

## Starpharma to present at Life Sciences Investor Forum

**Melbourne, Australia; 15 September 2022:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that a presentation by Dr Jackie Fairley, CEO, will be broadcast on Thursday 15 September 2022 (US ET) as part of the US OTCQX's Virtual Life Sciences Investor Forum.

The Life Sciences Investor Forum is a leading investor conference that provides a forum for companies to present to tens of thousands of retail investors as well as advisors.

Details of the forum are found via this link: [Virtual Life Sciences Investor Forum](#).

Starpharma's pre-recorded presentation features a company overview, including:

- the latest interim clinical trial results presented at ESMO oncology conference that show efficacy signals in 100% of prostate cancer patients assessed following DEP<sup>®</sup> cabazitaxel treatment;
- an overview of Starpharma's DEP<sup>®</sup> clinical-stage and preclinical assets, and corporate partnerships for its DEP<sup>®</sup> drug delivery platform, including with Merck & Co., Inc (MSD) and AstraZeneca; and
- a VIRALEZE<sup>™</sup> overview and recent antiviral nasal spray results, including excellent protection against the SARS-CoV-2 Omicron variant, as well as updates on Starpharma's portfolio more broadly.

The presentation is attached and also available on Starpharma's website.

---

### 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 respiratory viruses, DEP<sup>®</sup> drug delivery and VivaGel<sup>®</sup>. Starpharma has developed VIRALEZE<sup>™</sup>, an antiviral nasal spray that is registered for sale in >30 countries, and available outside Australia in certain markets online. VIRALEZE<sup>™</sup> is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> products have been licensed in >160 countries, are registered in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, 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. Starpharma's partnered DEP<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

[Starpharma.com](#) | [Twitter](#) | [LinkedIn](#)

---

### Media: Sumit Media

Grant Titmus  
Mob: +61 419 388 161  
[grant@sumitmedia.com.au](mailto:grant@sumitmedia.com.au)

### Starpharma Holdings Limited

Dr Jackie Fairley, Chief Executive Officer  
Nigel Baade, CFO and Company Secretary  
+61 3 8532 2704  
[investor.relations@starpharma.com](mailto:investor.relations@starpharma.com)  
4-6 Southampton Crescent  
Abbotsford Vic 3067

### 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", "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 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.



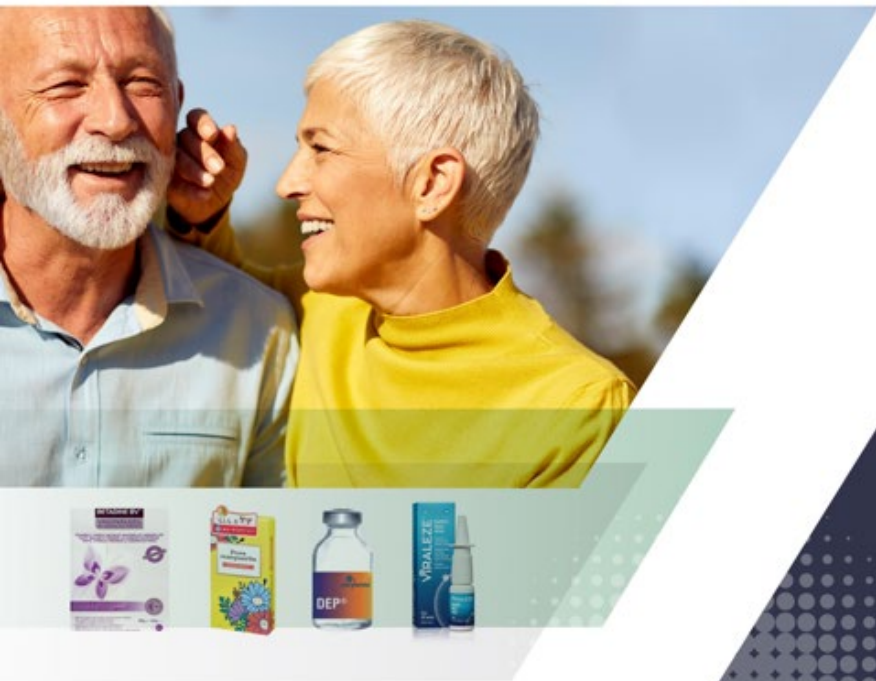
## Investor Presentation

OTC Life Sciences Investor Forum  
15 September 2022

---

Dr Jackie Fairley, CEO





## Important notice and disclaimer

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", "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 – 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).

**VIRALEZE™:** Always read the label and follow the instructions for use. This medical device is a regulated health product which bears, under this regulation, the CE marking in the EU. Do not use if you have a history of sensitivity to any ingredients 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 respiratory viruses. Not approved for sale or supply in Australia.

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



Through innovative research and development, Starpharma is creating therapies which have the potential to improve patient health worldwide.

- Unique polymer (dendrimer) platform creating valuable patented healthcare products (>200 patents)
- Deep portfolio of high-value products on-market and clinical stage assets, with current sales, near term potential commercial and clinical milestones
- Products address clear unmet medical need for large markets
- Established manufacturing and supply chain
- Successful partnerships with leading global companies
- Well funded (\$49.9M - 30 Jun 22); share register is made up of ~55% institutions, ~40% retail, ~5% staff & other



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



**VIRALEZE™ Nasal Spray** - Registered in >30 countries worldwide; available in pharmacies, retail outlets and online in certain markets



**VivaGel® BV** - Registered in >45 countries; licensed in >160 countries, marketed in the UK, Europe, Asia, South Africa, Australia & NZ



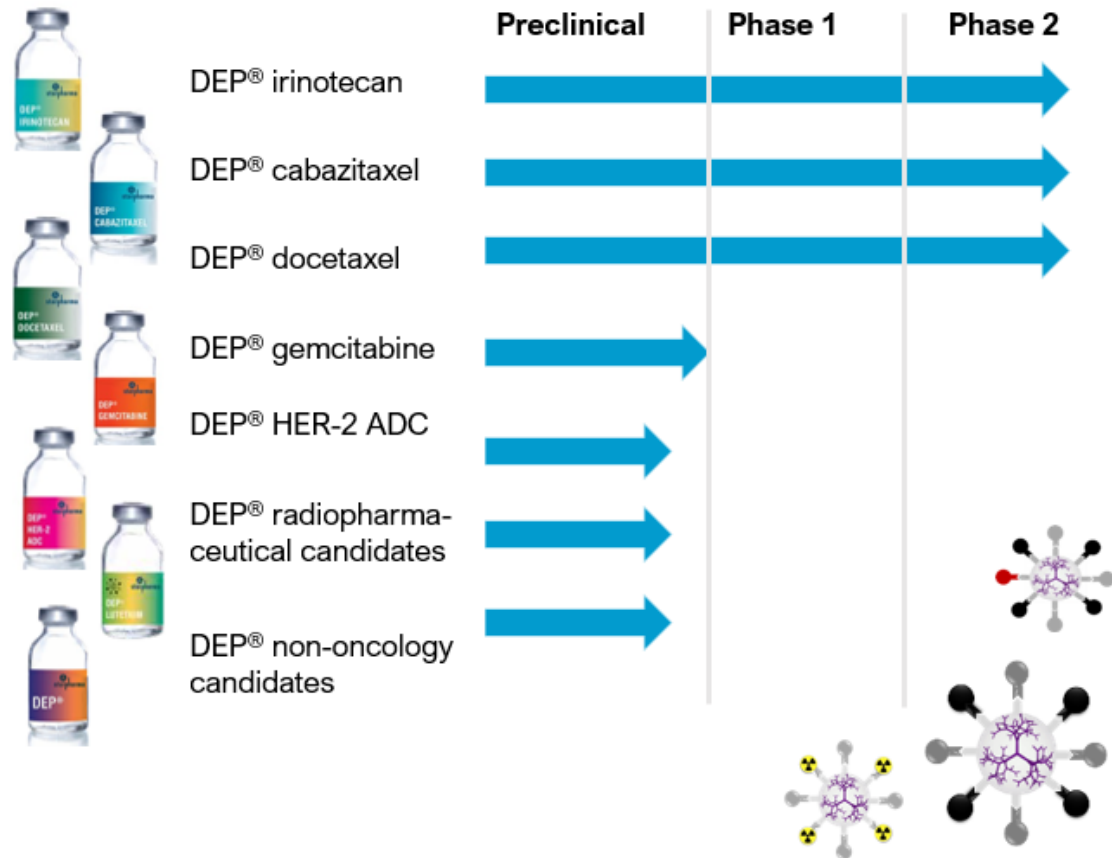
**VivaGel® condom** - Approved in Japan, Europe, Australia & Canada



# Starpharma's portfolio: High-value assets including VIRALEZE™, VivaGel® products on market, and multiple DEP® clinical-stage assets



## Internal DEP® Products



## Marketed Products



## Partnered DEP® Products & Programs



- Multiproduct DEP® licence, including the development of AZD0466
- Global clinical trial of AZD0466 in leukemia patients
- Global clinical trial of AZD0466 in non-Hodgkin's lymphoma patients



- DEP® agreement for dendrimer-based ADCs
- Second DEP® agreement for dendrimer-based ADCs



- DEP® partnership to develop DEP® nanoparticle formulations of an anti-infective drug



- DEP® program to develop and evaluate DEP® drug conjugates
- Second DEP® program to develop and evaluate additional DEP® drug conjugates

| Key Financial Data                     | FY22<br>A\$M | FY21<br>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)       |
| Net financing & investing cash inflows | 2.4          | 46.1         |

Cash as at 30 Jun 2022 : \$49.9M

### FY22 Result

- Strong cash position with a balance of \$49.9M as at 30 June 2022
- Revenue up 128% to \$4.9M (FY21: \$2.2M) 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 (FY21: \$19.7M)
- Receipt of \$7.7M R&D tax incentive


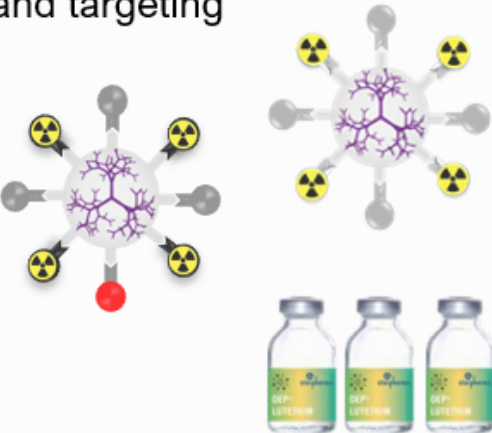




# Starpharma's DEP<sup>®</sup> platform - broad applicability and exceptional optionality



## Multiple DEP<sup>®</sup> products and therapeutic areas - partnered and internal programs



| Chemotherapeutics   | Radiotheranostics  | Antibody Drug Conjugates (ADCs)   | Non-oncology  |
|---|--|---|---|
| <ul style="list-style-type: none"> <li>• Franchise extension</li> <li>• Generic differentiation</li> <li>• New Chemical Entities</li> <li>• Combinations including immuno-oncology</li> </ul>  <p>AstraZeneca</p> | <ul style="list-style-type: none"> <li>• Radiotheranostic applications – growth area</li> <li>• Can use variety of isotopes and targeting</li> </ul>  | <ul style="list-style-type: none"> <li>• Flexible technology</li> <li>• Increased drug antibody ratio</li> <li>• Targeting group agnostic</li> <li>• Site selective payload attachment</li> </ul>  <p>MSD</p> | <ul style="list-style-type: none"> <li>• Antiviral</li> <li>• Anti-infective</li> <li>• Endocrinology</li> </ul>  <p>红日药业集团<br/>CHASE SUN</p> |



