

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

**Melbourne, Australia; 29 November 2022:** Attached is the Chairman's address together with the CEO's presentation to the Annual General Meeting (AGM) of Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY), to be held at 2:00pm (Melbourne time) today.

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### About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for DEP<sup>®</sup> drug delivery, respiratory viruses and VivaGel<sup>®</sup>.

Starpharma's proprietary drug delivery platform technology, DEP<sup>®</sup>, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP<sup>®</sup> versions of existing drugs, particularly in the area of anti-cancer therapies.

DEP<sup>®</sup> partnerships include oncology programs with AstraZeneca, with MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Partnered DEP<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE<sup>™</sup>, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE<sup>™</sup> is not approved for use or supply in Australia. SPL7013 is also utilised in the following products - VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> products have been licensed in >160 countries and are registered in >45 countries, including the UK, Europe, Japan, Southeast Asia, South Africa, Australia and New Zealand.

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

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### Disclosure

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

### Forward Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.



**Chairman's Address  
Starpharma Holdings Limited  
Annual General Meeting  
29 November 2022**

Good afternoon fellow shareholders,

On Behalf of the Board of Directors, it is my pleasure to welcome you to Starpharma's Annual General Meeting.

Since our last AGM, Starpharma has made significant progress across our portfolio, both internally and with our partners. We are proud to be one of a small handful of Australian healthcare companies which have brought new medical and healthcare products to market, while also progressing research and product development through our clinical oncology programs and securing valuable partnerships with major global companies.

Notable achievements this past year included Starpharma signing new research agreements with Genentech - a member of the Roche Group - and with MSD (Merck & Co., Inc.). These research agreements with leading pharmaceutical companies illustrate the value and broad applicability of our dendrimer enhanced product (DEP<sup>®</sup>) drug delivery portfolio. Starpharma is working with each of these global companies to develop DEP<sup>®</sup> versions of anti-cancer molecules.

Partnerships in the DEP<sup>®</sup> space are important for Starpharma as they have the potential to deliver meaningful value to both the Company and shareholders, by way of potential future milestones and royalties. A great example of the extraordinary potential of our DEP<sup>®</sup> platform is the multi-product license we have with AstraZeneca, which includes the development of AZD0466.

The AstraZeneca DEP<sup>®</sup> partnership is particularly exciting for Starpharma due to its significant potential for both patients and shareholders. Starpharma has already received US\$7 million in milestones for the development of AZD0466, under a license which has total milestones of up to US\$124 million, plus royalties.

AZD0466 is now being trialled in two international clinical studies in hard-to-treat blood cancers, with a commercial aim of facilitating expedited market access. Over the year, AstraZeneca continued the global expansion of this AZD0466 clinical program, opening new trial sites across the US, Europe, Asia and Australia, and commencing a new trial in non-Hodgkin lymphoma – the sixth most commonly diagnosed cancer in Australia this year<sup>i</sup>. We expect further positive announcements of progress to be made at the American Society of Hematology Annual Meeting in December this year.

We look forward to sharing future updates with you all as this and our other partnered programs progress.

Our partnerships with these major pharmaceutical companies – AstraZeneca, MSD, Chase Sun, and Genentech – not only endorse the potential of our DEP<sup>®</sup> technology, but also pave the way for novel and improved treatments which could reshape the future of oncology.

Internally, we have continued to advance our three clinical stage DEP<sup>®</sup> products – DEP<sup>®</sup> cabazitaxel, DEP<sup>®</sup> irinotecan, and DEP<sup>®</sup> docetaxel, which also have the potential to deliver significant value.

This year, Starpharma was very pleased to present clinical data for DEP<sup>®</sup> cabazitaxel at the European Society of Medical Oncology, from the advanced prostate cancer cohort of our

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Phase 2 DEP<sup>®</sup> cabazitaxel trial. In this trial cohort, DEP<sup>®</sup> cabazitaxel demonstrated longer progression-free survival and a lower incidence of key side effects, as well as a number of other advantages, compared to published data on conventional cabazitaxel<sup>ii</sup>.

These efficacy results are extremely encouraging given the prevalence of prostate cancer in the male population. To shed some light on just how far reaching this disease is, approximately 3,500 Australian men die every year from this cancer, with a further 24,000 diagnosed annually<sup>iii</sup>. In the US, 34,500 men die annually from this disease<sup>iv</sup>.

It is worth noting that the prostate cancer patients enrolled in our study were heavily pre-treated, each having received an average of four prior cancer treatment regimens, usually in addition to surgeries and radiotherapy. It is particularly encouraging that this heavily treated patient cohort, 95% of whom had already received other taxanes, was able to respond so positively and reinforces the potential of our DEP<sup>®</sup> platform technology to improve quality of life for patients undergoing cancer treatment.

Similarly, the DEP<sup>®</sup> irinotecan and DEP<sup>®</sup> docetaxel clinical programs have continued to make good progress this year, with encouraging responses observed in patients with a range of cancer types across both trials.

Dr Fairley will comment further on these programs during the CEO presentation. I do wish to emphasise that these clinical stage DEP<sup>®</sup> programs are aimed at producing clinical data to support further partner development and licensing. So, while shareholders are keen to see these programs conclude as soon as possible, the Company is already engaged in licensing discussions in relation to these DEP<sup>®</sup> assets to build value and drive revenue for the benefit of patients and shareholders alike.

In addition to our clinical DEP<sup>®</sup> portfolio, there are more valuable opportunities on the horizon in our preclinical pipeline, including in the areas of DEP<sup>®</sup> radiotheranostics and DEP<sup>®</sup> antibody drug conjugates.

The DEP<sup>®</sup> platform is a key driver of value given its exceptional optionality and therapeutic potential.

We also continue to commercialise and realise value for VIRALEZE<sup>™</sup>, Starpharma's antiviral nasal spray, which was developed in response to the global pandemic, but has much broader application across a range of cold/respiratory viruses, including influenza.

As we are still seeing the lingering effects of the pandemic, the biotech community recognises the need for solutions that appropriately combat potentially harmful respiratory infections. Vaccines and face masks are important measures to address these epidemics, as are interventions, such as VIRALEZE<sup>™</sup>, which help to minimise the spread and virality of infections.

Throughout the year, Starpharma announced VIRALEZE<sup>™</sup> distribution agreements with new partners in Hong Kong and Macau; Saudi Arabia; Vietnam; and Italy. We were pleased to see the product launched in pharmacies and online in Hong Kong, Macau, Vietnam and Italy. LloydsPharmacy also relaunched the product into the UK market. Starpharma continues to focus on expanding the sales and distribution of VIRALEZE<sup>™</sup>, particularly in regions which are commercially attractive and have rapid regulatory pathways.

We continue to generate data to support the ongoing commercialisation and rollout of VIRALEZE<sup>™</sup>.

With regard to our VivaGel<sup>®</sup> portfolio, Starpharma continues to work with its VivaGel<sup>®</sup> BV partners – Mundipharma and Aspen – to progress regulatory and commercial activities for the product, with new launches planned in Asia and the Middle East.

Alongside developing important products, Starpharma remains committed to our Environment, Social and Governance pillars and to corporate sustainability more broadly. Starpharma is proud to produce a standalone ESG Report each year. I encourage you to read this Report,

which highlights our commitments to good governance, our people, responsible supply chains, and mitigating our impact on the environment.

I would like to acknowledge the Starpharma team, who have continued to demonstrate dedication to the Company, and resilience throughout the pandemic and within the broader global macro environment. I would like to thank my fellow Board members for their leadership and foresight and Dr Fairley and Starpharma's executive team for being so resolute in advancing our high-value pipeline and securing agreements with global industry leaders.

I would also like to extend my sincere thanks to Ms Zita Peach, who retires at the conclusion of this AGM as part of Starpharma's board renewal program. Ms Peach has made a significant contribution to the Company during her tenure, including by serving as Chair of the Remuneration and Nomination Committee.

This year, we welcomed Dr Jeff Davies, a highly experienced former CSL executive, to the Board. Dr Davies has over 35 years of biopharmaceutical experience and a strong record of bringing highly successful products to market. Dr Davies will be of great value to Starpharma, and his re-election is one of today's items of business.

Thank you to our shareholders for continuing to support our vital work during a year when our share price did not reflect our strong operational and commercial achievements. We acknowledge that Starpharma's recent share price decrease may have caused some shareholder concern. However, despite this, Starpharma remains in a strong financial position with a cash balance of \$42.3 million (as at 30 September 2022) and multiple opportunities ahead. I believe the next 12 months will be an exciting time for Starpharma across our entire portfolio.

Starpharma's dendrimer technology can make a real contribution to the fight against a range of important diseases. Through our robust partnerships with global industry leaders, we are uniquely positioned to address these challenges and are in a strong financial position to do so. We are indeed perfectly placed to make a meaningful change in the world.

Thank you,  
Rob Thomas, AO  
Chairman

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<sup>i</sup> <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/rankings>

<sup>ii</sup> See [company announcement](#) dated 12 September 2022

<sup>iii</sup> <https://www.canceraustralia.gov.au/cancer-types/prostate-cancer/statistics>

<sup>iv</sup> <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>



# Annual General Meeting

29 November 2022

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Dr Jackie Fairley, CEO



**starpharma**  
ASX:SPL OTC:SPHY



## Important notice and disclaimer

This document is intended for investors and market participants only.

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", "outlook" or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this presentation and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document, nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.

**FLEURSTAT BVgel (VivaGel® BV)** for the treatment of BV and relief of symptoms: **ASK YOUR PHARMACIST ABOUT THIS PRODUCT.** 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 of completing a course, or if you consider you may be at risk of a sexually transmitted infection (STI). See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).

**VIRALEZE™:** Not approved for sale or supply in Australia. **ALWAYS READ THE LABEL AND FOLLOW THE DIRECTIONS FOR USE.** This medical device is a regulated health product that bears, under this regulation, the CE marking in the EU. Do not use if you have a history of sensitivity to any ingredient in the formulation. Not for use in children under the age of 12 years. See a doctor if you are pregnant or breastfeeding. Always follow recommendations from health authorities, including vaccination and good hygiene practices, such as the use of masks, physical distancing, and regular handwashing to ensure the best possible protection against cold/respiratory viruses.

## Innovative drug delivery platform, DEP®

Proprietary nanoparticle platform; ability to create innovative therapies and enhance existing drugs; significant optionality; accelerates path to market; and manages investment risk.

## Deep portfolio of high-value assets

Three promising internal clinical-stage assets under development; improved, patented versions of widely used cancer medications. Multiple products on market and preclinical stage assets.

## Multiple global pharma partnerships

Multiple partnered programs: AstraZeneca, MSD, Genentech & Chase Sun. Licenses projected to provide milestones & royalties. Funded by large pharma partners.

## Strong financial position

Cash balance of \$42.3M (at 30 Sept 2022), with additional R&D tax incentive receipt of ~\$7M expected in Dec '22 / Jan '23.

FY22 revenue up 128% to \$4.9M.

## Strong institutional share register

Significant shareholders include Allan Gray, Allianz, M&G and Fidelity. International share register comprising ~55% institutions, ~40% retail, ~5% staff/other.



