once weekly with GEM, DEP-GEM, Abraxane or Abraxane immediately followed by GEM

DEP[®] ADCs further build the value of the DEP[®] platform



2018 sales of Roche's Kadcyla[®] >US\$1B and Adcetris US\$870 million.

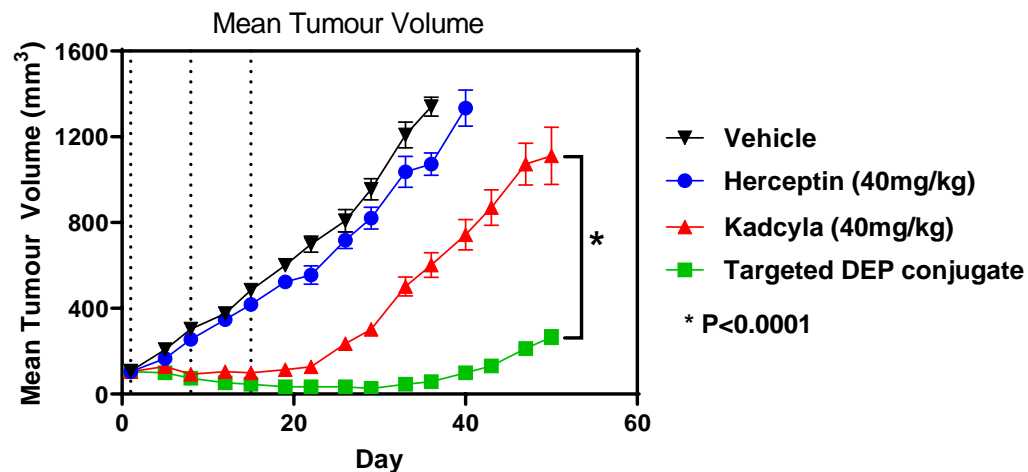
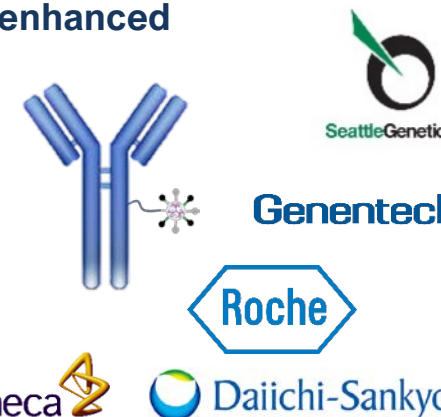


Strong corporate activity in ADCs is as illustrated by the recent licensing deal between AstraZeneca & Daiichi Sankyo, with an announced value of up to US\$6.9 billion for rights to a HER-2 targeted ADC.



Starpharma's DEP[®] technology provides **enhanced therapeutic benefits** to ADCs including:

- **greater homogeneity**
- **site specific attachment**
- **Higher drug antibody ratio (DAR)** than conventional ADC approaches.



Novel DEP[®] HER-2 ADC conjugate:

- **resulted in tumour regression and 100% survival, and**
- **significantly outperformed both Kadcyla[®] (T-DM1), a HER-2 targeted antibody-drug conjugate (ADC), and Herceptin[®] (Trastuzumab) itself, in a human ovarian cancer model.**

This experiment was conducted in a human ovarian cancer (SKOV-3) xenograft model in NOD SCID mice by an internationally recognised translational Cancer group. Groups of animals (6/group) were dosed once per week for 3 weeks with the novel HER-2 Targeted DEP[®] conjugate, Kadcyla[®], or a saline control. Another group of animals was treated with Herceptin[®] twice a week for 3 weeks. The tumour volume data represent the mean \pm standard error of the mean (SEM) and significance values determined using a Two-Way ANOVA (Tukey's post hoc). Survival analysis was carried out using Kaplan-Meier survival curves and the Log-rank test. (Note: If error bars do not display on the graphs, they are shorter than the height of the symbol and not visible.)



1 Overview

2 VivaGel® Portfolio

3 DEP®

4 Outlook

Outlook

VIVAGEL®



- Commercial roll-out of VivaGel® BV in Europe, South East Asia, NZ & other markets
- Dual strategy to address FDA request for confirmatory data
- Further VivaGel® BV licences for India, Canada & Israel
- Further regulatory approvals for VivaGel® BV
- Revenue from VivaGel® BV - milestones and sales/royalties
- VivaGel® condom approvals/launch in additional regions, such as Europe & China
- Further development / co-development of SPL7013 ophthalmic drops

COMMERCIAL OUTCOMES



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

DEP®



- Progress DEP® docetaxel, DEP® cabazitaxel & DEP® irinotecan clinical trials
- AZD0466 trial start & revenue from milestones
- Exercise of Option Agreement and deals for further compounds
- Explore value-adding DEP® combinations including commencement of DEP® docetaxel + gemcitabine combination in the clinic
- Advance other DEP® products, including DEP® gemcitabine, DEP® radiopharmaceuticals, DEP® ADCs
- Progress partnered DEP® deals & program developments, including DEP® ADCs



Leveraging the DEP® platform to build value



Advancing internal DEP® assets builds value for future licensing



Partnered DEP® - upfront fees, milestones, royalties



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