# DEP<sup>®</sup> benefits

Starpharma's DEP<sup>®</sup> platform is highly versatile, it conveys multiple benefits, and it enhances the commercial value of a wide range of drugs



**Improved Efficacy** – better drug targeting, improved PK and controlled release



**Improved Safety** – control release kinetics of drug which minimises C<sub>max</sub> related toxicities



**New Patent Life** – create new intellectual property and extending patent life



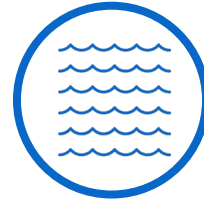
**Tumour Targeting** – 40-70x more drug in tumour cf. the original drug



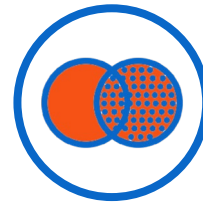
**DEP ADC's** – multiple benefits and unique flexibility



**Improved PK & Half-Life** – DEP allows tuning of drug release and plasma half life



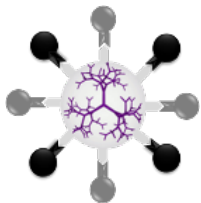
**Improved Solubility** – highly water soluble; removal of toxic excipients



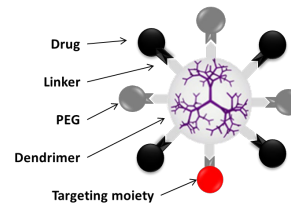
**Benefit in Combination Therapy Regimens** – ideal for combination therapy



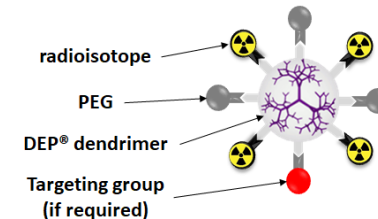
**Radiotheranostics** – flexibility in the development of radiotherapeutics and radiodiagnostics



*DEP dendrimer-drug conjugate*



*Dendrimer-based antibody drug conjugate*



*Dendrimer-based radiotheranostic*

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



- **AZD0466** is a highly optimised DEP<sup>®</sup> nanoparticle formulation of AstraZeneca's dual Bcl-2/xL inhibitor (AZD4320)
- Dual Bcl-2/xL inhibition with AZD0466 has potential for broader activity than the marketed Bcl-2 inhibitor, venetoclax (Venclexta<sup>®</sup>). In 2020, Venclexta<sup>®</sup> had sales of ~US\$1.34 billion (+69% cf. 2019)
- Clinical program significantly expanded and advanced in 2021, to a multi-region Phase 1/2 clinical trial in advanced haematological malignancies; AstraZeneca is now recruiting at sites in South Korea, Italy, Germany, Australia and USA
- This new phase 1/2 trial is aimed at seamless transition to phase 2, to facilitate expedited marketing approval; A new multi-centre trial for AZD0466 in patients with non-Hodgkin's lymphoma, announced by AstraZeneca, is recruiting at sites in the USA and South Korea, with further planned recruitment at sites in Italy, France, Spain, Portugal, Canada, and Australia.
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AZ; US\$7M in milestones received to date
- Total AZD0466 deal up to US\$124M milestones + royalties (est. up to A\$2.4B revenue to SPL)
- AZD0466 studies in a human mesothelioma model were recently [published in Nature Biotechnology](#)



| Clinical program for AZD0466   | Status                         |
|--|--------------------------------|
| Global phase 1/2 study in advanced haematological malignancies (AML & ALL) | Recruiting & opening new sites |
| Global phase 1/2 study in non-Hodgkin lymphoma                             | Recruiting & opening new sites |
| <i>Additional indication planned</i>                                       | <i>Details TBA</i>             |

## AstraZeneca presented AZD0466 posters at 2021 Annual Society of Hematology (ASH) Meeting

**Poster 1:** 2353 NIMBLE: A Phase I/II Study of AZD0466

<https://ash.confex.com/ash/2021/webprogram/Paper147482.html>

**Poster 2:** 1867 Combination Therapy of Bcl-2/XL dual Inhibitor AZD0466 with Acalabrutinib to Overcome Therapeutic Resistance in Aggressive R/R Mantle Cell Lymphoma

<https://ash.confex.com/ash/2021/webprogram/Paper151609.html>



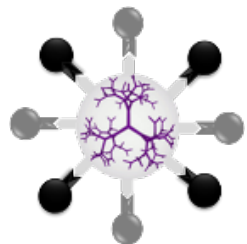
# DEP<sup>®</sup> partnering creates significant value and optionality

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



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

- Clinical program significantly expanded and advanced in 2021, to a multi-region, global Phase 1/2 clinical trial in advanced haematological malignancies
- Clinical program expanded further in 2022 to include an additional indication, non-Hodgkin's lymphoma
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AstraZeneca; US\$7M in milestones received to date
- Total AZD0466 deal up to US\$124M milestones + royalties (est. up to A\$2.4B revenue to SPL)

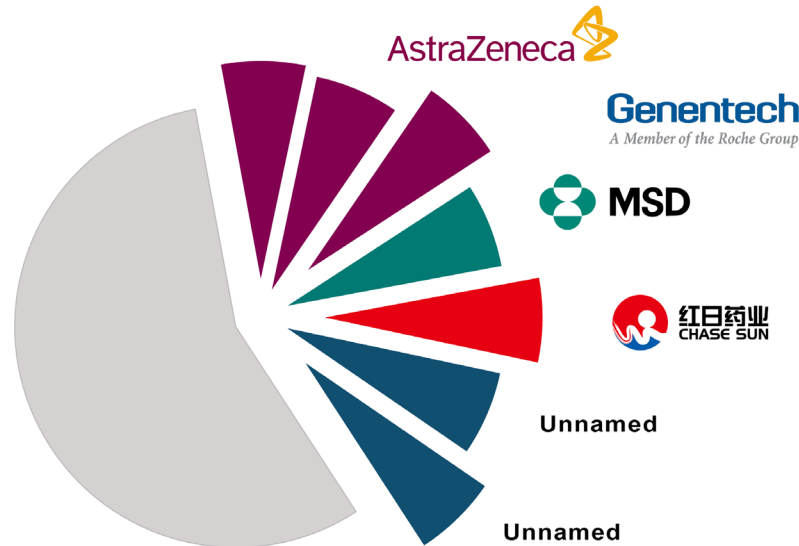


AstraZeneca



## DEP<sup>®</sup> platform allows for multiple partnerships

Starpharma has multiple partnered DEP<sup>®</sup> programs, including with large pharma companies: AstraZeneca, Merck & Co., Inc., and Chase Sun.

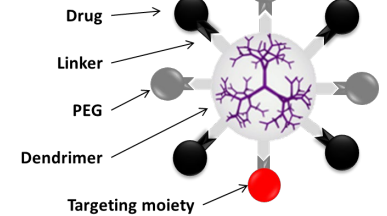


DEP<sup>®</sup> platform offers optionality, enabling multiple licences to run in parallel

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

*“MSD is a recognised leader in oncology, and we are delighted to have signed this new Research Agreement in such an innovative and valuable area”*

Dr Jackie Fairley, CEO Starpharma



## Starpharma has a research partnership with Chase Sun to develop several DEP<sup>®</sup> nanoparticle formulations for an anti-infective drug



# DEP<sup>®</sup> internal oncology programs

## Multiple clinical-stage assets with high commercial value potential



**PHASE 2**




**DEP<sup>®</sup> DOCETAXEL:**  
Enhanced 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

**Advantages of DEP<sup>®</sup> docetaxel<sup>##</sup>:**  
Reduction in neutropenia; detergent-free formulation; no steroid pre-treatment; tumour-targeting (~70x more); improved efficacy; improved pharmacokinetics; patent filings to 2032 (plus up to an additional ~5 years).

**PHASE 2**




**DEP<sup>®</sup> CABAZITAXEL:**  
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>)

**Cabazitaxel (Jevtana<sup>®</sup>)** – global sales of ~US\$600M for 2020 despite having multiple US FDA “**Black Box**” warnings

**Advantages of DEP<sup>®</sup> cabazitaxel<sup>##</sup>:**  
Improved toxicity profile; detergent-free formulation; no steroid pre-treatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).


**PHASE 2**




**DEP<sup>®</sup> IRINOTECAN:**  
Improved version of irinotecan (Camptosar<sup>®</sup>) - predominantly used for colorectal cancer

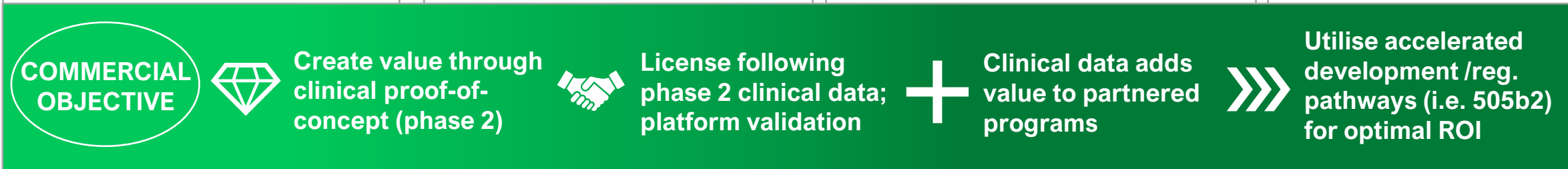
**Camptosar<sup>®</sup>** had peak global sales of **US\$1.1B** despite having multiple US FDA “**Black Box**” warnings.

**Advantages of DEP<sup>®</sup> irinotecan<sup>##</sup>:** Irinotecan is a pro-drug that is converted to the more 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).