**VIRALEZE™  
Nasal Spray**



**VivaGel® BV**



**VivaGel®  
Condom**

# Recent highlights

## DEP<sup>®</sup>

New and expanded DEP<sup>®</sup> Research Agreement with **Genentech**  
A Member of the Roche Group



Additional trial sites open for **AstraZeneca** global Phase 1/2 clinical trial of AZD0466 in patients with advanced haematological malignancies

Positive interim findings from the prostate cancer cohort of the Phase 2 DEP<sup>®</sup> cabazitaxel trial show efficacy signals in 100% of evaluable patients; presented at ESMO Congress



DEP<sup>®</sup> drug delivery platform showcased at *Novel Format Conjugates Summit* in Boston, USA

Recruitment initiated for the second global Phase 1/2 clinical trial of AZD0466 in Non-Hodgkin Lymphoma



New DEP<sup>®</sup> Research Agreement with **MSD** involving antibody drug conjugates ('ADCs')

## Marketed products



VivaGel<sup>®</sup> BV regulatory approvals achieved in Middle Eastern countries

New VivaGel<sup>®</sup> condom range launched in Japan by



VIRALEZE<sup>™</sup> agent (SPL7013) shown to be virucidal against influenza A & B viruses, and outperformed other antiviral agents, iota-carrageenan and HPMC in preclinical studies

VIRALEZE<sup>™</sup> demonstrated high levels of protection against Omicron in a preclinical viral challenge model



VIRALEZE<sup>™</sup> launched in Hong Kong and Macau

VIRALEZE<sup>™</sup> sales and distribution arrangements signed for Italy; Vietnam; the Middle East; and Hong Kong and Macau

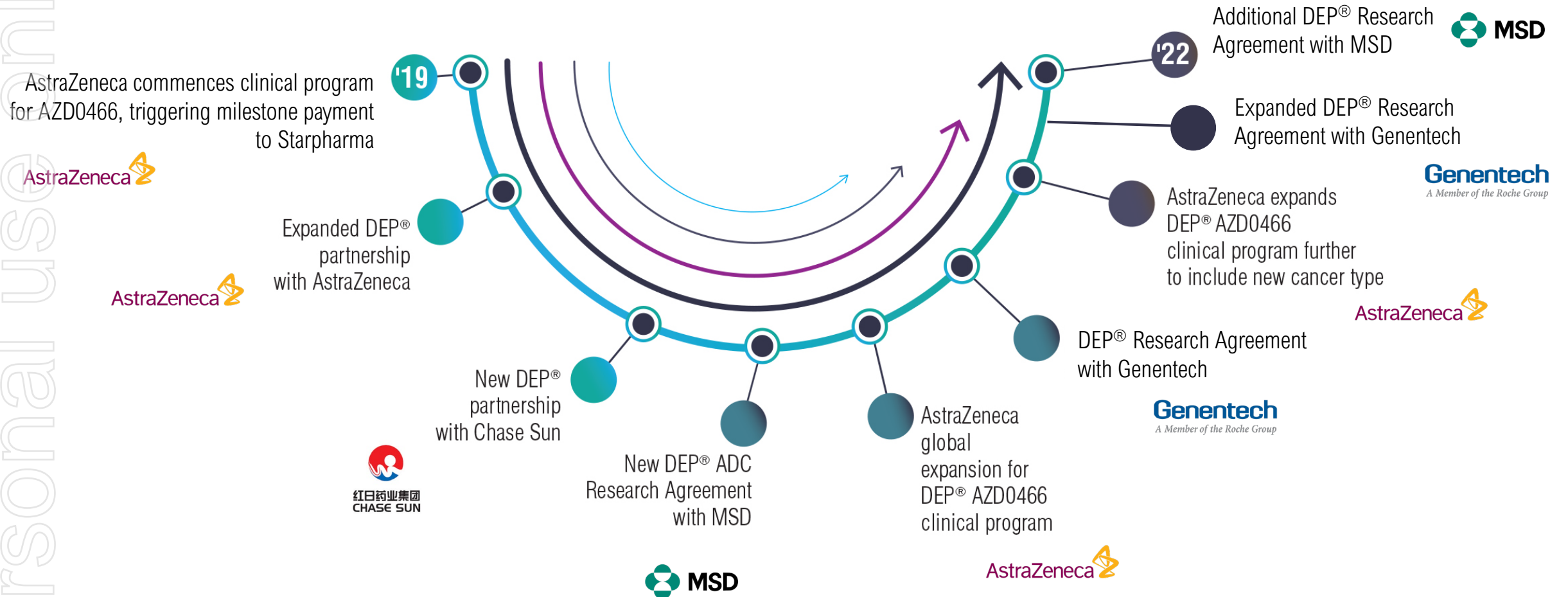


VIRALEZE<sup>™</sup> launched in Vietnam, Italy; and relaunch by **LloydsPharmacy** in the UK



# Momentum building for partnered DEP<sup>®</sup> programs

Starpharma has secured partnerships with several of the world's largest biotechnology and pharmaceutical companies



# Starpharma's DEP<sup>®</sup> platform

Broad applicability and exceptional optionality

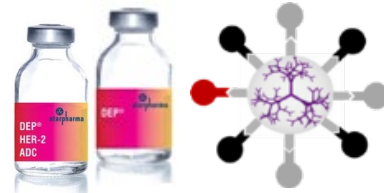
Multiple DEP<sup>®</sup> therapeutic areas across partnered and internal programs

## DEP<sup>®</sup> platform



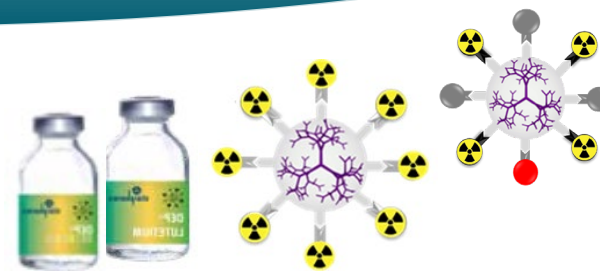
- Franchise extension
- Generic differentiation
- New chemical entities
- Combinations including immuno-oncology

**Chemotherapeutics**



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

**Antibody Drug Conjugates**



- Radiotheranostic applications
- Can use a variety of isotopes and targeting approaches

**Radiotheranostics**



- Applicable to antivirals and anti-infectives
- Endocrinology

**Non-oncology**

ersonal use only

# Financial Summary

Strong balance sheet with revenues from product sales and partnerships

## Key Financial Data

	FY22 A\$M	FY21 A\$M
Revenue	4.9	2.2
Other Income	0.3	1.3
Loss for the period	(16.2)	(19.7)
Net operating cash outflows	(13.2)	(14.8)

## FY22 Result

- Revenue up 128% to \$4.9M on the rollout of VIRALEZE™
- Lower Other Income with the completion of the MRFF grant for VIRALEZE™ during the year, corresponding with lower VIRALEZE™ development costs
- Reported Loss down 18% to \$16.2M
- Receipt of \$7.7M R&D tax incentive in Jan '22

Cash as at 30 Sept 2022: \$42.3M\*

\*Excludes anticipated R&D tax incentive of ~\$7M, expected to be received in Dec '22 / Jan '23



# Starpharma's portfolio of high-value assets

Multiple clinical-stage DEP<sup>®</sup> assets, multiple corporate partnerships and products on market

## DEP<sup>®</sup> Products

Product	Active / Payload	Target indication	Preclinical	Phase 1	Phase 2
DEP <sup>®</sup> cabazitaxel	Cabazitaxel	Prostate and other cancers	▶		
DEP <sup>®</sup> irinotecan	SN38	Colorectal and other cancers	▶		
DEP <sup>®</sup> docetaxel	Docetaxel	Pancreatic and other cancers	▶		
AZD0466	AZD4320 (Bcl2/xL inhibitor)	Haematological cancers	Developed by AstraZeneca		
DEP <sup>®</sup> gemcitabine	Gemcitabine	Solid cancers	▶		
DEP <sup>®</sup> HER-2 ADC	Not disclosed	Solid cancers	▶		
DEP <sup>®</sup> HER-2 radiotherapy	<sup>177</sup> Lu	Solid cancers	▶		
DEP <sup>®</sup> HER-2 radiodiagnostic	<sup>89</sup> Zr	Diagnostic	▶		
Other collaborations	Various	Various			

## Marketed Products



## Partnered DEP<sup>®</sup> Products & Programs

Multiproduct DEP<sup>®</sup> license with AstraZeneca, including the development of AZD0466 for multiple indications



Two DEP<sup>®</sup> ADC Research Agreements with MSD (Merck & Co., Inc.)



DEP<sup>®</sup> anti-infective research partnership with Chase Sun



Two DEP<sup>®</sup> Research Agreements with Genentech



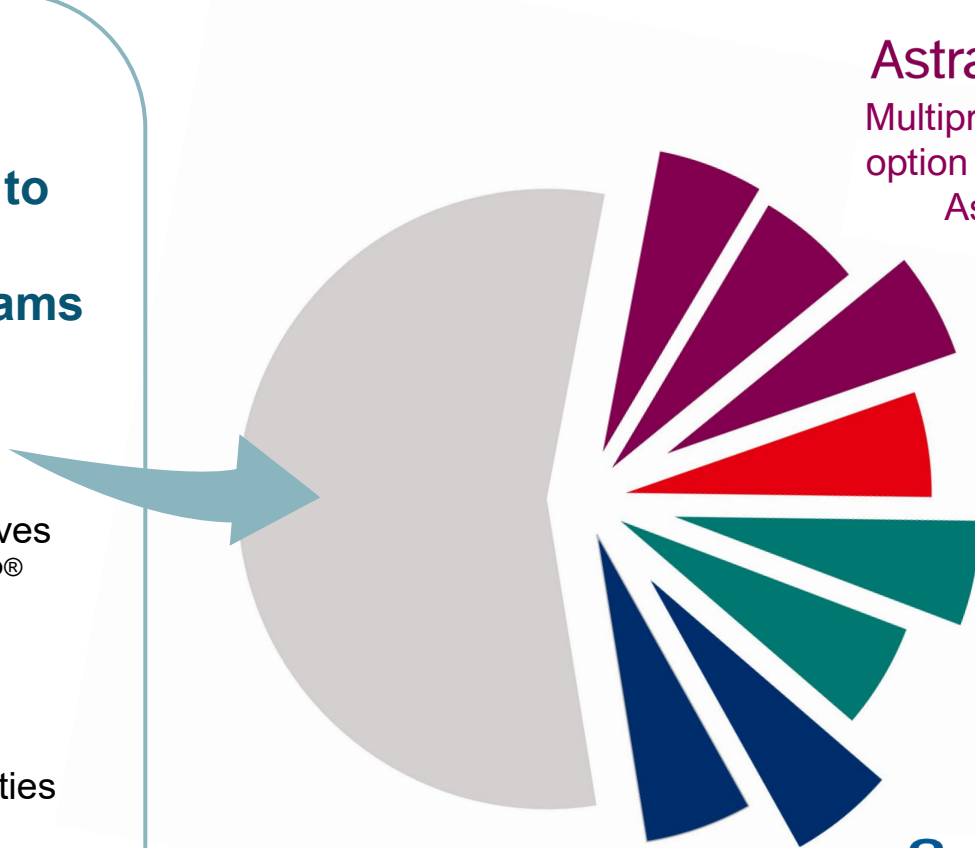
# DEP<sup>®</sup> partnering creates significant value and optionality

Starpharma's DEP<sup>®</sup> platform enhances the commercial and therapeutic value of a wide range of drugs, creating multiple potential revenue streams and significant IP leverage

DEP<sup>®</sup> platform offers significant optionality, enabling multiple licenses to run in parallel without Starpharma funding programs

## DEP<sup>®</sup> partnering process

- **Research Phase** - typically involves Starpharma making multiple DEP<sup>®</sup> candidates followed by testing by Partner; funded by Partner
- **Commercial Phase** – typically a license with milestones and royalties payable to Starpharma
- Development costs funded by Partners



**AstraZeneca**

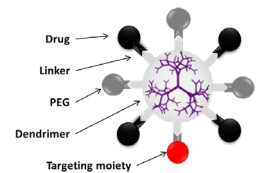
Multiproduct license & option agreement with AstraZeneca



DEP<sup>®</sup> anti-infective research partnership with Chase Sun



Two DEP<sup>®</sup> ADC Research Agreements with MSD



**Genentech**

A Member of the Roche Group

Two DEP<sup>®</sup> Research Agreements with Genentech

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

Global clinical development program in multiple indications

- AZD0466 is a highly optimised DEP<sup>®</sup> nanoparticle formulation of AstraZeneca's dual Bcl2/xL inhibitor (AZD4320)
- Dual Bcl2/xL inhibition with AZD0466 has potential for broader activity than the marketed Bcl2 inhibitor, venetoclax (Venclexta<sup>®</sup>). In 2021, Venclexta<sup>®</sup> had sales of ~US\$1.82 billion
- **Clinical program significantly expanded – now includes two Phase 1/2 multi-centre trials with others under consideration**
  - **Phase 1/2 clinical trial in patients with advanced haematological malignancies**
  - **Phase 1/2 trial is aimed at seamless transition to Phase 2, to facilitate expedited marketing approval**
- AZD0466 is the first candidate in Starpharma's multiproduct license with AstraZeneca; US\$7M in milestones received to date
- **Total AZD0466 eligible milestone receipts of up to US\$124M plus royalties (total estimated receipts up to A\$2.4B to Starpharma over the product life)**
- In addition to the multiproduct license with AstraZeneca, Starpharma also has a Development and Option Agreement with AstraZeneca, which remains on foot




AZD0466 Clinical Program	Status	Clinical Trial Sites
Global Phase 1/2 study in advanced haematological malignancies (acute myeloid leukaemia (AML) or acute lymphoblastic leukaemia (ALL))	12 sites recruiting; 36 planned	Australia, US, EU & Asia
Global Phase 1/2 study in non-Hodgkin lymphoma	4 sites recruiting; 26 planned	Australia, US, Canada, EU & Asia
<i>Additional indication planned</i>	<i>Details TBA</i>	

# AstraZeneca to present preliminary AZD0466 clinical results at the *American Society of Haematology*

AstraZeneca will present initial clinical results for *AZD0466* in advanced haematological malignancies at the American Society of Haematology Meeting, 10 – 13 December 2022 in New Orleans

- AZD0466 is a highly optimised DEP® nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor (AZD4320)
- Phase 1/2 trial underway at 12 sites in the US, Europe, Asia and Australia

## AZD0466 Preliminary Results<sup>^</sup> – to be presented at *ASH 2022*







- Multiple dose escalations already successfully completed
- 18 patients received AZD0466 across the dose levels
- AZD0466 well tolerated
- No dose-limiting toxicities (DLTs) to date
- No discontinuations due to treatment-related AEs to date
- The Phase 1/2 trial continues to enrol with further dose escalation underway; progressing to Phase 2 as soon as the Phase 2 dose is identified (escalation complete)

<sup>^</sup>as at 13 October 2022



# Starpharma's internal DEP<sup>®</sup> oncology portfolio

Multiple clinical-stage assets with high commercial value potential

DEP <sup>®</sup> Program	Original Drug Formulation	Advantages of DEP <sup>®</sup> Product <sup>**</sup>
<b>DEP<sup>®</sup> cabazitaxel (Phase 2)</b> 	Dendrimer version of leading prostate cancer drug cabazitaxel (Jevtana <sup>®</sup> ) 	Cabazitaxel (Jevtana <sup>®</sup> ) – global sales of ~US\$500M for 2021 despite having multiple US FDA “Black Box” warnings. Improved toxicity profile; detergent-free formulation; no steroid pre-treatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).
<b>DEP<sup>®</sup> docetaxel (Phase 2)</b> 	Dendrimer version of docetaxel (Taxotere <sup>®</sup> ) – widely used for breast, lung & prostate cancer 	Docetaxel (Taxotere <sup>®</sup> ) was a blockbuster cancer drug with peak global sales >US\$3B despite having multiple US FDA “Black Box” warnings. Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; tumour-targeting (~70x more drug in tumour); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).
<b>DEP<sup>®</sup> irinotecan (Phase 2)</b> 	Dendrimer version of irinotecan (Camptosar <sup>®</sup> ) - predominantly used for colorectal cancer 	Camptosar <sup>®</sup> had peak global sales of US\$1.1B despite having multiple US FDA “Black Box” warnings. Tumour-targeting; irinotecan is a pro-drug converted to the active metabolite, SN38; DEP <sup>®</sup> solubilises SN38 and allows direct dosing, avoiding the need for liver conversion and patient variability; improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).

COMMERCIAL OBJECTIVE



Create value through clinical proof-of-concept (Phase 2)



License following Phase 2 clinical data; platform validation



Clinical data adds value to partnered programs



Utilise accelerated development/reg. pathways (i.e. 505(b)(2)) for optimal ROI

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

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



# DEP<sup>®</sup> cabazitaxel: Phase 2 trial ongoing

*Encouraging efficacy signals across multiple tumour types enhancing market potential*

## DEP<sup>®</sup> cabazitaxel

- Phase 2 trial, ongoing
- 75 patients recruited to date, with final recruitment focused on gastro-oesophageal cancer
- Recruitment expected to complete within 1-2 months

### Interim observations

- Encouraging efficacy signals, including significant tumour shrinkage and substantial tumour biomarker reductions, observed in multiple cancers, including the original Jevtana<sup>®</sup> indication (prostate cancer), as well as new indications, including **ovarian, gastro-oesophageal, cholangiocarcinoma and head & neck cancer.**
- These impressive tumour responses have been observed in heavily pre-treated patients, some of which have failed multiple other lines of cancer treatment, and hard-to-treat tumours.
- Significantly fewer and less severe side effects, particularly bone marrow toxicity (myelosuppression), than published data on Jevtana<sup>®</sup>.

### Trial Sites



## Jevtana<sup>®</sup>

2021 sales  
~US\$500M



### FDA “Black Box” warnings:

1. Neutropenic deaths (febrile neutropenia)
2. Severe hypersensitivity (polysorbate-80 detergent)

### Extensive premedication:

- Antihistamine (required)
- Corticosteroid (required)
- H2 antagonist (required)
- Antiemetic prophylaxis (recommended)

### Prophylactic G-CSF

**recommended** for older/high-risk patients (to prevent severe myelosuppression)

### Short-Term Patents

- EU – expired
- US – 2031

## DEP<sup>®</sup> cabazitaxel

Starpharma’s patented, nanoparticle formulation



Detergent-free formulation; no neutropenic deaths or severe hypersensitivity observed; therefore, would not expect “black box” warnings

**Premedication not required;** polysorbate-80/detergent-free formulation

**Prophylactic G-CSF not required;** significantly less myelosuppression in high-risk patients: e.g., patients with low neutrophil count and ≥75yrs

### New / extended IP

- EU – 2039
- US – 2039 (potential for 5-year extension)

## DEP<sup>®</sup> cabazitaxel Phase 2 Trial Prostate Cancer Cohort

- 25 heavily pre-treated patients with Stage IV hormone-refractory prostate cancer
- Prior to entering the DEP<sup>®</sup> cabazitaxel study, patients had received:
  - **Average of 4 prior anti-cancer treatments and >70 months/cycles**
  - **>95% had received prior taxanes**, including docetaxel and cabazitaxel (Jevtana<sup>®</sup>)
  - 56% had received  $\geq$  two prior chemotherapy regimens (compared to 16%<sup>^</sup> of Jevtana<sup>®</sup> patients in published trial data)
- **DEP<sup>®</sup> cabazitaxel patients did not need prophylactic steroids** or antihistamines as polysorbate-80 free aqueous formulation
- **DEP<sup>®</sup> cabazitaxel required no primary G-CSF<sup>1</sup> prophylaxis**, despite older patient cohort and low neutrophil counts

1: G-CSF: granulocyte-colony stimulating factor, is used as a therapy for myelosuppression

2: Evaluable patients are those who received  $\geq$ 1 dose DEP<sup>®</sup> cabazitaxel and had an applicable efficacy assessment conducted post treatment. 3 patients were not evaluable for efficacy

<sup>^</sup>: Eisenberger, M, et al. J Clin Oncol, 2017;35(28):3198-206 .

## DEP<sup>®</sup> cabazitaxel Phase 2 Trial Interim Results in Prostate Cancer

- Highly encouraging anti-tumour activity, including RECIST partial response for more than 45 weeks, and stable or improved bone disease for up to 45 weeks
- **Median progression-free survival (PFS) of 3.9 months - more than 30% longer than published PFS data** for standard cabazitaxel (2.9 months<sup>^</sup>)
- **100% of evaluable patients<sup>2</sup> achieved a response in  $\geq$ 1 measure of efficacy**
- **52% of patients evaluable for PSA achieved PSA reduction  $\geq$ 50%** from baseline
- **83% of patients evaluable for bone disease experienced an improvement or no progression**
- 68% of patients evaluable for 2 or 3 efficacy measures achieved a response for all evaluable measures (soft tissue disease, PSA, and bone disease)
- No patients required routine steroid pre-medication or daily oral steroid
- DEP<sup>®</sup> cabazitaxel was generally well-tolerated, with Adverse Events ('AEs') similar in character to those observed with standard cabazitaxel



# DEP<sup>®</sup> cabazitaxel Phase 2 trial

Key interim efficacy and safety findings in prostate cohort vs. Jevtana<sup>®1,2</sup>

## Key Efficacy Measures

Efficacy Measure	DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> )	Jevtana <sup>®1</sup> (20 mg/m <sup>2</sup> )
PSA Reduction ≥50%	52.4%	29.5%
Partial Response <sup>#</sup>	18.2%	18.5%
Improved/stable Bone Disease	83.3%	Not reported



## Key Safety Measures

DEP<sup>®</sup> cabazitaxel had significantly fewer Grade 3/4 Treatment Related Adverse Events vs. Jevtana<sup>®</sup>

DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®1</sup> (20 mg/m <sup>2</sup> ) (N=580 <sup>†</sup> )	Jevtana <sup>®1</sup> (25 mg/m <sup>2</sup> ) (N=595 <sup>†</sup> )
7.5%	39.7%	54.5%

## Longer Progression-Free Survival (PFS) (median)

DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®1</sup> (20 mg/m <sup>2</sup> ) (N=598*)	Jevtana <sup>®1</sup> 25 mg/m <sup>2</sup> (N=602*)	Jevtana <sup>®2</sup> (25 mg/m <sup>2</sup> ) (N=378*)
3.9 months	2.9 months	3.5 months	2.8 months

PFS = Composite endpoint from date of randomization to date of first tumour progression, PSA progression, or death.

Note that the Jevtana studies<sup>1,2</sup> also included pain progression

\* Intent-to-treat populations

Safety Outcomes	DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25)	Jevtana <sup>®2</sup> (20 mg/m <sup>2</sup> ) (N=580 <sup>†</sup> )
Neutropenia ≥ grade 3	16.0%	41.8%
Febrile neutropenia ≥ grade 3	0%	2.1%
Thrombocytopenia ≥ grade 3	0%	2.6%
Neutropenic infection / sepsis	0%	2.1%

1 – Eisenberger, M., et al., PROSELICA. *J Clin Oncol*, 2017, 35(28):3198-206.

2 – Heidenreich, A, et al. *Eur J Cancer*, 2014,50:1090-9.

# Partial Response: ≥30% reduction in measurable target tumour size

† Safety populations (received at least 1 dose)



## 69-year-old woman with stage IV platinum resistant ovarian cancer

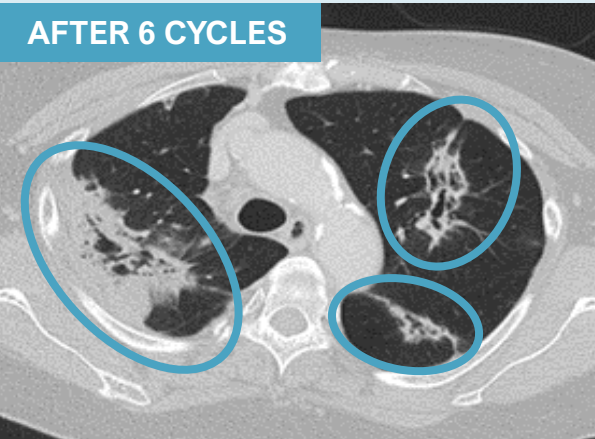
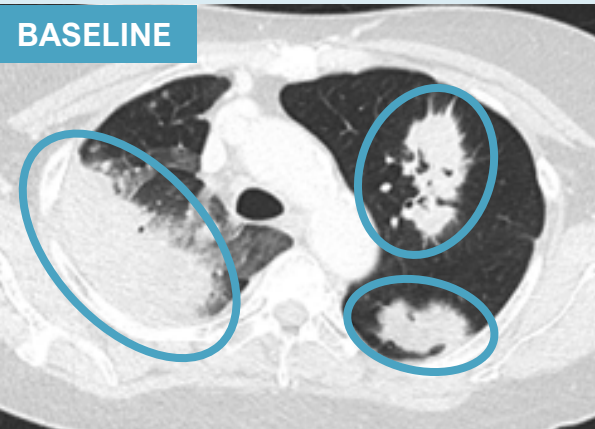
**Patient's cancer had progressed prior to entering the DEP<sup>®</sup> cabazitaxel study, following:**

- 12 cycles of two different platinum treatment regimens
- Extensive surgery and radiation therapy
- Extensive lung metastases with long-standing cough and related findings on chest examination