Starpharma's deep preclinical pipeline includes DEP<sup>®</sup> candidates including:



- DEP<sup>®</sup> gemcitabine
- DEP<sup>®</sup> radiotherapeutic candidates
- DEP<sup>®</sup> antibody drug conjugate (ADC) candidates
- Other therapeutic areas



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

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

# DEP<sup>®</sup> cabazitaxel: Advantages over Jevtana<sup>®</sup> many commercial parallels with Abraxane<sup>®</sup> (paclitaxel)

|   | <b>Jevtana<sup>®</sup></b><br><b>2020 sales</b><br><b>US\$600M</b>   | <b>DEP<sup>®</sup> cabazitaxel</b><br><b>(Improved nanoparticle formulation)</b>  |
|---|---|--|
| <b>FDA Black box warning</b>                              | 1. Neutropenic Deaths (febrile neutropenia)   | <ul style="list-style-type: none"> <li>• Not observed</li> </ul>   |
|   | 2. Severe hypersensitivity (polysorbate-80 detergent)   | <ul style="list-style-type: none"> <li>• Not observed; detergent-free formulation</li> </ul>   |
| <b>Premedication</b>                                      | <ul style="list-style-type: none"> <li>• Antihistamine (required)</li> <li>• Corticosteroid (required)</li> <li>• H2 antagonist (required)</li> <li>• Antiemetic prophylaxis (recommended)</li> </ul> | <ul style="list-style-type: none"> <li>• Not required; polysorbate-80/detergent-free formulation</li> </ul>  |
| <b>Primary G-CSF prophylaxis (bone marrow protection)</b> | <ul style="list-style-type: none"> <li>• Prophylactic G-CSF recommended for older/high-risk patients (to prevent severe myelosuppression)</li> </ul>  | <ul style="list-style-type: none"> <li>• Not required</li> <li>• Significantly less bone marrow toxicity (myelosuppression)</li> </ul>                               |
| <b>Patent</b>   | <ul style="list-style-type: none"> <li>• EU – expired</li> <li>• US – 2031</li> </ul>   | <ul style="list-style-type: none"> <li>• EU – 2039</li> <li>• US – 2039 (potential for 5-year extension)</li> </ul>  |

## Abraxane<sup>®</sup> Case study



- Abraxane<sup>®</sup> is an improved nanoparticle formulation of Taxol (paclitaxel), which had peak sales US\$1.6B prior to patent expiry
- Abraxane<sup>®</sup> approved in 2005 by the FDA initially for the treatment of breast cancer with further indications added
- Celgene acquired Abraxis<sup>^</sup> in 2010 for ~\$2.9B; Abraxane<sup>®</sup> sales were US\$314M in 2009
- Abraxane<sup>®</sup> sales in 2020 – US\$1.24B (Celgene now part of BMS)
- Abraxane<sup>®</sup> now accounts for ~97% of paclitaxel sales (\$)



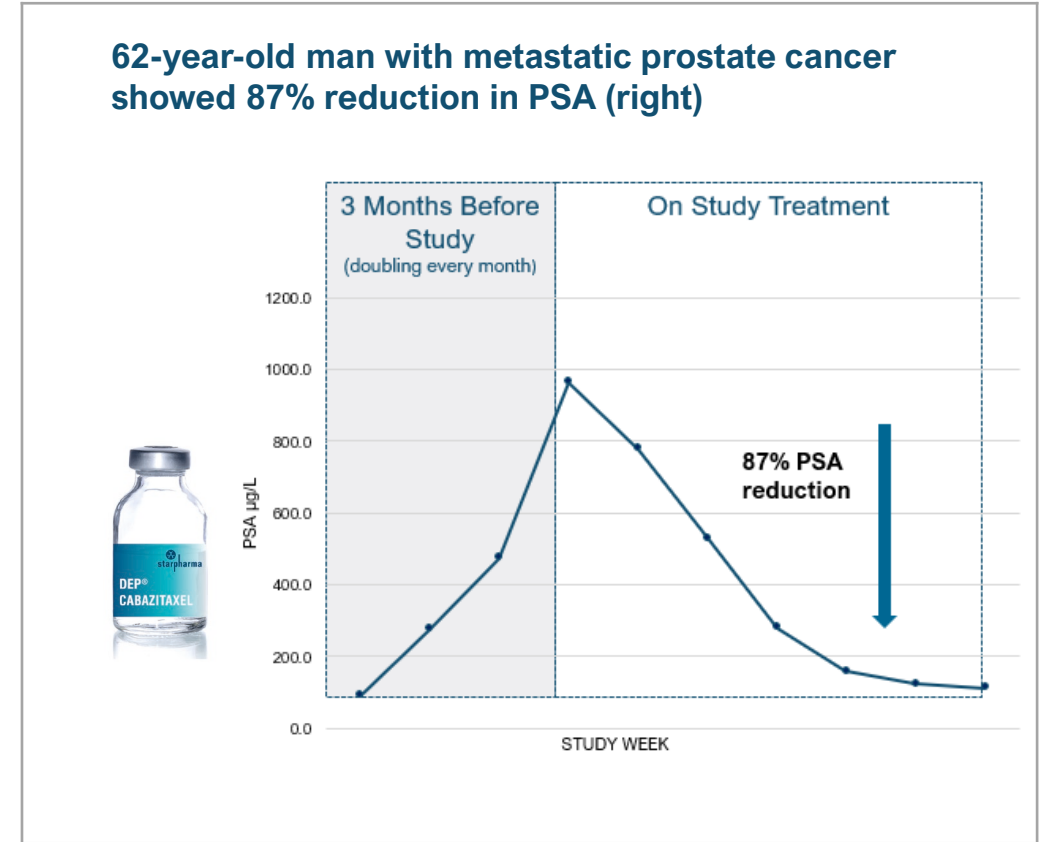
Data ex IMS  
<sup>^</sup>Abraxis Biosciences Inc. was the owner of the product, Abraxane<sup>®</sup>

# DEP<sup>®</sup> cabazitaxel: phase 2 trial ongoing, encouraging efficacy signals

Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana<sup>®</sup>)



|                                  |  |
|----------------------------------|--|
| <b>Trial status:</b>             | Phase 2, ongoing, 70 patients recruited  |
| <b>Efficacy signals seen in:</b> | Prostate, ovarian, gastro-oesophageal, cholangiocarcinoma, head & neck, lung, thymic and other cancers   |
| <b>Interim observations:</b>     | <ul style="list-style-type: none"> <li>• <b>Encouraging efficacy signals</b> have been observed, including radiological responses, significant target tumour shrinkage and substantial tumour biomarker reductions (e.g., Prostate Specific Antigen (PSA)), in cancers including prostate, ovarian, lung, gastro-oesophageal, head and neck and other cancers.</li> <li>• These impressive tumour responses were observed in heavily pre-treated patients and include significant tumour shrinkage including in prostate and ovarian cancer, in patients who have failed multiple other lines of cancer treatment.</li> <li>• Significantly fewer and less severe side effects, particularly bone marrow toxicity, than is usually associated with Jevtana<sup>®</sup>.</li> </ul> |



**Sites:**

# DEP<sup>®</sup> cabazitaxel Phase 2 Trial – Positive Interim Results in Prostate Cancer Cohort Presented at ESMO



## DEP<sup>®</sup> cabazitaxel - Phase 2 prostate cancer cohort

- 25 heavily pre-treated patients with Stage (IV) hormone-refractory prostate cancer
- DEP<sup>®</sup> cabazitaxel patients (56%) had received at least two prior chemotherapy regimens, whereas only 16%<sup>†</sup> of patients in published Jevtana<sup>®</sup> data had received this level of prior treatment
  - Average of 4 prior anti-cancer treatments and >70 months/cycles
  - >95% had received prior taxanes, including docetaxel and cabazitaxel (Jevtana<sup>®</sup>)
- No need for prophylactic steroids or antihistamines as polysorbate 80-free aqueous formulation
- No primary G-CSF<sup>4</sup> prophylaxis required, despite age and low neutrophil counts

## DEP<sup>®</sup> cabazitaxel - Phase 2 interim results in prostate cancer

PARIS 2022 ESMO congress

- 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 PFS of 3.9 months, which is more than 30% longer than published PFS data for standard cabazitaxel (2.9 months<sup>^</sup>)
- 100% of evaluable patients 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 no progression or an improvement
- 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 AEs similar in character to those observed with standard cabazitaxel



1: <https://www.uicc.org/news/globocan-2020-new-global-cancer-data>

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.

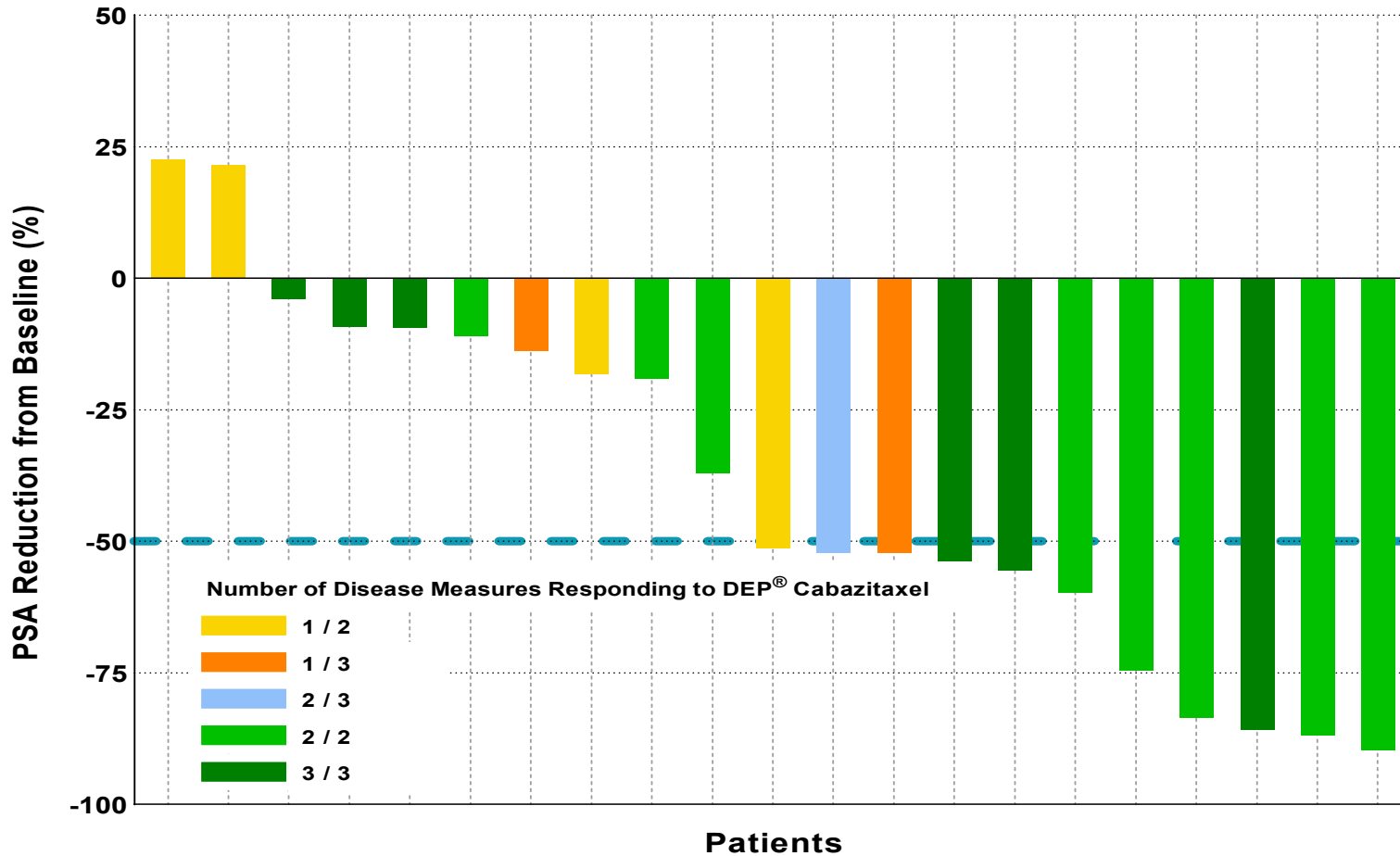
3: Scher, H.I., et al., Trial design and objectives for castration-resistant prostate cancer: updated recommendations from the Prostate Cancer Clinical Trials Working Group 3. *J Clin Oncol*, 2016, 34(12):1402-18.

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

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

# DEP<sup>®</sup> cabazitaxel vs. Jevtana<sup>®</sup> Key interim efficacy findings cont'd

Maximum Percent Reduction in PSA from Baseline



100% of evaluable patients demonstrated

≥1 positive efficacy signal:

- 67% with 3/3 efficacy signals (9 evaluable)
- 69% with 2/2 efficacy signals (13 evaluable)

90% of PSA evaluable patients<sup>^</sup> with a PSA reduction

52.4% patients PSA reduction ≥ 50%

<sup>^</sup> Patients evaluable for PSA response required a baseline PSA of ≥ 10ng/mL, as well as a post-baseline PSA assessment



# DEP<sup>®</sup> cabazitaxel Key interim efficacy and safety findings in Phase 2 Prostate cohort vs. published Jevtana<sup>®</sup> results



## Key Efficacy Measures

| Efficacy Measure              | DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) | Jevtana <sup>®</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                                   |

## Longer Progression Free Survival (median)

| DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ) (N=25) | Jevtana <sup>®</sup> 1 (20 mg/m <sup>2</sup> ) (N=598*) | Jevtana <sup>®</sup> 1 (25 mg/m <sup>2</sup> ) (N=602*) | Jevtana <sup>®</sup> 2 (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>2,3</sup> also included pain progression

\* Intent-to-treat (ITT) populations

## Key Safety Measures

### Significantly fewer Grade 3/4 TRAEs

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

† Safety populations (received at least 1 dose) TRAEs; treatment related adverse events

| Safety Outcomes   | DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> )       | Jevtana <sup>®</sup> † (20 mg/m <sup>2</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%  |
| # Partial Response: ≥30% reduction in measurable target Tumour size | DEP <sup>®</sup> cabazitaxel (20 mg/m <sup>2</sup> ): N=25 | Jevtana <sup>®</sup> † (20 mg/m <sup>2</sup> ): N=580 |

## 80-year-old man with stage IV prostate cancer



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

- *Progressed following 33 cycles/months of 3 different anti-cancer therapies*

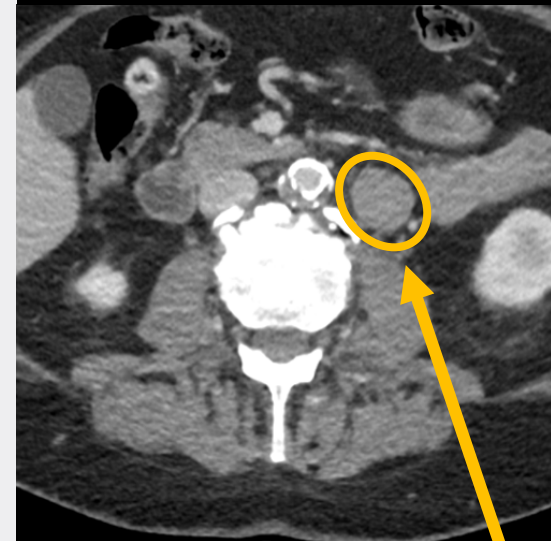


**Following treatment with DEP<sup>®</sup> cabazitaxel (seven cycles), the patient achieved these responses:**

- *87% reduction in PSA (prostate specific antigen)*
- *Partial response (significant tumour shrinkage) lasting more than 24 weeks, including a 62% decrease in size of target lymph node*
- *No G-CSF therapy required*
- *Notable absence of clinically significant Neutropenia, Anaemia, and Thrombocytopenia*

### CT Scans of Lymph Node metastasis

**BASELINE**



**POST-TREATMENT**



**62% reduction in size of cancerous lymph node, returned to normal size**

## Oesophageal cancer

- Oesophageal cancer is the sixth leading cause of cancer-related mortality worldwide.<sup>1</sup>
- The diagnosis typically occurs in patients with locally advanced unresectable or metastatic disease, when palliative chemotherapy is the primary treatment option.
- The 5-year survival rates can be as low as 5%.<sup>2</sup>

1.Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;71(3):209-249. doi:10.3322/caac.21660  
2.Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin.* 2021;71(1):7-33. doi:10.3322/caac.21654

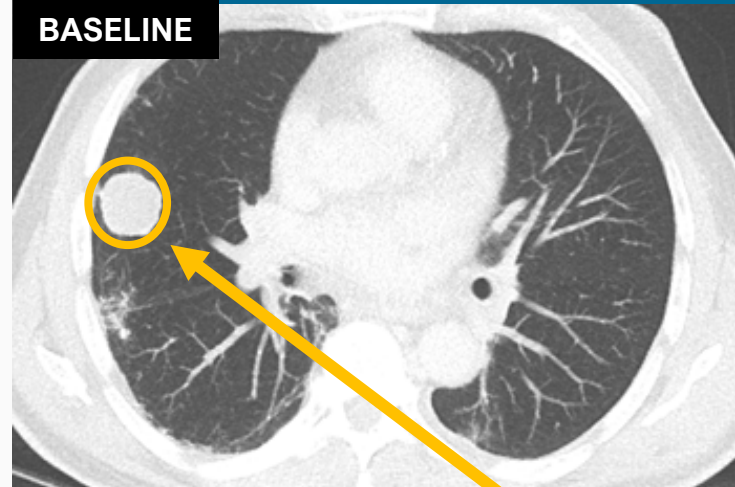
## 73-year-old man with stage IV oesophageal cancer



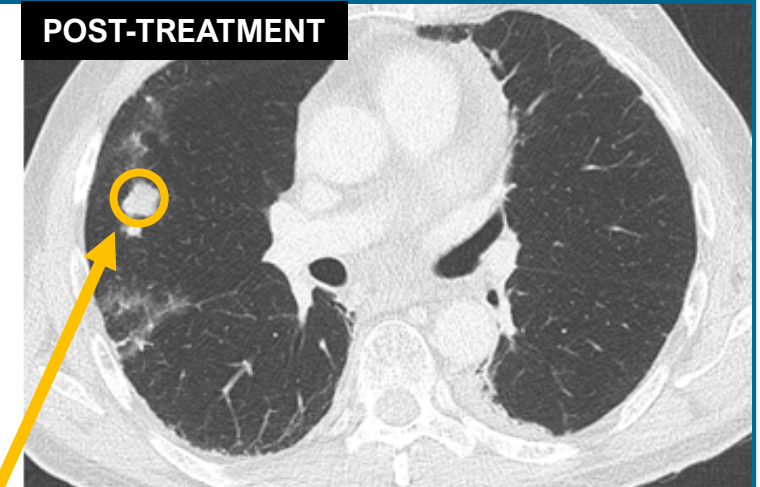
- Cancer progressed following extensive radiation therapy and chemotherapy
- Achieved partial response (significant tumour shrinkage) following 5 cycles of DEP<sup>®</sup> cabazitaxel:
  - 42% overall decrease in tumour burden
  - 45% reduction in size of lung metastasis

### CT scans of cancer metastasis in lung

BASELINE



POST-TREATMENT



**45% reduction in size of lung metastasis**

# DEP<sup>®</sup> irinotecan: phase 2 trial underway, encouraging efficacy signals

Enhanced version of irinotecan (Camptosar<sup>®</sup>) - predominantly used for colorectal cancer



|                                  |   |
|----------------------------------|---|
| <b>Trial status:</b>             | Phase 2, ongoing, 83 patients recruited   |
| <b>Efficacy signals seen in:</b> | Breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer  |
| <b>Interim observations:</b>     | <ul style="list-style-type: none"> <li>Encouraging efficacy signals observed include <b>prolonged stable disease, impressive tumour shrinkage and reductions</b> in tumour marker levels for a number of tumour types, <b>including breast, colorectal, ovarian, pancreatic, lung and oesophageal cancer</b></li> </ul> |
| <b>Combinations:</b>             | <ul style="list-style-type: none"> <li>Combinations, based on investigator interest and preclinical studies, being explored with partners to create value</li> </ul>  |
| <b>Sites:</b>                    |   |

## Results from DEP<sup>®</sup> irinotecan phase 1 trial:

- Encouraging efficacy signals observed in 50% of evaluable<sup>^</sup> patients, all of whom were heavily pretreated
- Efficacy signals observed included prolonged stable disease and substantial tumour shrinkage in tumour types including CRC, pancreatic and breast cancer
- No cases of the severe high-grade diarrhoea with DEP<sup>®</sup> irinotecan – this side effect is experienced by 20-40% of patients with conventional irinotecan, and often requires hospitalisation
- Patients treated with DEP<sup>®</sup> irinotecan generally experienced less severe side effects than typically associated with Camptosar<sup>®</sup>; AEs observed included nausea, vomiting, alopecia and neutropenia



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

DEP<sup>®</sup> irinotecan:

- Provides the ability to solubilise the active metabolite, SN38
- Removes the need for liver metabolism
- Showed improved efficacy and survival benefit in preclinical models
- Patented formulation

## Phase 1/2 Combination arm

DEP<sup>®</sup> irinotecan in combination with 5-FU+ Leucovorin ('FOLFIRI') – a commonly used combination treatment, particularly first-line, in colorectal cancer has commenced