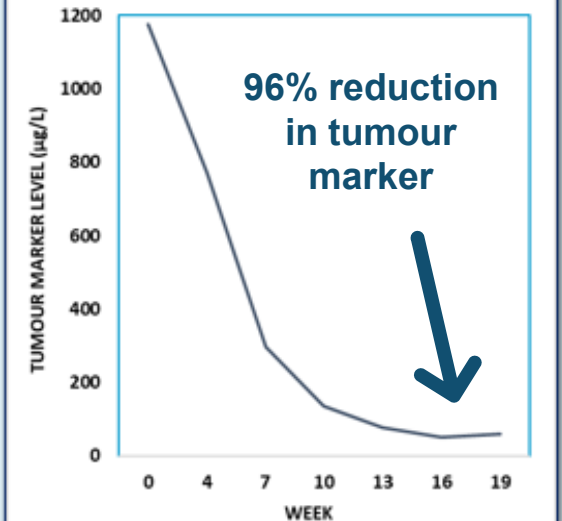
**Following treatment with DEP<sup>®</sup> cabazitaxel (6 cycles), the patient achieved:**

- Partial response (significant tumour shrinkage);
- Up to 43% reduction in size of individual lung metastasis
- Anticancer response maintained for 34 weeks
- 96% reduction in CEA tumour marker
- Cough and chest exam abnormalities resolved after cycle 3

### CT scans of lung metastases



### Reduction in Tumour Marker on DEP<sup>®</sup> cabazitaxel treatment



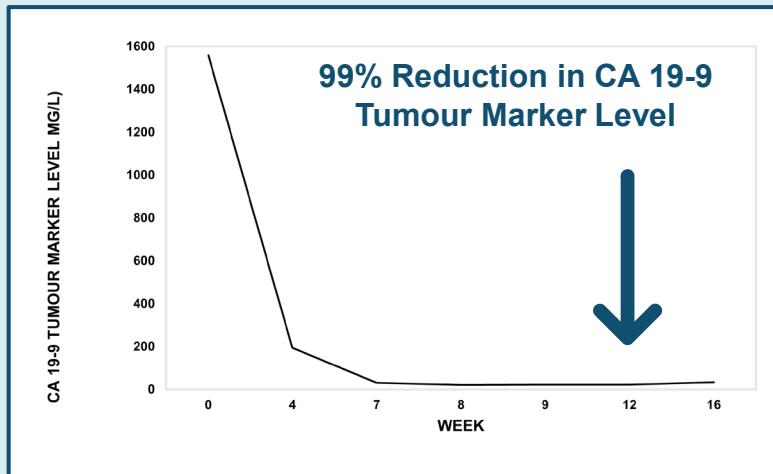


## 55-year-old woman with stage IV refractory oesophageal adenocarcinoma

Patient had progressed prior to entering the **DEP<sup>®</sup> cabazitaxel** study, following multiple cycles of platinum-based chemotherapy.

**Following treatment with DEP<sup>®</sup> cabazitaxel the patient achieved:**

- 36% reduction in target lesion in the liver (partial response)
- 99% reduction in CA 19-9 tumour marker level



## 54-year-old woman with stage IV platinum resistant ovarian cancer

**Patient had progressed prior to entering the DEP<sup>®</sup> cabazitaxel study, following:**

- 18 cycles of three different regimens of platinum combination treatment and 12 cycles of PARPi maintenance treatment and extensive surgery

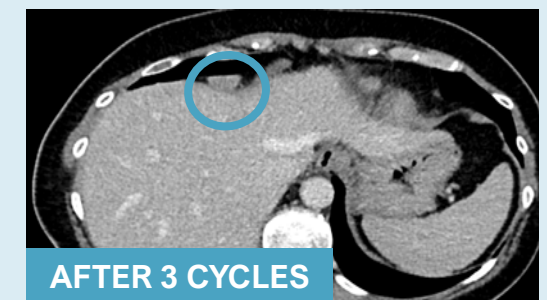
**Following DEP<sup>®</sup> cabazitaxel treatment the patient achieved:**

- Partial response (significant tumour shrinkage)
- 38% decrease in tumour burden
- 91% reduction in CA-125 tumour marker level

**38% reduction in size of lymph node metastasis**



BASELINE



AFTER 3 CYCLES

# DEP<sup>®</sup> docetaxel

Encouraging efficacy signals across multiple tumour types

## DEP<sup>®</sup> docetaxel

- Phase 2 trial, ongoing
- 75 patients recruited (monotherapy and combination)
- Monotherapy recruitment expected to complete within 1-2 months

### Interim observations

- Encouraging efficacy signals observed, including prolonged stable disease and significant tumour shrinkage in patients with a focus on **pancreatic, gastro-oesophageal, and cholangiocarcinoma**. Includes heavily pre-treated patients who have failed multiple other lines of treatment.
- These impressive tumour responses with DEP<sup>®</sup> docetaxel include stable disease for up to 40 weeks and significant tumour shrinkage in late-stage oesophageal cancer.
- Final patient recruitment is focused on hard-to-treat cancers, in parallel with the combination arm of DEP<sup>®</sup> docetaxel + gemcitabine.
- No anaphylaxis, notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects including hair-loss, mouth ulcers and oedema.

### Combination studies

- DEP<sup>®</sup> docetaxel + gemcitabine (Gemzar<sup>®</sup>)
- DEP<sup>®</sup> docetaxel + nintedanib (Vargatef<sup>®</sup>)

### Trial Sites



## Taxotere<sup>®</sup>

Peak sales  
~US\$3.1B

### FDA “Black Box” warnings:

1. Neutropenia
2. Severe hypersensitivity (polysorbate-80 detergent)

### Premedication required:

Oral corticosteroids

### Expired Patents

- EU – expired
- US – expired



## DEP<sup>®</sup> docetaxel

Starpharma's patented, nanoparticle formulation

No neutropenic deaths or severe hypersensitivity observed; detergent-free formulation; therefore, would not expect “black box” warnings

### Premedication not required;

polysorbate-80/detergent-free formulation

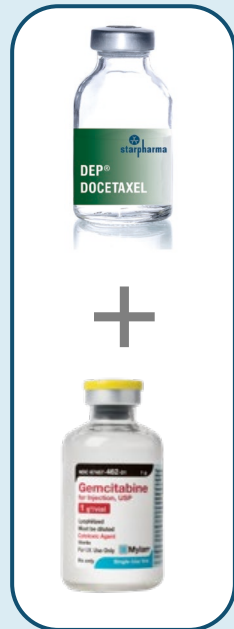
### New/extended IP

- EU – 2032
- US – 2032 (potential for 5-year extension)

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

DEP<sup>®</sup> docetaxel in combination with gemcitabine

## 60-year-old woman with stage IV uterine cancer



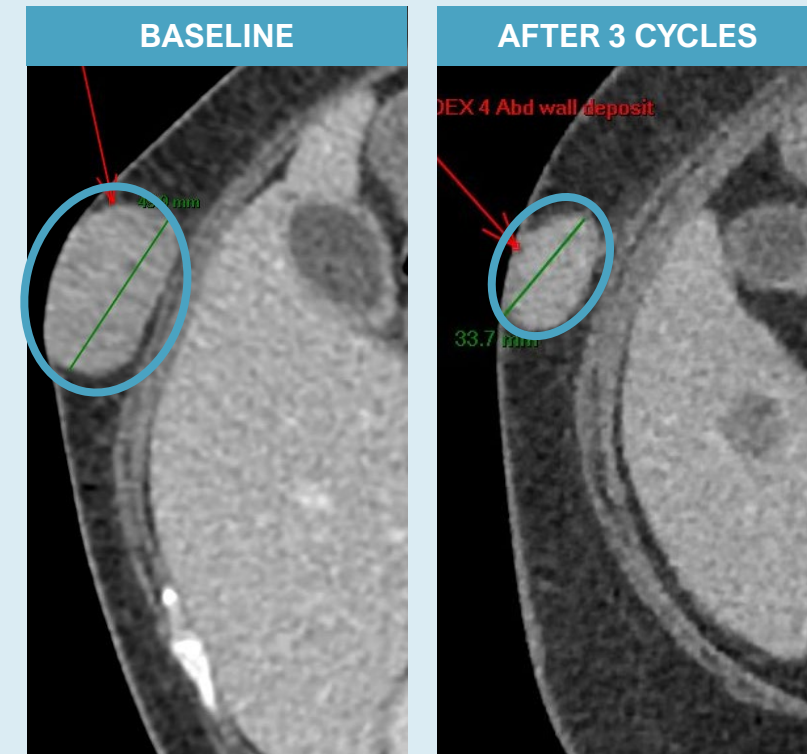
### Patient heavily pre-treated prior to entering the study:

- >11 treatment cycles of 3 different kinds of anti-cancer therapies

### Following treatment with DEP<sup>®</sup> docetaxel in combination with gemcitabine, the patient achieved:

- Stable disease response maintained for >23 weeks
- Tumour lesion reductions of up to 52% observed

### 32% reduction in tumour lesion



# DEP<sup>®</sup> irinotecan: Phase 2 trial ongoing

Encouraging efficacy signals across multiple tumour types enhancing market potential

## DEP<sup>®</sup> irinotecan

- Phase 2 trial underway; encouraging efficacy results
- 83 patients recruited to date (monotherapy), with final recruitment focused on platinum resistant ovarian cancer
- Monotherapy recruitment expected to complete within 2-3 months

### Interim observations

- Encouraging efficacy signals observed include prolonged stable disease, impressive tumour shrinkage and reductions in tumour marker levels for a number of tumour types, including **colorectal** and hard-to-treat tumours such as **ovarian** (including **platinum resistant**), **gastroesophageal**, and pancreatic cancers.
- No cases of severe diarrhoea with DEP<sup>®</sup> irinotecan – this side effect is experienced by 20-40% of patients with conventional irinotecan, and often requires hospitalisation<sup>^</sup>.
- Less severe side effects than typically associated with Camptosar<sup>®</sup>; AEs observed included nausea, vomiting, alopecia and neutropenia.

### Combination study (recruiting):

- DEP<sup>®</sup> irinotecan + 5-FU + Leucovorin ('FOLFIRI')

### Trial Sites

The ROYAL MARSDEN  
NHS Foundation Trust

  
Guy's and St Thomas'  
NHS Foundation Trust

  
WEST OF SCOTLAND CANCER CENTRE

  
The Newcastle Upon  
Tyne Hospitals  
NHS Foundation Trust

  
The Christie  
TOWARDS A FUTURE WITHOUT CANCER

  
The Kinghorn  
Cancer  
Centre

## Camptosar<sup>®</sup>

Peak sales - US\$1.1B



### FDA "Black Box" warnings:

1. Severe, life-threatening diarrhoea
2. Myelosuppression

Formulation requires conversion to SN-38 (active component of irinotecan) in the body

**Other AEs** include early diarrhoea which may be accompanied by cholinergic symptoms (*salivation, diarrhoea, blurry vision, sweating, incontinence*)

### Indication:

- Colorectal, in combination with 5-fluorouracil (5-FU) and leucovorin
- Colorectal (single agent)

### Expired Patents

- EU – expired
- US – expired

## DEP<sup>®</sup> irinotecan

(SN38 nanoparticle formulation)



- No severe diarrhoea observed;
- Less myelosuppression / neutropenia

DEP<sup>®</sup> conjugate of SN38 does not require hepatic conversion – less interpatient variability, reduced toxicity

**No cases of severe diarrhoea and no cholinergic symptoms observed**

### Indication:

- Colorectal
- Additional potential indications include ovarian, gastro-oesophageal, and pancreatic

### New/extended IP

- EU – 2039
- US – 2039 (potential for 5-year extension)

<sup>^</sup> H.Bleiberg. & E.Cvitkovic. (1996) Characterisation and Clinical Management of CPT-11 (Irinotecan)-induced Adverse Events. *European Journal of Cancer*, Volume 32 Supplement 3.