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

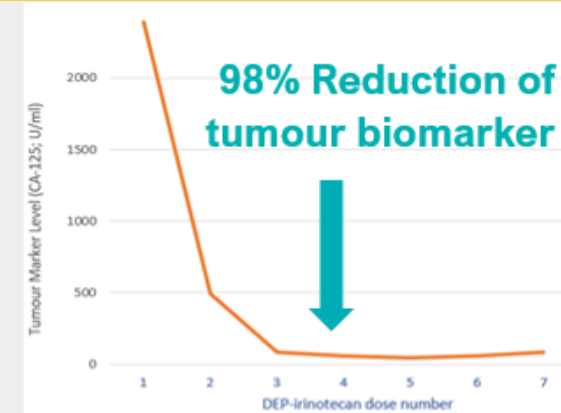
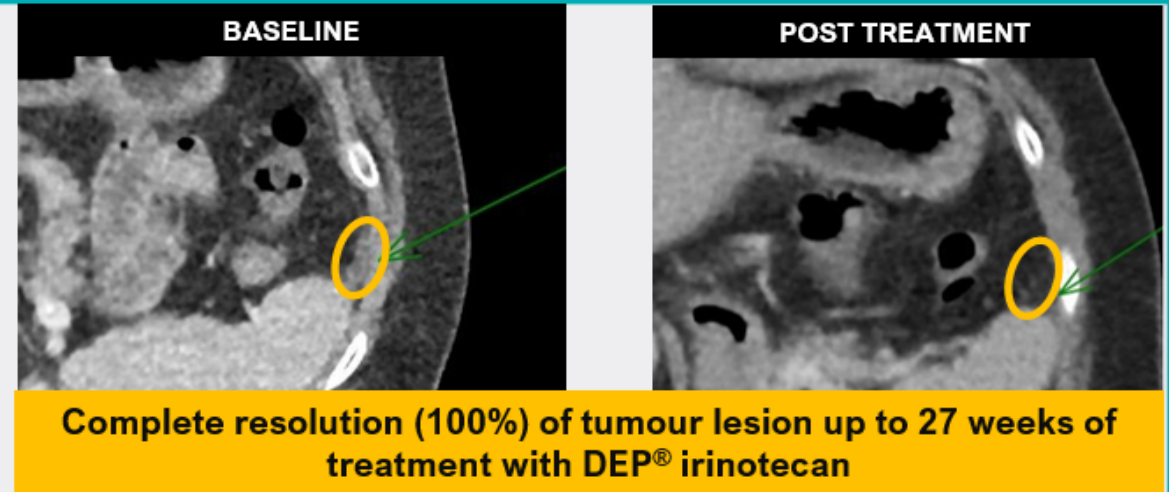
## 55-year-old woman with heavily pre-treated stage IV ovarian cancer



Ovarian cancer has the lowest survival rate of women's cancer\* with a 5-year survival of ~17% for Stage IV

- Patient was **heavily pre-treated with > 60 treatment cycles of 6 different kinds** of anti-cancer therapy
- **Platinum and PARP-resistant ovarian cancer**
- Received 10 cycles of DEP<sup>®</sup> irinotecan
- Response to DEP<sup>®</sup> irinotecan:
  - **Complete resolution of target tumour lesion after 3 cycles** of treatment;
  - Partial Response **maintained for up to 27 weeks**
  - **98% reduction** in tumour biomarkers

\* [https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts\\_2019\\_-FINAL.pdf](https://ovariancancer.net.au/wp-content/uploads/2019/01/Ovarian-Cancer-Facts_2019_-FINAL.pdf)



## Oesophageal cancer

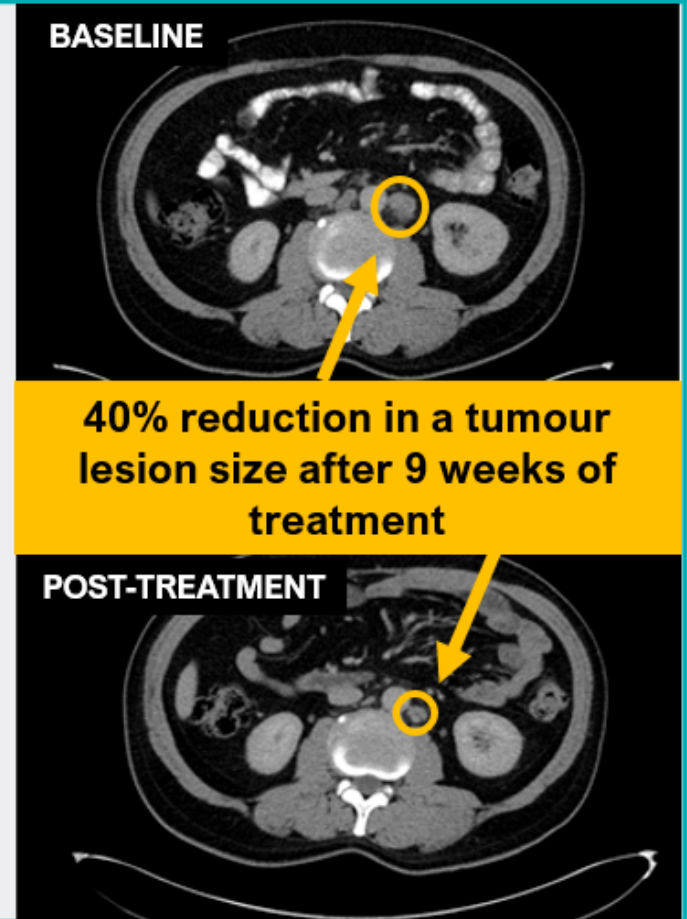
- Oesophageal cancer is the sixth leading cause of cancer-related mortality worldwide.<sup>1</sup>
- The diagnosis typically occurs in patients with locally advanced unresectable or metastatic disease, when palliative chemotherapy is the primary treatment option.
- The 5-year survival rates can be as low as 5%.<sup>2</sup>

1.Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;71(3):209-249. doi:10.3322/caac.21660  
2.Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin.* 2021;71(1):7-33. doi:10.3322/caac.21654

## 60-year-old man with stage IV oesophageal cancer



- Pre-treated with 3 different prior anti-cancer agents
- Received 7 cycles of DEP<sup>®</sup> irinotecan
- Significant tumour lesion reduction (40%) observed after 3 cycles of DEP<sup>®</sup> irinotecan
- Stable disease >18 weeks
- 87% reduction in tumour biomarker



# DEP<sup>®</sup> docetaxel: phase 2 trial ongoing, encouraging efficacy signals

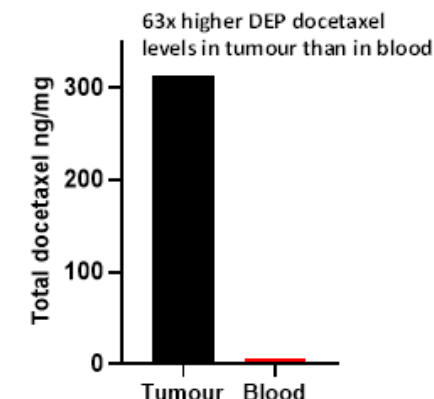
Enhanced version of docetaxel (Taxotere<sup>®</sup>) – widely used for breast, lung & prostate cancer



|                                  |   |
|----------------------------------|---|
| <b>Trial status:</b>             | Phase 2 trial ongoing, 72 patients recruited <sup>^</sup>   |
| <b>Efficacy signals seen in:</b> | Lung, pancreatic, oesophageal, cholangiocarcinoma, gastric cancers (and others)   |
| <b>Combinations:</b>             | + gemcitabine (Gemzar <sup>®</sup> ), targeting pancreatic cancer<br>+ nintedanib (Vargatef <sup>®</sup> ), targeting lung cancer   |
| <b>Interim observations:</b>     | <ul style="list-style-type: none"> <li>• <b>Encouraging efficacy signals</b> observed, including prolonged stable disease and significant tumour shrinkage in patients with pancreatic, oesophageal, cholangiocarcinoma, and gastric cancer. These impressive tumour responses include stable disease for up to 40 weeks and significant tumour shrinkage in a heavily pre-treated late-stage oesophageal cancer patient.</li> <li>• <b>Notable lack of bone marrow toxicity</b> (e.g., neutropenia) and other common side effects incl. hair-loss, mouth ulcers, anaphylaxis and oedema.</li> <li>• Efficacy signals observed in heavily pre-treated patients (treated with up to 40 cycles and 9 different anti-cancer regimens previously).</li> </ul> |
| <b>Sites:</b>                    |   |



The same tumour targeting observed with DEP<sup>®</sup> in animal studies has been replicated in patients treated with DEP<sup>®</sup> docetaxel, **delivering substantially higher levels of drug to the tumour (> 63x) than in blood**



## DEP<sup>®</sup> docetaxel clinical combination studies

### DEP<sup>®</sup> docetaxel + gemcitabine (Gemzar<sup>®</sup>)

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

### DEP<sup>®</sup> docetaxel + nintedanib (Vargatef<sup>®</sup>)

- Encouraging efficacy signals observed
  - Prolonged stable disease & tumour shrinkage in non-small cell lung cancer; heavily pre-treated patients
  - Notable lack of bone marrow toxicity (e.g., neutropenia) and other common side effects, including mouth ulcers, anaphylaxis and oedema

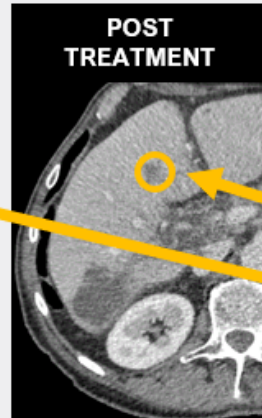
<sup>^</sup>including across monotherapy and in combination

## 66-year-old man: stage IV oesophageal cancer with liver metastases (monotherapy)



Oesophageal cancer is the sixth leading cause of cancer-related mortality worldwide<sup>1</sup>; 5-year survival rates can be as low as 5%<sup>2</sup>

- Patient had progressive disease after radiotherapy and 9 cycles of two different treatment regimens
- Response to DEP<sup>®</sup> docetaxel:
  - Reduction in size of tumour lesions of up to 48%; maintained for >16 weeks



**48% reduction in size of tumour lesion**

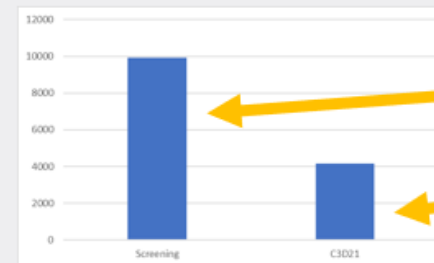
1: Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2021;71(3):209-249. doi:10.3322/caac.21660  
 2: <https://www.cancerresearchuk.org/about-cancer/oesophageal-cancer/survival>