## DEP<sup>®</sup> irinotecan - improved tolerability profile c.f. published data on Camptosar<sup>®†</sup>

### Gastro-intestinal toxicity much improved with DEP<sup>®</sup> irinotecan treatment:

- ~20-40% of Camptosar<sup>®</sup> treated patients suffer from severe diarrhoea (≥ 7 stools per day), often require hospitalisation
- **DEP<sup>®</sup> irinotecan patients experienced no severe diarrhoea**

### No cholinergic syndrome:

- ~47% colorectal cancer patients treated with Camptosar<sup>®</sup> experienced cholinergic syndrome
- **No DEP<sup>®</sup> irinotecan patients experienced cholinergic syndrome**

#### Severe diarrhoea

- **Grade 3:** ≥7 stools per day over baseline; hospitalisation indicated.
- **Grade 4:** life-threatening consequences, and urgent intervention is required.

#### Cholinergic syndrome

Symptoms include sweats, flushing, diarrhoea, abdominal cramping, salivation, visual disturbances, miosis and lacrimation.

Safety Outcome	DEP <sup>®</sup> irinotecan*	Camptosar <sup>®†^</sup>
<b>GASTROINTESTINAL</b>		
Diarrhoea ≥ grade 3	0	~20-40%
Nausea ≥ grade 3	2.2%	~10%
Vomiting ≥ grade 3	1.1%	~10%
<b>NERVOUS SYSTEM</b>		
Cholinergic Syndrome	0%	~47%

\*(8 - 15 mg/m<sup>2</sup> SN38)  
Q3W | N=90

^(350 mg/m<sup>2</sup>)  
Q3W | N=765

†H.Bleiberg. & E.Cvitkovic. (1996) Characterisation and Clinical Management of CPT-11 (Irinotecan)-induced Adverse Events. *European Journal of Cancer*, Volume 32 Supplement 3.

‡<https://www.medicines.org.uk/emc/product/6506-UK> SmPC April 2022



## 55-year-old woman with stage IV colorectal cancer

*Colorectal cancer is the 3<sup>rd</sup> most commonly diagnosed cancer and 4<sup>th</sup> leading cause of cancer death worldwide\**

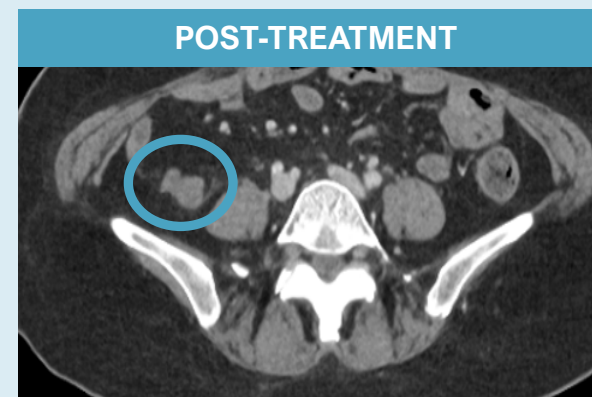
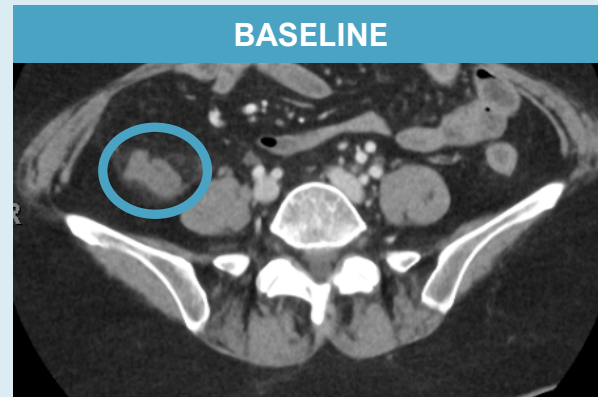
**Patient was heavily pre-treated prior to entering the DEP<sup>®</sup> irinotecan study, following:**

- 19 treatment cycles of 4 different kinds of anti-cancer therapy
- Progressed on prior irinotecan combination therapy

**Following treatment with DEP<sup>®</sup> irinotecan, the patient achieved:**

- Significant shrinkage of tumour lesions and reduction in tumour biomarkers
- Up to 74% reduction in tumour biomarkers
- Response maintained for more than 27 weeks

### 24% reduction in tumour after treatment with DEP<sup>®</sup> irinotecan



\*Favoriti et al, Worldwide burden of colorectal cancer: a review. Updates in Surgery: 68, 7-11, 2016.



## 56-year-old woman with heavily pre-treated stage IV platinum resistant ovarian cancer

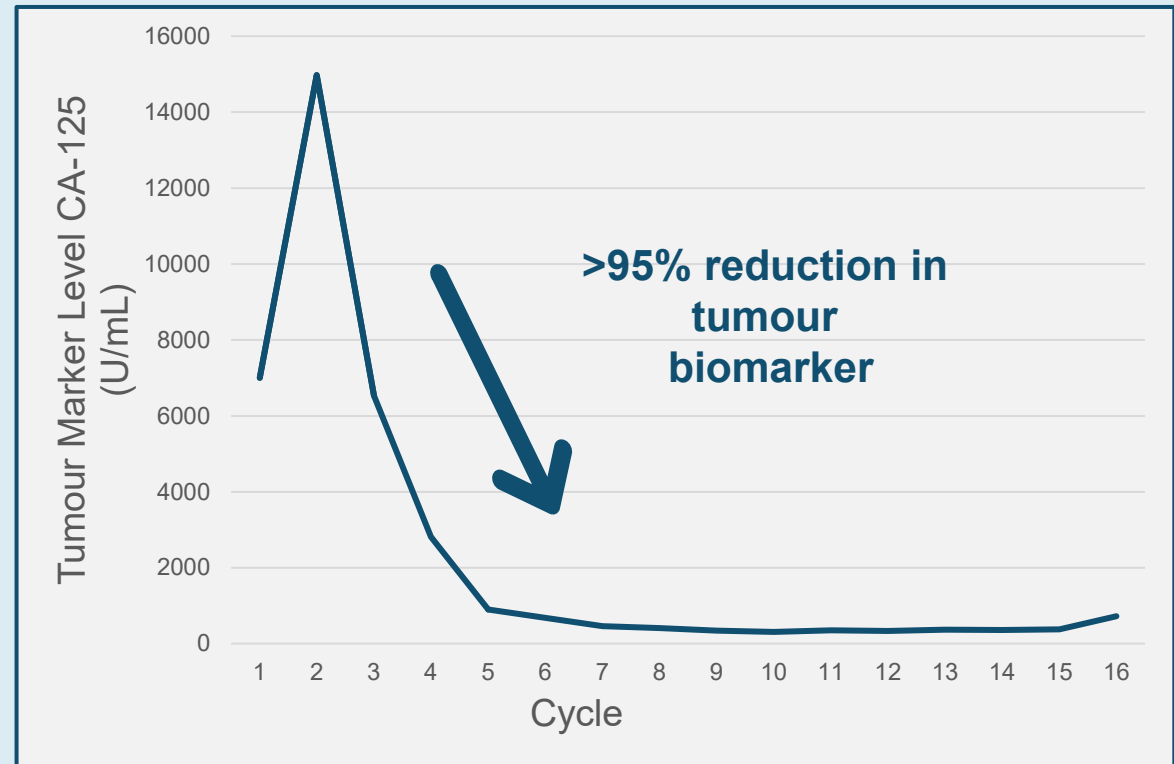
*Stage IV ovarian cancer has a 5-year survival rate of approximately 17%\**

**Patient was heavily pre-treated prior to entering the DEP<sup>®</sup> irinotecan study, following**

- 16 treatment cycles of 5 different kinds of anti-cancer therapy

**Following treatment with DEP<sup>®</sup> irinotecan, the patient achieved:**

- Complete resolution of cancer-related ascites and pleural effusion
- >95% reduction in tumour biomarker (CA-125)
- **Response maintained for more than 36 weeks**



\*<https://ocrahope.org/patients/about-ovarian-cancer/staging/>

# DEP<sup>®</sup> antibody drug conjugate (ADC) partnerships with leading companies

- The innovative therapeutic area of ADCs continues to grow, with many high value deals signed in recent years
- The ADC market is expected to reach to more than US\$15 billion by 2030\*
- Starpharma's DEP<sup>®</sup> technology represents a valuable partnering platform which has the potential to generate revenue through royalties and milestones

Starpharma has two DEP<sup>®</sup> research agreements with MSD for dendrimer-based ADCs using DEP<sup>®</sup> technology.



## Significant corporate activity in ADCs

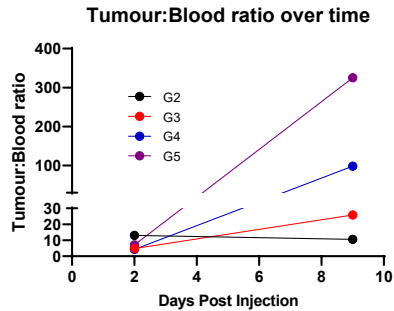


<p><b>US\$6B</b> Jul 2020</p>	<p><b>US\$2.75B</b> Nov 2020</p>	<p><b>€1.2B</b> Dec 2020</p>	<p><b>US\$3.1B</b> Jun 2021</p>	<p><b>US\$1.7B</b> Feb 2022</p>	<p><b>US\$936M</b> Jul 2022</p>

\*Colombo and Rich, The therapeutic window of antibody drug conjugates: A dogma in need of revision, Cancer Cell (2022), <https://doi.org/10.1016/j.ccell.2022.09.016>

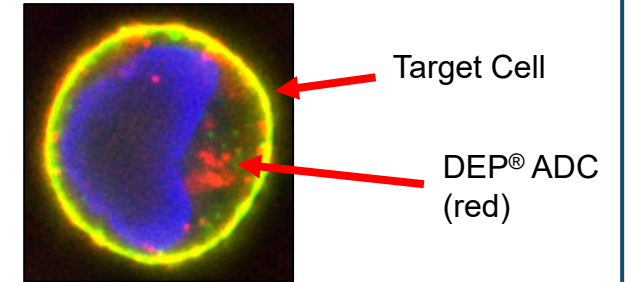
# DEP<sup>®</sup> ADCs offer multiple benefits

Can be tuned to provide optimal characteristics

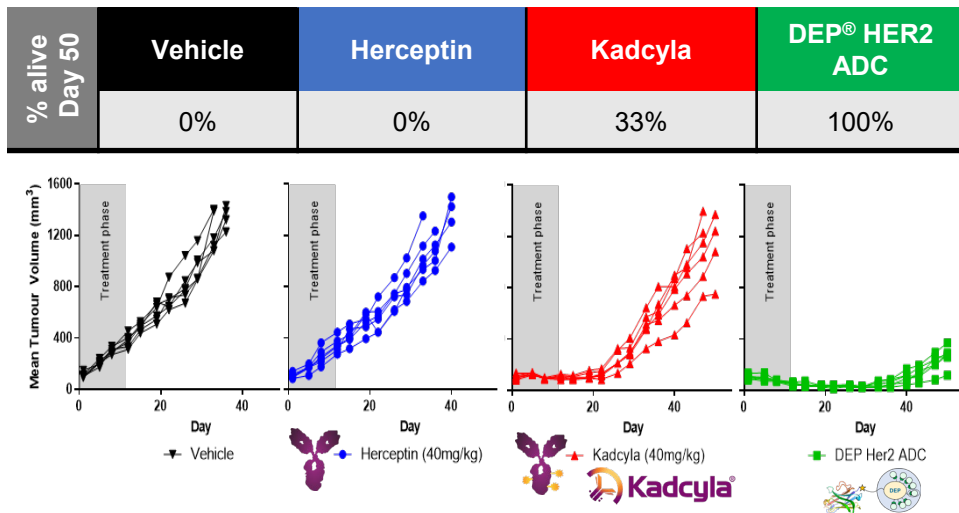


Benefits of DEP<sup>®</sup> ADCS

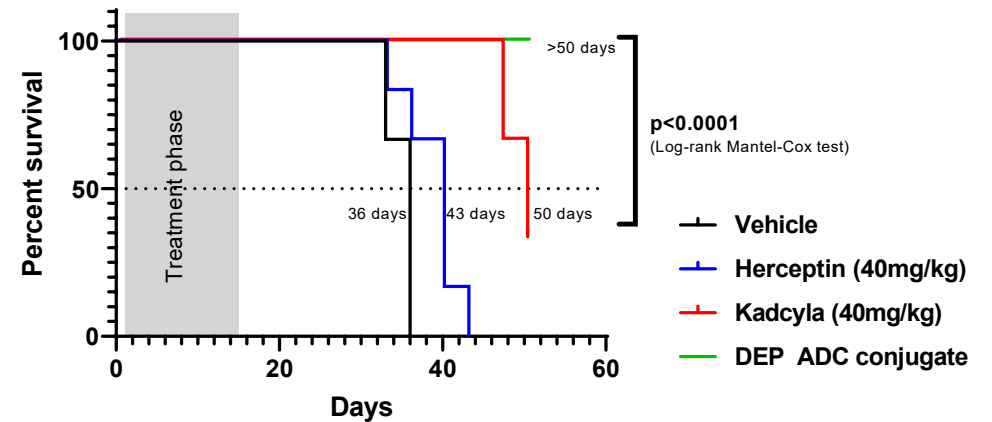
Penetrate deeply into tumours, bind strongly to target cells and are internalised for enhanced performance