## 74-year-old man with stage IV pancreatic cancer (in combination with gemcitabine)



Pancreatic cancer is the 12<sup>th</sup> most common cancer worldwide.<sup>3</sup> The 5-year survival rate is only 10.7%.<sup>4</sup>

- Progressed following surgery and ~34 cycles of two different treatment regimens, including 6 cycles of gemcitabine
- Received 5 cycles of DEP<sup>®</sup> docetaxel + gemcitabine
- Response to combination therapy:
  - 58% reduction in tumour biomarker CA19-9 after 13 weeks
  - Stable disease for >19 weeks



**58% reduction in tumour biomarker**

3: <https://www.wcrf.org/dietandcancer/pancreatic-cancer-statistics/>  
 4: <https://www.cancer.gov.au/about-us/news/tackling-one-australias-deadliest-cancers>



# Starpharma has a number of partnerships with leading antibody drug conjugate companies















Starpharma's DEP<sup>®</sup> technology represents a valuable partnering platform which has the potential to generate revenue through royalties and milestones

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



## Significant commercial momentum in ADCs



|  |  |   |  |  |  |
|--|--|---|--|--|--|
| <br> | <br> | <br> | <br> | <br> | <br> |
| <p>AstraZeneca &amp; Daiichi Sankyo,<br/><b>US\$6.9B,</b><br/><i>July 2020</i></p>   | <p>Gilead &amp; Immunomedics,<br/><b>US\$21B,</b><br/><i>Sep 2020</i></p>  | <p>Seattle Genetics &amp; Merck,<br/><b>US\$6.8B,</b><br/><i>Sep 2020</i></p>   | <p>Merck &amp; VelosBio,<br/><b>US\$2.75B,</b><br/><i>Nov 2020</i></p>   | <p>Boehringer Ingelheim &amp; NBE Therapeutics,<br/><b>€1.2B,</b><br/><i>Dec 2020</i></p>  | <p>BMS &amp; Eisai,<br/><b>US\$3.1B,</b><br/><i>June 2021</i></p>  |

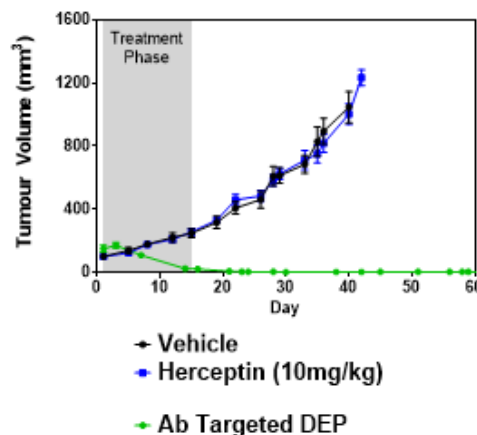
# DEP<sup>®</sup> platform delivers multiple benefits and unique flexibility in Antibody Drug Conjugates (ADCs)

Starpharma's DEP<sup>®</sup> technology provides advantages, including enhanced efficacy, over conventional ADCs

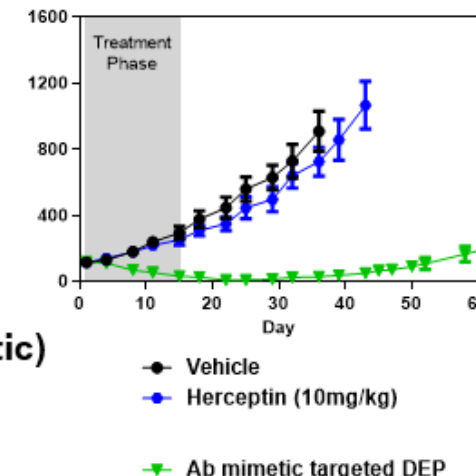
## Starpharma's DEP<sup>®</sup> ADCs – Multiple Benefits

- Allows increased payload per dendrimer conjugate (DAR)
- Flexibility in use of wide range of targeting molecules e.g., full antibodies, antibody fragment, small molecules
- Can use a wide range of payloads and drug linkers to meet desired drug release requirements
- Readily scalable - precisely manufactured
- Can also deliver increased solubility and formulation benefits

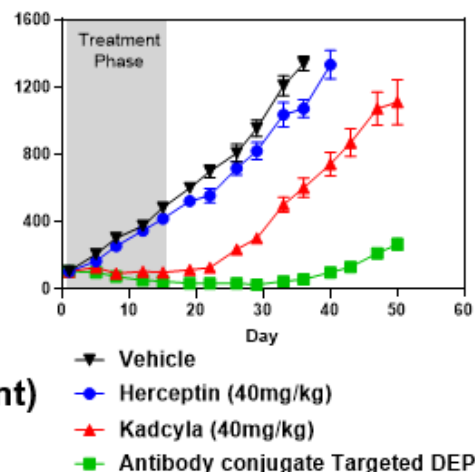
Full antibody



Affibody (antibody mimetic)



Nanobody (antibody fragment)

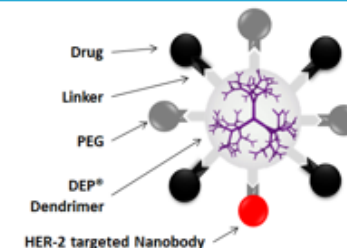


## DEP<sup>®</sup> HER-2 ADC

DEP<sup>®</sup> HER2-ADC demonstrated significant tumour regression and 100% survival, outperforming Herceptin<sup>®</sup> & Kadcylla<sup>®</sup> in a human ovarian cancer model



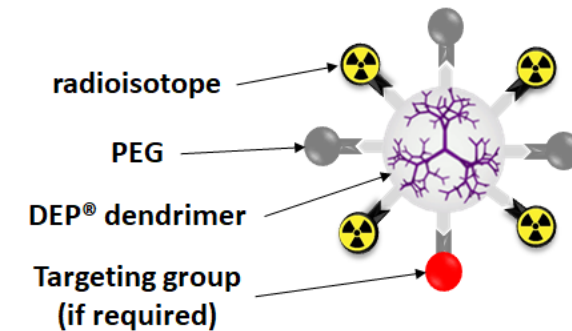
2019 sales of Roche's Kadcylla<sup>®</sup> US\$1.62B and Adcetris >US\$1B















# DEP<sup>®</sup> - a valuable platform with application to multiple radiotheranostics



- Radiotheranostics is a rapidly developing area of cancer treatment and diagnosis with sales estimated to grow to \$12–15 billion by 2030<sup>^</sup>
- Significant corporate activity in recent years
- Starpharma's DEP<sup>®</sup> platform has yielded multiple radiotheranostic DEP<sup>®</sup> products
- Starpharma continues discussions with potential partners regarding access to Starpharma's DEP<sup>®</sup> platform and licensing DEP<sup>®</sup> radiotheranostic/radiopharmaceutical candidates



|  <b>Deals involving radiopharmaceuticals</b>  |   |   |   |   |
|---|---|---|---|---|
|     |   |   |   |   |
| Novartis & Advanced Accelerator Applications (acquisition)<br><b>US\$3.9B,</b><br><i>Oct 2017</i>   | Novartis & Endocyte (acquisition)<br><b>US\$2.1B,</b><br><i>Oct 2018</i>  | Lantheus & Progenics (acquisition)<br><b>US\$641M,</b><br><i>Oct 2019</i>   | Telix & China Grand (licence)<br><b>AU\$40M,</b><br><i>Nov 2020</i>   | Fusion & Ipsen (product acquisition)<br><b>€417.5M,</b><br><i>Jan 2021</i>  |

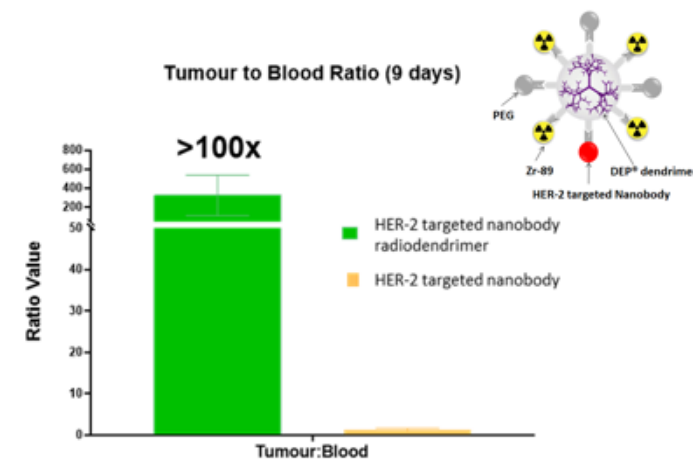
<sup>^</sup>Nuclear medicine world market report & directory, MEDDraysintell, 2016)

# Starpharma has developed multiple novel radiotheranostic (radiodiagnostics and radiotherapeutics) candidates

## DEP® radiodiagnostic

### DEP® HER2-zirconium

- DEP® HER2-zirconium achieved significant tumour accumulation: >100x in tumour vs. blood in a human HER2-positive ovarian cancer model
- DEP® HER2-zirconium accumulation in tumour is significantly greater than nanobody alone products due to dendrimer delivery advantages (EPR effect)
- DEP® HER2-zirconium pharmacokinetics allow for optimal visualization in PET imaging

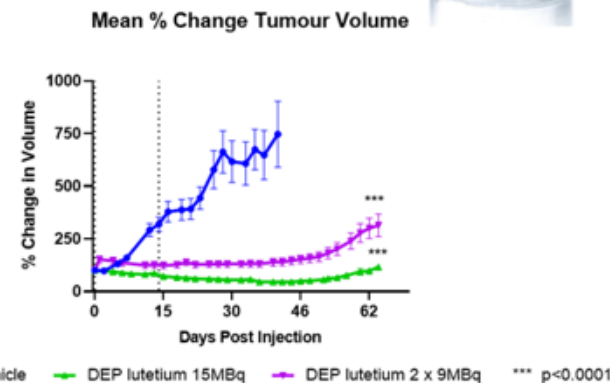
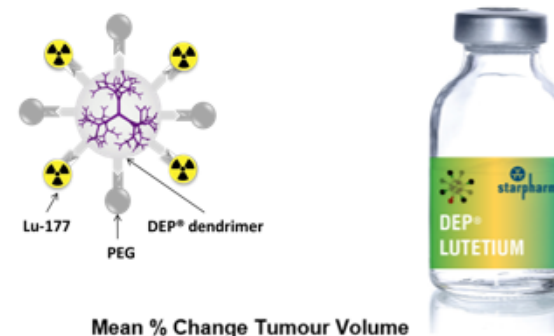


EPR: Enhanced permeation and retention effect

## DEP® radiotherapeutics

### DEP® lutetium

- DEP® lutetium showed significant anticancer activity, with tumour regression
- 100% survival in a human prostate cancer model<sup>1</sup>