Highly efficacious – enhanced anticancer activity\*

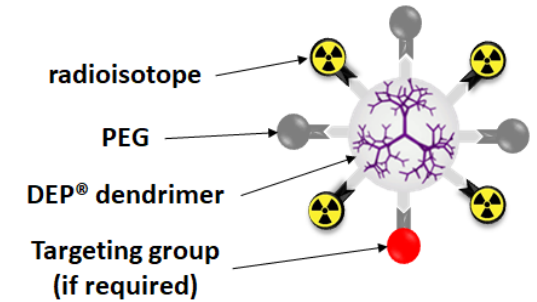


Enhanced efficacy leads to enhanced survival\*



# DEP<sup>®</sup> - a versatile platform with flexible applicability to a range of radiopharmaceuticals

- **Radiotheranostics is a rapidly developing area of cancer treatment and diagnosis** - the global radiopharmaceutical market is projected to reach US\$35 billion by 2031<sup>^</sup>
- **Significant corporate activity in recent years** - over US\$17 billion invested in M&A transactions between 2014 and June 2022\* in the radiopharmaceutical market
- **Starpharma's DEP<sup>®</sup> platform has yielded multiple radiotheranostic DEP<sup>®</sup> candidates** and Starpharma continues to evaluate licensing opportunities for its internal radiotheranostic candidates and engages in discussions with potential partners exploring access to Starpharma's DEP<sup>®</sup> platform



<b>Significant Corporate Deals in Radiotheranostics</b>						
<b>US\$3.9B</b> Oct 2017	<b>US\$2.1B</b> Oct 2018	<b>US\$641M</b> Oct 2019	<b>€418M</b> Jan 2021	<b>US\$300M</b> Mar 2021	<b>€520M</b> Dec 2021	<b>~US\$2B</b> Nov 2022

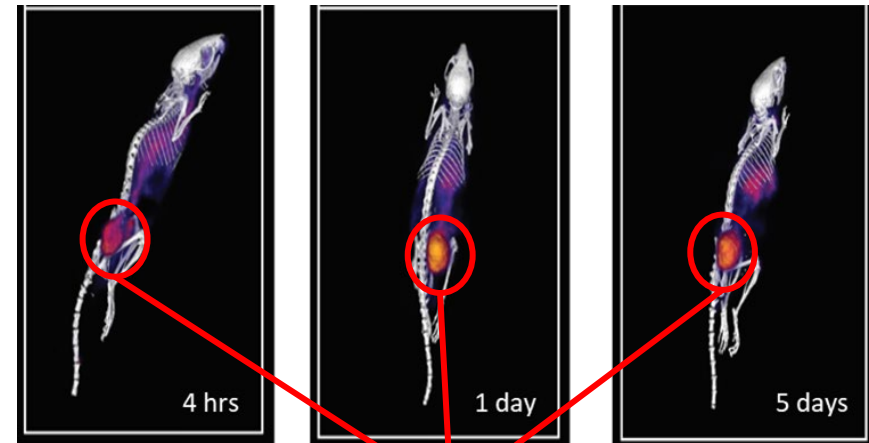
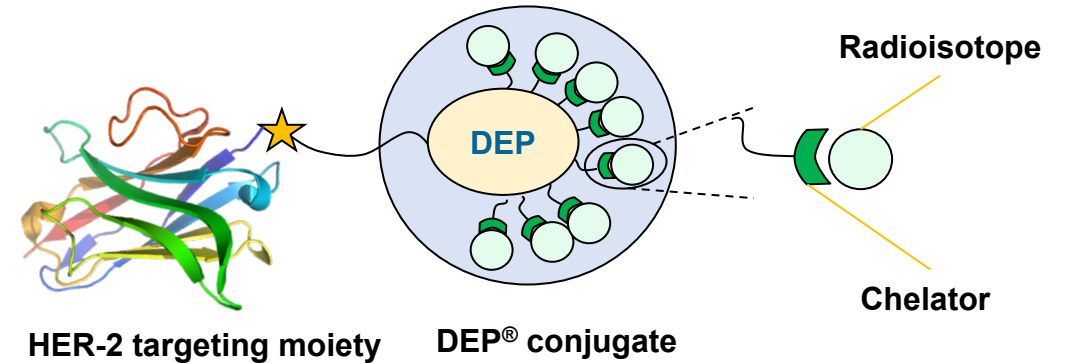
<sup>^</sup>MEDDraysintell Nuclear medicine report Edition 2022

\*[https://www.meddraysintell.com/\\_files/ugd/1beeab\\_6bc27b0bbe664527aca68f41bf7de2bc.pdf](https://www.meddraysintell.com/_files/ugd/1beeab_6bc27b0bbe664527aca68f41bf7de2bc.pdf)

# Targeted DEP<sup>®</sup> radiotheranostics offer multiple benefits

## DEP<sup>®</sup> benefits include:

- Flexibility in size and structure of nanoparticle (allowing different targeting groups and pharmacokinetics)
- Enhanced tumour accumulation due to the enhanced permeability and retention (EPR) effect (10x nanobody alone)
- Enhanced tissue targeting and retention due to specific receptor binding (and internalisation)
  - Enhanced entry and specific accumulation allows for enhanced PET visualisation (diagnostic)
  - Enhanced accumulation and cellular internalisation in tumours delivers enhanced efficacy and less off-target toxicity
  - Potential to use DEP<sup>®</sup> in diagnostic and therapeutic approaches



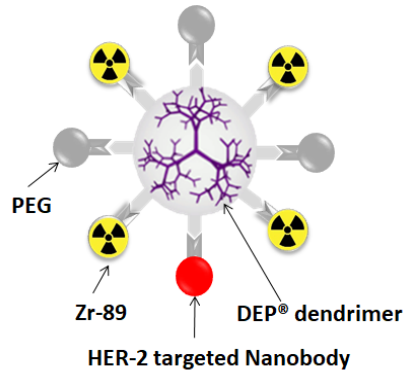
High levels of accumulation in tumour tissue allows targeted DEP<sup>®</sup> radio conjugates to be valuable in radiotheranostics

# Novel DEP<sup>®</sup> radiotheranostics (radiodiagnostic and radiotherapeutic)

## DEP<sup>®</sup> radiodiagnostic

### DEP<sup>®</sup> HER2-zirconium

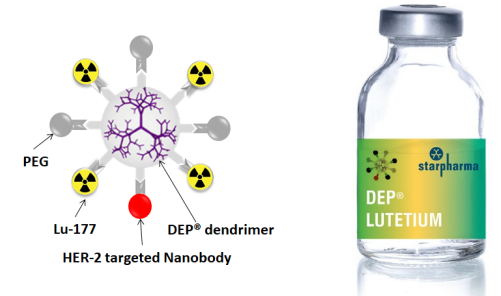
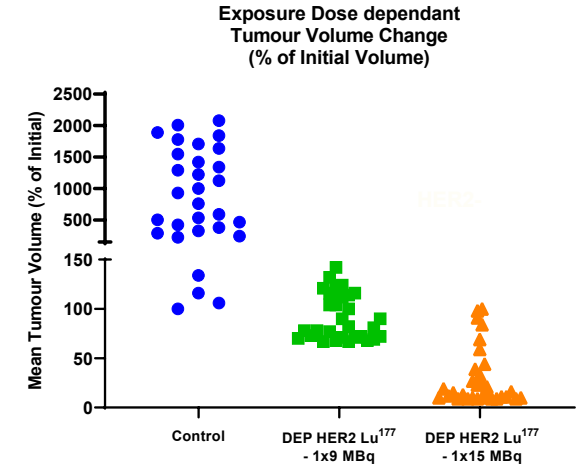
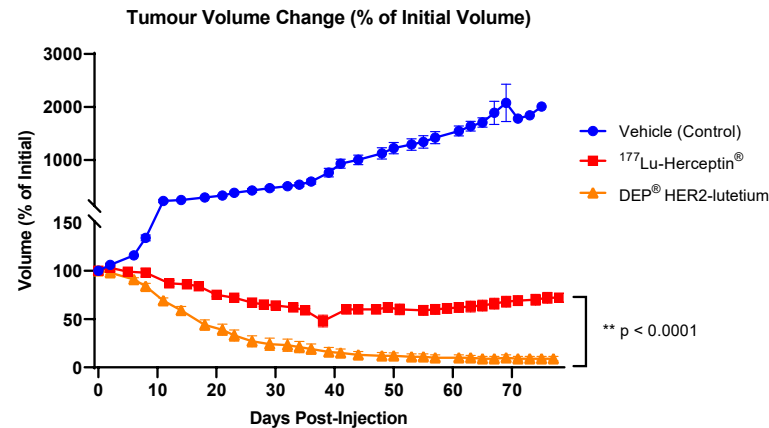
- Achieved significant tumour accumulation: >100x in tumour vs. blood in a preclinical human HER2-positive ovarian cancer model
- DEP<sup>®</sup> HER2-zirconium pharmacokinetics allow for optimal visualisation in PET imaging



## DEP<sup>®</sup> radiotherapeutics

### DEP<sup>®</sup> HER2-lutetium

- Achieved complete tumour regression in a preclinical human HER2-positive breast cancer model
- Was extremely well tolerated
- 100% survival throughout experiment
- Anti-tumour effect was dose-dependent
- Outperformed HER2 antibody, Herceptin<sup>®</sup>, labelled with <sup>177</sup>Lu





# Marketed products

Multiple revenue streams with a growing distribution network



**VIRALEZE™ Nasal Spray**



**VivaGel® BV**



**VivaGel® Condom**



Etqan & Nazahah Company



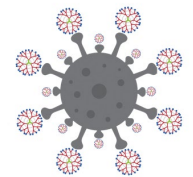
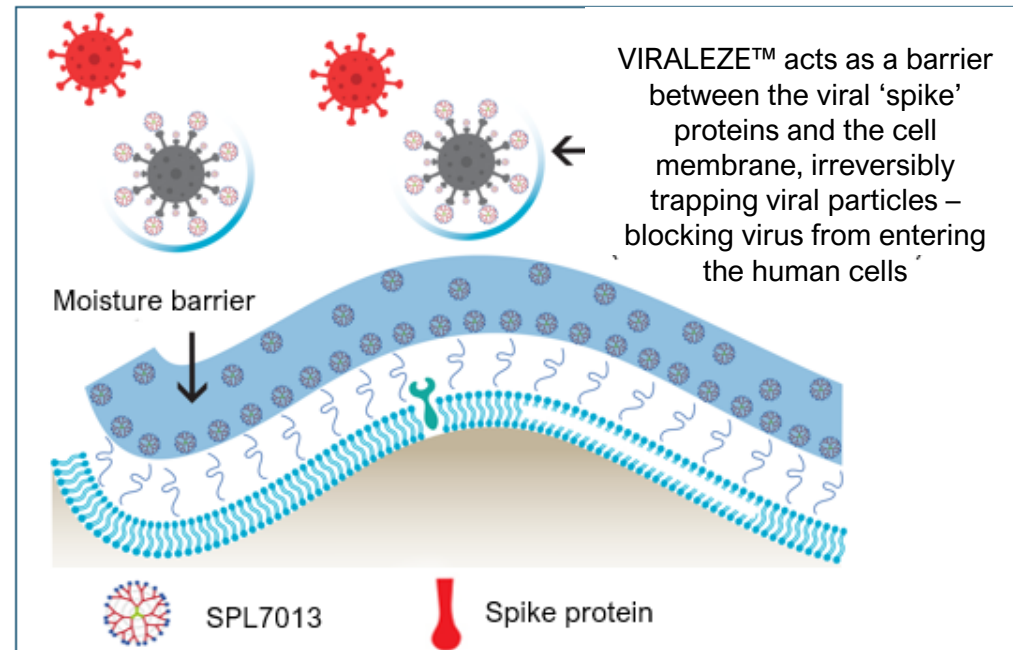
## VIRALEZE™ features

- Broad-spectrum antiviral nasal spray
- Contains a novel dendrimer molecule, SPL7013, which traps and blocks multiple cold/respiratory viruses including influenza, RSV, coronaviruses
- Blocks virus replication in lab studies both before and after exposure of cells to virus
- Well tolerated; acts locally in the nasal cavity and is not absorbed into the bloodstream
- Provides a protective moisture barrier to help keep nasal tissue hydrated
- Room temperature storage
- Convenient for use in a range of settings, including travel, work, events, and other crowded environments



## How VIRALEZE™ works

- Viruses infect human cells by using viral surface proteins, or “spikes”, to attach to receptor proteins on the surface of human cells
- Antiviral agent in VIRALEZE™, SPL7013, physically traps and blocks viral spike proteins thus preventing infection of cells



**SPL7013**

# VIRALEZE™ protects against SARS-CoV-2 Omicron and reduces infectivity in challenge model

New data to be presented at International Virology Conference – Dec '22

**VIRALEZE™ treated animals showed markedly reduced viral load after challenge with SARS-CoV-2 virus**

**VIRALEZE™ effectively eliminated SARS-CoV-2 Omicron virus (≥99.999% reduction in viral load) in lung and trachea of mice challenged with virus when compared with saline-treated animals, even when administered only after exposure to virus.**

VIRALEZE™ Regimen	Tissue	Reduction in SARS-CoV-2 Omicron Viral Load vs Saline
Pre- and Post-challenge	Lung	>99.999%
Post-challenge		>99.999%
Pre- and Post-challenge	Trachea	>99.999%
Post-challenge		99.999%
Pre- and Post-challenge	Nasal Swab	99.4%
Post-challenge		82.9%

Full data to be presented at RespiDART 2022 Conference in Mexico

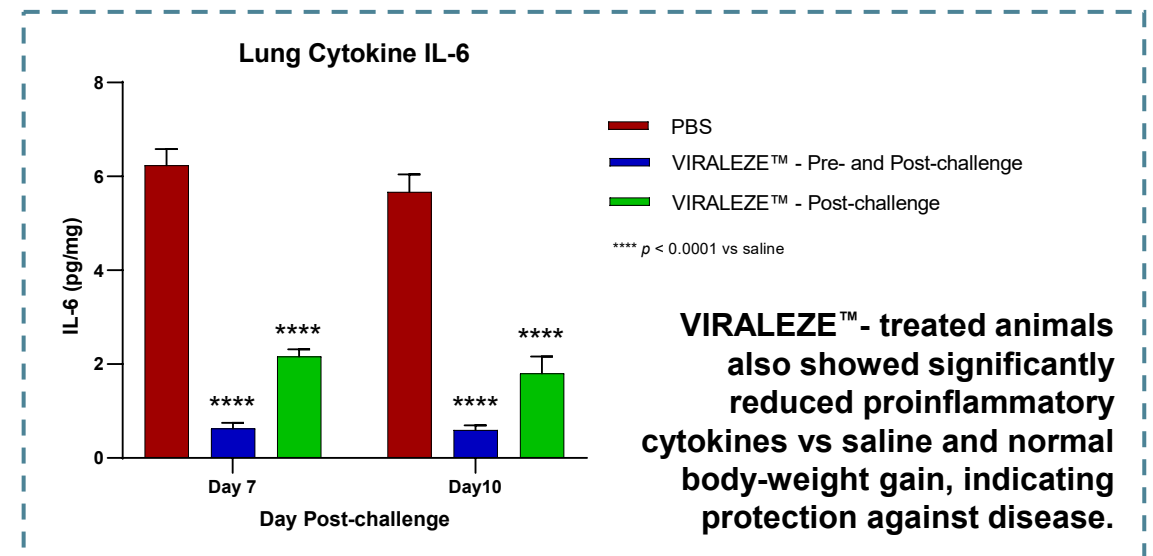
**VIRALEZE™ treated animals showed markedly reduced infectious SARS-CoV-2 virus in the respiratory tract**

**100% of animals<sup>^</sup> treated with VIRALEZE™ showed no evidence of infectious SARS-CoV-2 Omicron virus in**

- lung,
- trachea,
- nasal cavity, and
- blood.



**Reduced infectivity**



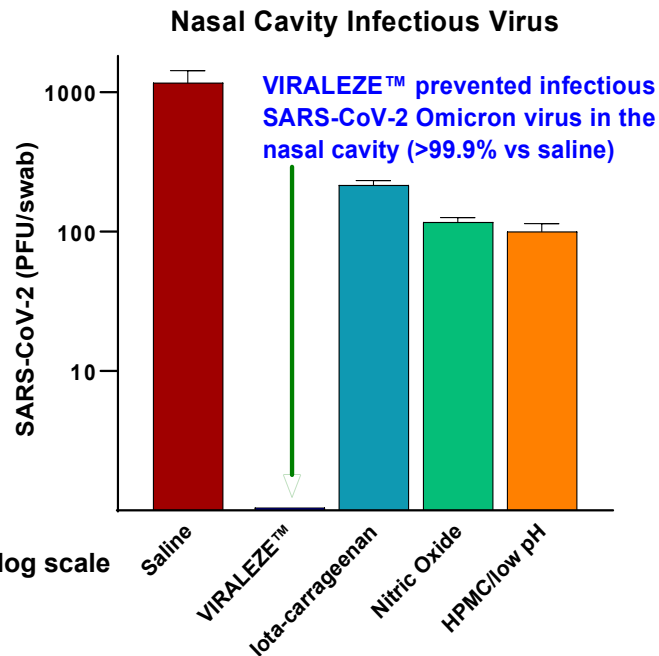
# VIRALEZE™ antiviral nasal spray outperforms comparators in SARS-CoV-2 Omicron challenge model

New data to be presented at International Virology Conference – Dec '22

## VIRALEZE™ significantly outperformed comparator nasal sprays in:

- reducing SARS-CoV-2 Omicron viral load by 99.4% vs saline; and
- VIRALEZE™ reduced the level of infectious virus in nasal cavity, lung, trachea<sup>^</sup>

Nasal Spray	Reduction in Infectious SARS-CoV-2 Omicron in Lung vs Saline
<b>VIRALEZE™</b>	<b>&gt;99.9%</b>
lota-carrageenan (e.g., <b>Cold Defence</b> )	<b>49.9%</b>
Nitric Oxide ( <b>NONS™</b> , <b>SaNOtize</b> )	<b>74.9%</b>
HPMC/low pH ( <b>Vicks® First Defence</b> )	<b>74.9%</b>



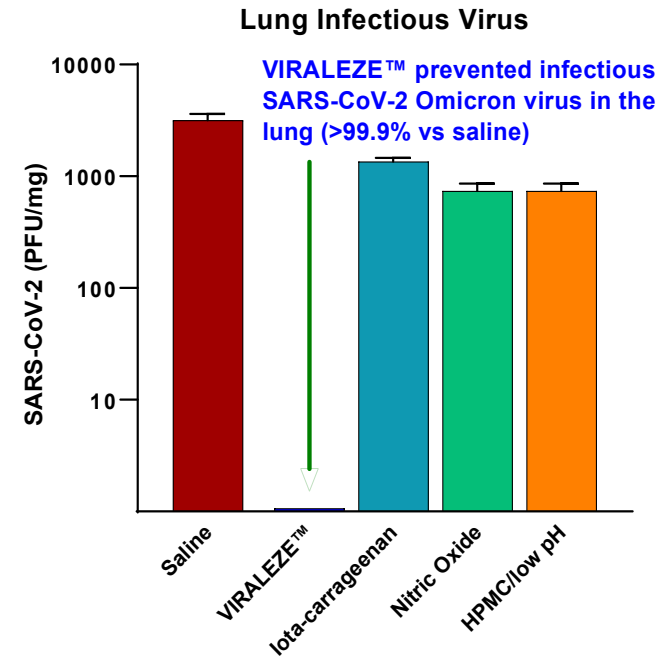
NB: Y axis = log scale



Full data to be presented at  
RespiDART 2022 conference in  
Mexico

RespiDART 2022

LOS CABOS, MEXICO • 6-8 DECEMBER 2022



<sup>^</sup>Day 7 post-challenge

# VIRALEZE™ clinical trial in patients with COVID-19

## UK Post-market Clinical Study of VIRALEZE™ Planned

- Small, post-market randomised clinical study of VIRALEZE™ vs. placebo nasal spray in patients with COVID-19 (80 patients per group)
- Will generate valuable clinical data to support ongoing marketing, commercialisation and regulatory activities
- Will examine the antiviral performance and ability of VIRALEZE™ to reduce viral load, as well as to monitor its impact on duration of symptoms and disease progression
- Study to be conducted at St Peter's Hospital, UK, an experienced site that has conducted other nasal spray studies; with other sites as necessary
- Primary endpoint: cumulative SARS-CoV-2 viral load, or “area under the curve”, over a seven day treatment period
- Trial design is based on other similar studies of products that VIRALEZE™ outperformed in nonclinical studies



# VIRALEZE

- VIRALEZE™ antiviral nasal spray is registered in more than 30 countries around the world\*
- Available in pharmacies, retail outlets and online in a number of markets
- Partnered with:
  - LloydsPharmacy in the UK; **LloydsPharmacy**
  - ADMENTA Italia Group in Italy; **ADMENTA** Italia
  - HealthCo/TBL & Nam Thanh Medical in Vietnam;
  - E&N in countries in the Middle East; **Etqan & Nazahah Company**
  - Hengan International Group in Hong Kong and Macau
- Other VIRALEZE™ regulatory submissions are in progress and commercial discussions for multiple regions/countries underway



Starpharma is also in discussions with multiple potential commercial partners in other regions with a focus on *commercially attractive* markets (i.e., good margins) which have rapid regulatory pathways

\*VIRALEZE™ is not approved for use or supply in Australia

ersonal use only

# VIRALEZE™ product launches and partners' promotional activities

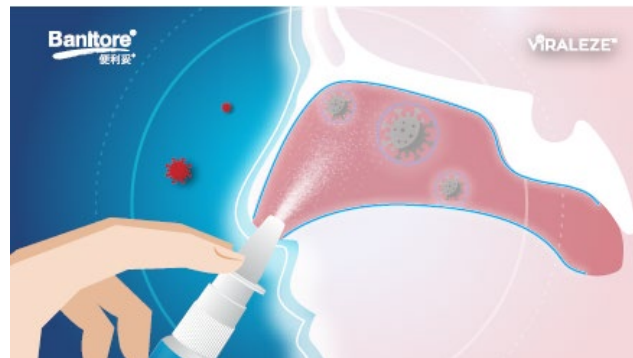
## VIRALEZE™ recently launched in Hong Kong and Macau

- Starpharma recently signed a supply and distribution agreement for VIRALEZE™ with Hengan in Hong Kong and Macau
- Hengan is listed on the Hong Kong Stock Exchange (HKSE:1044.HK), and is engaged in the manufacture, distribution and sales of COVID-19-related products, including face masks and rapid antigen tests, and other personal care products
- VIRALEZE™ is marketed in Hong Kong and Macau through leading pharmacy chains, including Mannings, and their online stores as well as other retail stores (e.g., PARKnSHOP)
- VIRALEZE™ also carries the well-known Banitore® brand in Hong Kong and Macau

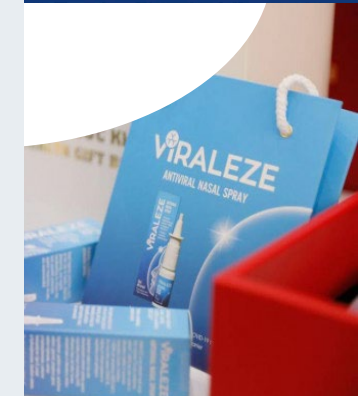
## VIRALEZE™ promotional activity by Partners