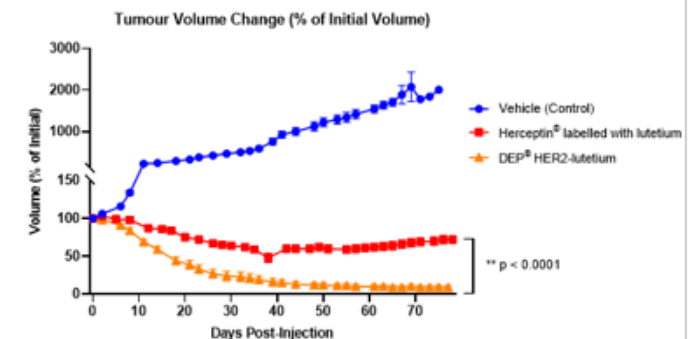
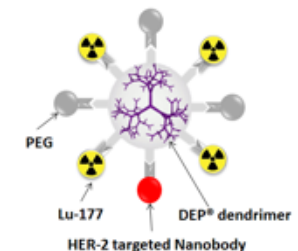
<sup>1</sup> 100% survival to >66 days

human prostate cancer model (DU-145)z

### DEP® HER2-lutetium

DEP® HER2-lutetium:

- Achieved complete tumour regression
- Outperformed Herceptin® labelled with lutetium, in a human HER2-positive breast cancer model
- Was extremely well tolerated



# VIRALEZE™ antiviral nasal spray agent, SPL7013, is virucidal against SARS-CoV-2 variants and influenza A and B

## VIRALEZE™ advantages

- ✓ Broad-spectrum, works against multiple strains of SARS-CoV-2 and multiple respiratory viruses
- ✓ Virucidal, irreversibly and rapidly inactivating >99.9% of coronavirus/SARS-CoV-2 within one minute (Paull, 2021)
- ✓ Irreversible virucidal properties against influenza virus A and B - SPL7013 achieved 95% and 99.7% reduction of virus against A and B, respectively
- ✓ Potent antiviral activity against multiple strains of SARS-CoV-2, including 'Variants of Concern', Omicron, Delta, Alpha, Beta and Gamma
- ✓ Ability to inactivate virus either before or after exposure
- ✓ Well-tolerated; acts locally in the nasal cavity and is not absorbed into the bloodstream
- ✓ Provides a moisturising and protective barrier to help keep nasal tissue hydrated
- ✓ Room temperature storage, easy and convenient for regular use

Paull J.R.A., et al. Virucidal and antiviral activity of astodimer sodium against SARS-CoV-2 in vitro. *Antiviral Res* 2021;191:105089 (<https://doi.org/10.1016/j.antiviral.2021.105089>)

## VIRALEZE™ market & regulatory activity

- ✓ VIRALEZE™ is registered in more than 30 countries worldwide
- ✓ Available in pharmacies, retail outlets and online in a number of markets
- ✓ VIRALEZE™ is partnered with LloydsPharmacy in the UK; ADMENTA Italia Group in Italy; HealthCo/TBL & Nam Thanh Medical in Vietnam; and E&N in countries in the Middle East
- ✓ VIRALEZE™ regulatory submissions (including TGA) made, others in progress and commercial discussions for multiple countries well advanced



LloydsPharmacy

ADMENTA Italia

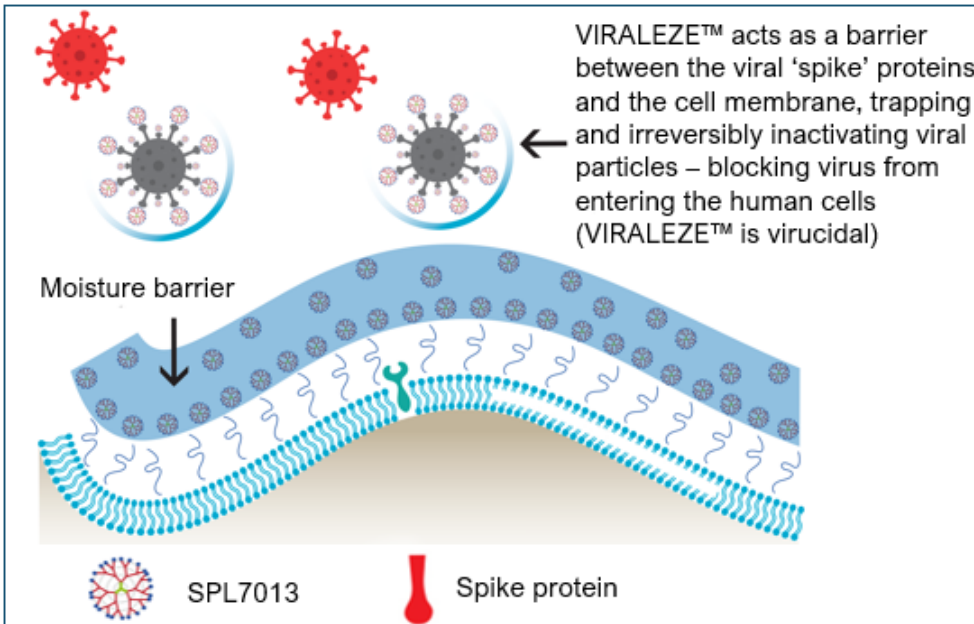
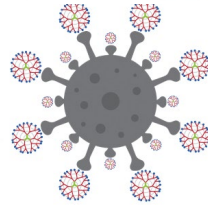
VIRALEZE



TRUONG BAO LAND  
HEALTHY VIBE, HEALTHY LIFE!

# How VIRALEZE™ works and why it maintains activity despite mutations

- SARS-CoV-2 infects human cells by using the characteristic viral surface proteins, or “spikes”, to attach to receptor proteins on the surface of human cells
- Antiviral agent in VIRALEZE™, SPL7013, irreversibly traps viral spike proteins, inactivating virus and preventing infection**



# VIRALEZE™ (SPL7013) has potent and virucidal activity against multiple variants of SARS-CoV-2



- Antiviral testing has confirmed SPL7013 (VIRALEZE™ antiviral agent) has **potent (>99%) virucidal activity against the Omicron, Delta, Alpha, Beta and Gamma** variant strains of SARS-CoV-2 coronavirus in laboratory studies
- The **broad-spectrum antiviral activity of VIRALEZE™** is an important advantage for the product, especially as new variants of SARS-CoV-2, including the latest Omicron Variant of Concern, continue to emerge<sup>^</sup>
- SPL7013 mode of action and activity has **not been adversely impacted by mutations in the spike proteins**

Mutations that make SARS-CoV-2 more infectious (bind more tightly to cells) appear to make the virus *more susceptible* to trapping by SPL7013

| Virus:<br>SPL7013 <sup>†</sup><br>Incubation<br>Time | Percent Reduction of Infectious Virus vs Virus Control <sup>^</sup> |        |      |       |         |        |
|--|---|--------|------|-------|---------|--------|
|  | US  | Alpha  | Beta | Gamma | Delta   | Kappa  |
| 30 seconds   | >99.9%  | >99.9% | >99% | >99%  | >99.99% | >99.9% |

<sup>†</sup> 10 mg/mL SPL7013; <sup>^</sup> virus without exposure to SPL7013

*“It is particularly exciting to see a product with this level of virucidal activity, especially against these Variants of Concern... The latest data are consistent with our previous data showing robust antiviral and virucidal effects of SPL7013 against the US strain of SARS-CoV-2 and suggests a mechanism of action that is not impacted by mutations affecting the virus spike proteins.”*

- Professor Philippe Gally, Scripps Research institute



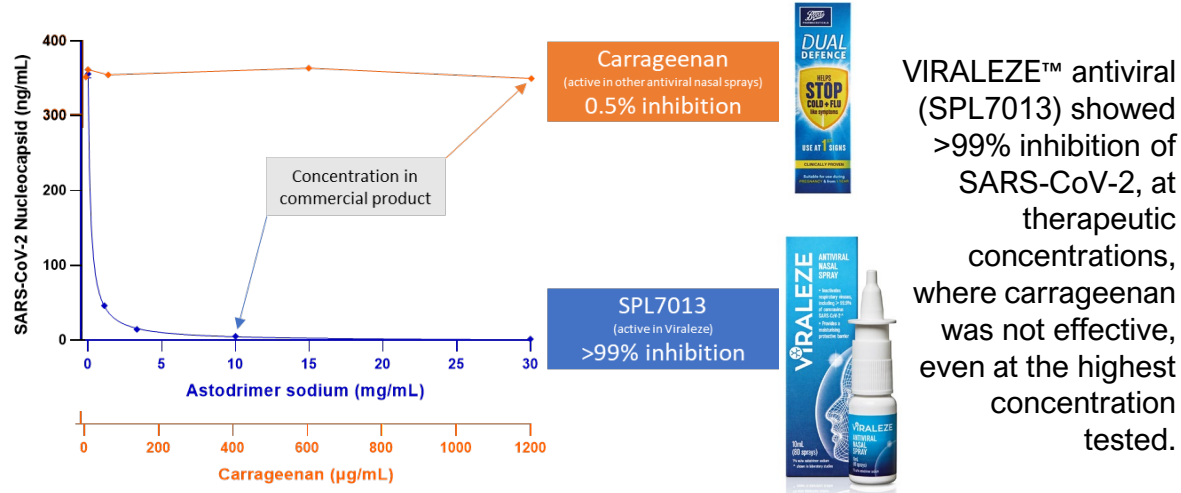
# SPL7013 has potent antiviral activity across a wide range of respiratory viruses

- Extensive research has been conducted at **The Scripps Research Institute** in the US and is published in the prestigious, peer reviewed scientific journal, **Antiviral Research**
- A 1% w/w concentration of SPL7013 (the concentration found in VIRALEZE™) has been shown to **inactivate >99.9% of SARS-CoV-2 within 30 seconds**; maintains its antiviral effects when **applied either before or after exposure to virus**
- SPL7013 has been shown to have potent antiviral effects against **influenza viruses and RSV** as well as other respiratory viruses that have caused pandemics - **SARS, MERS, and Swine Flu (H1N1)**



## The antiviral effect of SPL7013 compares favorably with other antiviral agents:

### Antiviral effects of SPL7013 against SARS-CoV-2 vs. carrageenan



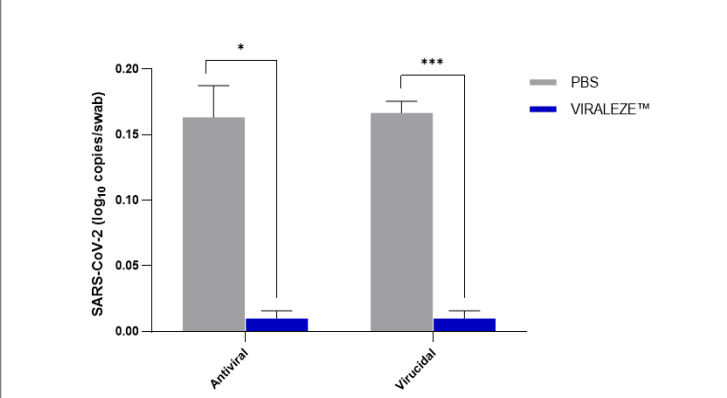
# VIRALEZE™ protects against infection in SARS-CoV-2 challenge model