**Banitore®**  
便利妥®



**Viraleze™**  
**Barrier nasal spray**  
Helps trap colds and respiratory viruses



\*VIRALEZE™ is not approved for use or supply in Australia

Starpharma Holdings Limited: AGM Presentation to Shareholders

Registered indications may differ by market

## About Bacterial Vaginosis ('BV')

- Bacterial vaginosis or BV is the most common vaginal infection worldwide, affecting 1 in 3 women globally<sup>1</sup>. BV is associated with causing complications related to the reproductive health of women<sup>2</sup>
- BV treatment has typically involved antibiotics (e.g., metronidazole). Antibiotic resistance is a problem, antibiotics have unpleasant side effects, and there is demand for alternative approaches. Other current BV therapies do not prevent BV recurring

## VivaGel® BV

- Novel, non-antibiotic therapy
- Prevents pathogenic bacteria from adhering to the vaginal wall and disrupts and inhibits the formation of pathogenic bacterial biofilms
- Well tolerated, with vulvovaginal candidiasis being the only treatment-related adverse event reported to occur more often than with the placebo



**BETADINE BV GEL**  
BACTERIAL VAGINOSIS  
REZOLVENJE ZA MIKROBIOCELE  
DOLGOVAJEDNO

**PHARMACIST ONLY MEDICINE**  
KEEP OUT OF REACH OF CHILDREN  
**Fleurstat BVgel**  
VAGINAL GEL

**BREAKTHROUGH THERAPY FOR A SIGNIFICANT UNMET NEED**

- Rapid relief of odour in 24 hours
- Blocks BV-causing bacteria
- Helps restore vaginal flora and normalise pH levels
- Clinically proven to prevent recurrent BV\*
- Clinically proven to treat BV
- Non-antibiotic and not absorbed into the blood stream

\*Registered indications may differ by market

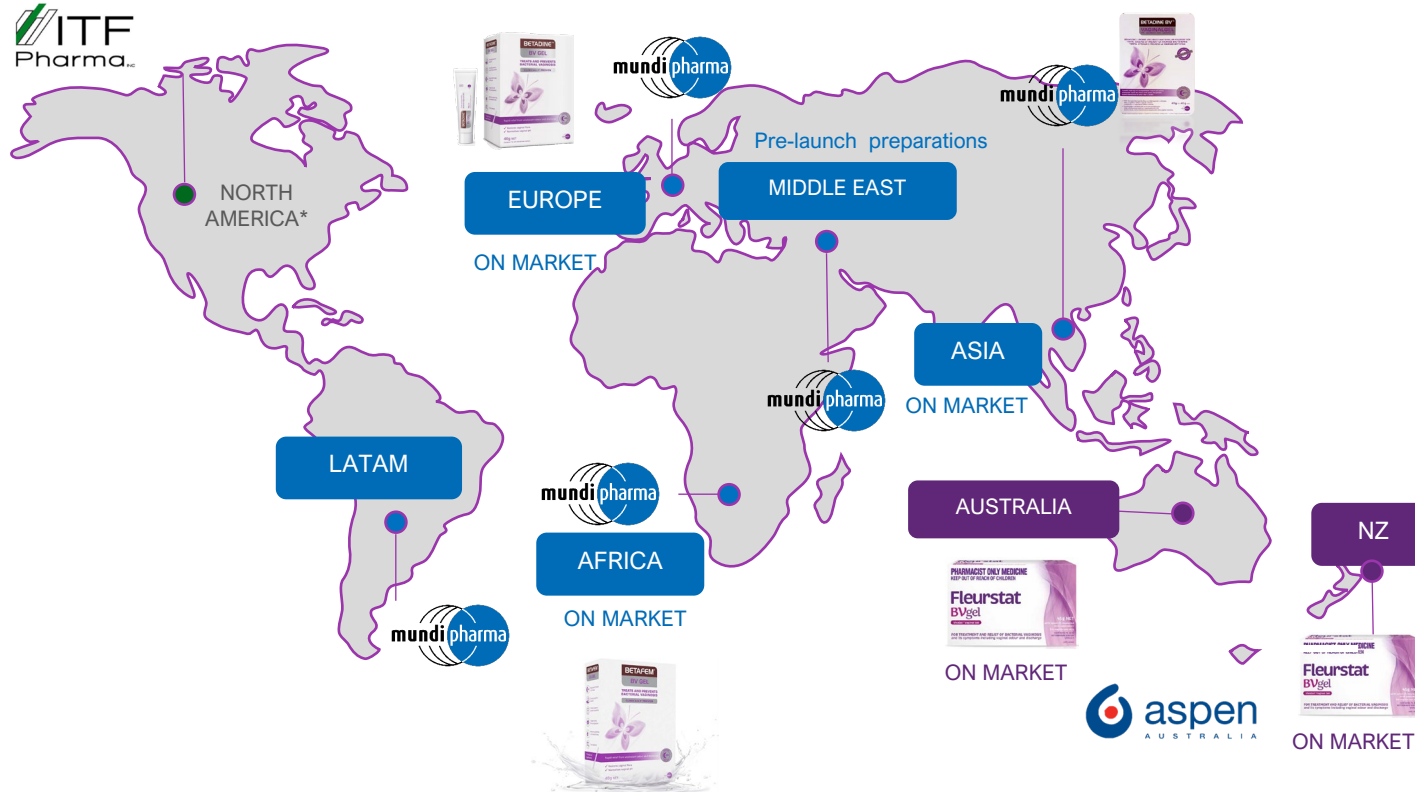
1. Peebles K, et al., (2019). High global burden and costs of bacterial vaginosis: a systematic review and meta-analysis. *Sex Transm Dis* 46(5), 304.  
2. Turovskiy Y, et al., (2011). The aetiology of bacterial vaginosis. *J Appl Microbiol* 110(5), 1105.



# VivaGel® BV distribution network and regulatory activity



- Registered in >45 countries
- Launched in Europe, the UK, Asia, South Africa, Australia & New Zealand
- Further launches and regulatory submissions progressing in multiple regions



In the US, a formal dispute resolution process is ongoing with the FDA for VivaGel® BV.

As part of this process, Starpharma has had extensive external advice, met with FDA multiple times and made a number of submissions of data and analyses to FDA. Starpharma continues to work with our advisors and the FDA, as part of this ongoing dispute resolution process and we are planning a further submission in Q1 2023.



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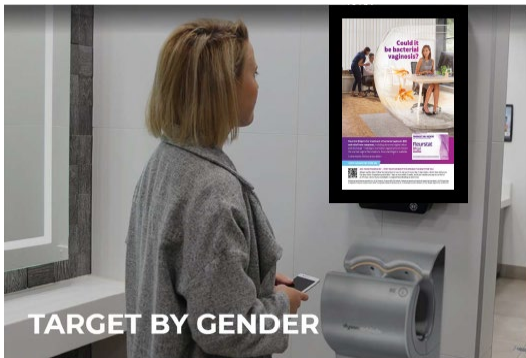
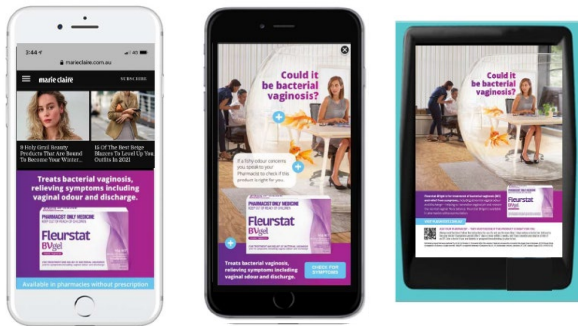
# VivaGel® BV marketing activities

Include multichannel promotions and publications to support clinical guidelines

## Marketing Campaigns by Partners to build Brand Awareness and Sales



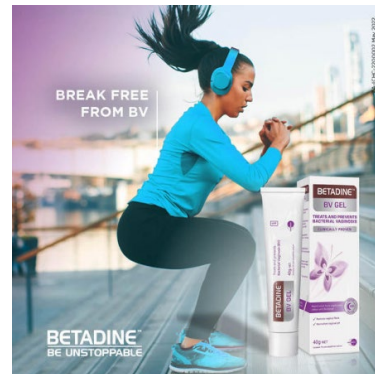
Consumer marketing, including digital marketing campaigns and washroom advertising



TARGET BY GENDER



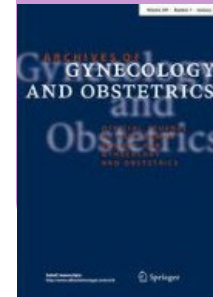
Healthcare professional marketing



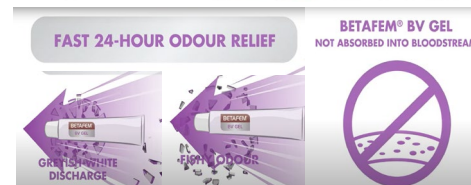
Peer-reviewed journal articles to support clinical guideline inclusion



“Astodimer sodium has the potential to improve outcomes for patients with BV as there is no potential to cause antibiotic resistance, it is not systemically absorbed, and the gel adheres to the vaginal wall, avoiding vaginal leakage. Non-antibiotic BV treatment represents significant progress in the treatment of BV and may benefit women affected by this widespread condition.”

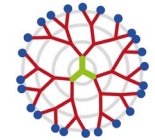


Prof Dr Werner Mendling & Prof Dr Holzgreve Wolfgang  
(2022) Astodimer sodium and bacterial vaginosis: a mini review. Arch Gynecol Obstet 306(1), 101.





- The VivaGel<sup>®</sup> condom incorporates SPL7013 antiviral, which has demonstrated activity in HIV, HSV-2, HPV
- Okamoto launched an additional VivaGel<sup>®</sup> condom range in Japan, under the brand name *Pure Marguerite*, targeting youth and female segments of the market
- Starpharma continues to support its marketing partner, Okamoto, to progress registration in multiple countries in Asia to support further commercialisation of the VivaGel<sup>®</sup> condom



SPL7013

## DEP® Drug Delivery



### Internal DEP® Clinical-stage Assets

- Complete Phase 2 trials
- Progress value-adding combination studies



### Partnered DEP® Programs

- Progress existing partnerships with AstraZeneca, MSD, Chase Sun, and Genentech
- Execute new and/or expand existing DEP® partnerships



### AZD0466 Clinical Program

- AstraZeneca clinical progress - completion of escalation - Phase 2 start, expansion and receipt of milestones



### Preclinical DEP® Programs

- Advance DEP® radiotheranostics, DEP® ADCs and other DEP® candidates

## SPL7013 Products



### VIRALEZE™ Nasal Spray

- Further commercial roll-out and product launches
- Further registrations in other regions
- Further distribution and marketing arrangements with commercial partners
- Continued testing to support commercialisation



### VivaGel® BV

- Commercial roll-out in Europe, Asia and other markets
- Further regulatory approvals and launches for VivaGel® BV; milestones, product sales/royalties
- FDA review process



### VivaGel® condom

- Approvals/launches in additional countries



### SPL7013

- Further development/co-development
- Continued testing against important infectious pathogens

# Starpharma's continued commitment to Environment, Social and Governance (ESG)

## ENVIRONMENT



Appropriate systems in place to comply with relevant federal, state, and local government environment regulations.



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

Starpharma has adopted documented procedures and processes to ensure all waste products are disposed of strictly in accordance with relevant environmental regulations.



View our [Climate Change Position Statement online](#)

## SOCIAL



>40% of roles, including leadership roles are held by female.

Starpharma's supplier code includes a wide range of business practices to provide suppliers with clear expectations regarding their conduct.

17 countries represented by a small, diverse group of employees.



*'Having a diverse workforce drives better outcomes for our business and provides the company with greater breadth of experience and ideas'.*

## GOVERNANCE

Compliance with ASX Corporate Governance Principles and Recommendations.

No breaches of:  
 - Code of Conduct  
 - Anti-bribery  
 - Whistleblowing



Director Independence



BOARD 80%

COMMITTEES 100%

Starpharma is committed to the principles underpinning best practice in corporate governance, with a commitment to the highest standards of legislative compliance and financial and ethical behaviour.

The nature of Starpharma's products affords the opportunity of changing lives for the better

> [Download ESG Report](#)



## Investor Relations Queries:

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