VIRALEZE™ protected animals and significantly reduced their viral load in a WHO recommended, humanized animal model of SARS-CoV-2 infection published in the peer-reviewed journal, **Viruses**

- **VIRALEZE™ administered nasally reduced viral load by >99.9% in the lungs and trachea** (vs. saline control) of animals challenged with SARS-CoV-2
- **Viral load in the nasal cavity** of animals treated with VIRALEZE™ was also **significantly lower (>90%)** compared with the control animals
- VIRALEZE™ treated animals had no infectious virus detected in brain or liver, in contrast to all control animals
- Pro-inflammatory cytokines (IL-6, IL-1 $\alpha$ , IL-1 $\beta$ , TNF $\alpha$  and TGF $\beta$ ) in serum, lung and trachea were significantly lower in VIRALEZE™ treated animals v. saline

### Viral Load in Nasal Cavity of SARS-CoV-2 infected K18-hACE2 mice treated with PBS or VIRALEZE™



<https://www.mdpi.com/1999-4915/13/8/165>

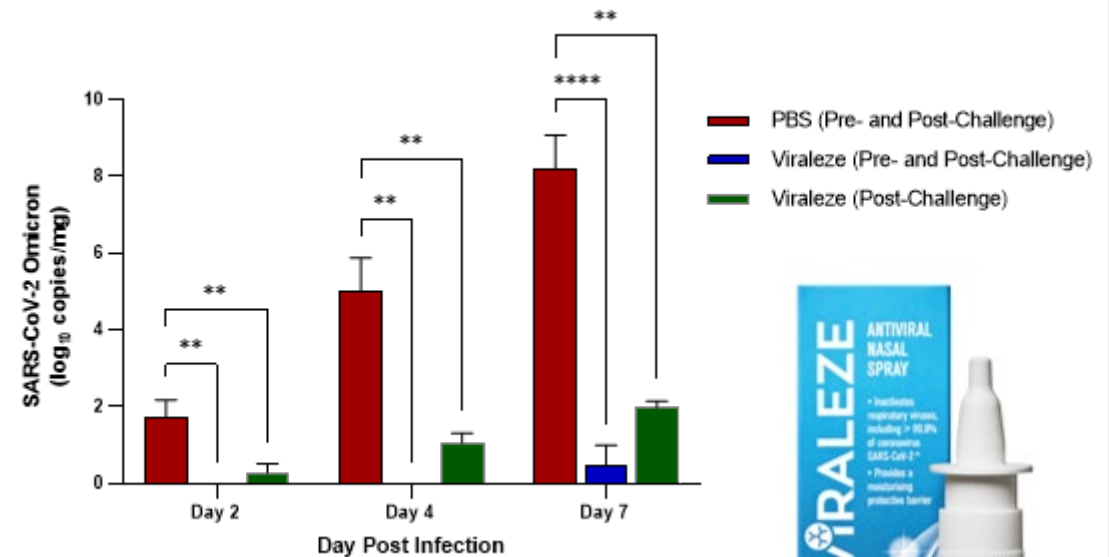
**Figure 2.** The number of SARS-CoV-2 (USA-WA1/2020) viral genome copies (qRT-PCR) on Day 7 per nasal swab from K18-hACE2 mice treated with PBS or VIRALEZE™ nasal spray and infected with SARS-CoV-2 (USA-WA1/2020) (Antiviral) or infected with SARS-CoV-2 (USA-WA1/2020) inoculum pre-incubated with PBS or VIRALEZE™ nasal spray (Virucidal). Columns and error bars represent mean  $\pm$  SEM. \*  $p < 0.05$ , \*\*\*  $p < 0.001$ , paired t-tests.

Source: Testing conducted at The Scripps Research Institute 2: Paull, J.R.A., et al. 2020. Virucidal and antiviral activity of astodimer sodium against SARS-CoV-2 in vitro. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3830085](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3830085)

# VIRALEZE™ demonstrates high levels of protection against Omicron variant of SARS-CoV-2 in *in vivo* viral challenge model

- 100% of animals treated with VIRALEZE™ **before and after** Omicron virus challenge had no detectable virus in lung, trachea or nasal cavity at up to four days after challenge
- VIRALEZE™ was also highly effective **even if used only after** exposure to virus – animals treated with VIRALEZE™ only after dosing with Omicron virus exhibited a >99.999% reduction in viral load in both lung and trachea, compared with saline-treated animals, at day seven
- **This finding is important because it suggests that even when VIRALEZE™ is used after exposure to virus (e.g., if you forget to use the spray before exposure to a high-risk situation), it still has potential to provide significant benefit.**
- All VIRALEZE™-treated animals also showed markedly reduced pro-inflammatory cytokines compared with saline-treated animals, indicating reduced severity of disease

## SARS-CoV-2 Omicron Viral Load in Lung – VIRALEZE™ vs PBS/Saline Control



**Figure 1.** SARS-CoV-2 viral genome copies (RT-qPCR) per mg of lung in K18-hACE2 mice treated intranasally with PBS or VIRALEZE™ nasal spray pre- and post-challenge, and post-challenge only, with SARS-CoV-2 (Omicron hCoV-19/USA/MD-HP20874/2021). Columns and error bars represent mean  $\pm$  SD. Statistical analyses were two-way analyses of variance (ANOVA) with Tukey multiple comparisons for PBS vs Viraleze groups. \*\*  $p < 0.01$ , \*\*\*\*  $p < 0.0001$ . Note: virus was undetectable in the Viraleze Pre- and Post-challenge group at both Day 2 and Day 4 post exposure.





# VIRALEZE™ antiviral nasal spray launched in UK/EU 1HCY21, further registrations achieved, and further launches to follow



## VIRALEZE



VIRALEZE™ is registered in >30 countries worldwide. Registration of VIRALEZE™ is also being sought in multiple regions worldwide

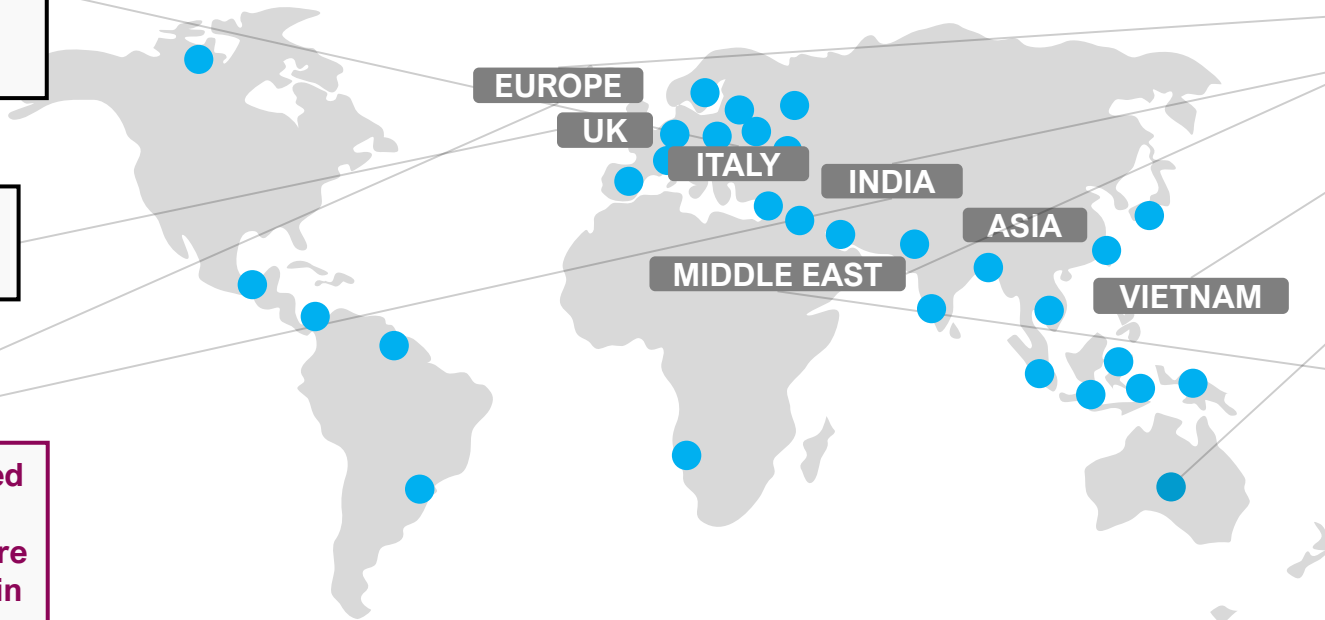
**ADMENTA** Italia

VIRALEZE™ partnered with ADMENTA Italia Group for the sales and distribution of VIRALEZE™ in Italian pharmacies

**LloydsPharmacy**

VIRALEZE™ partnered with LloydsPharmacy in the UK

Starpharma is also in advanced discussions with potential commercial partners elsewhere in Europe, multiple countries in Asia, and other regions



VIRALEZE™ partnered with HealthCo/TBL for supply and distribution in Vietnam



VIRALEZE™ partnered with E&N for sales and distribution in countries in the Middle East

VIRALEZE™ Webstore ships internationally  
[www.Viraleze.co](http://www.Viraleze.co)

# VivaGel® BV - a breakthrough product for the treatment of BV and prevention of recurrent BV

- Bacterial vaginosis or BV is the most common vaginal infection worldwide, affecting 1 in 3 women
- BV is caused by an imbalance of naturally occurring normal bacterial vaginal flora and can lead to a range of medical issues
- BV treatment has typically involved antibiotics (e.g., metronidazole). Antibiotic resistance is a problem and antibiotics have unpleasant side effects and there is demand for alternative approaches. Other current BV therapies do not prevent BV recurring

## VivaGel® BV has a novel mechanism of action

**Astodimer sodium physically prevents bacterial adhesion and biofilm formation**



- 1 Astodimer Gel forms a mucoadhesive and protective barrier
- 2 Astodimer sodium molecule has a negative charge and is held at the epithelial surface by the mucoadhesive gel
- 3 Negatively charged bacteria approach surface, and are naturally repelled by negatively charged astodimer sodium dendrimers, physically preventing bacteria from attaching
- 4 Astodimer sodium can also sequester positively charged metal ions, which help reduce the impact of the repulsive forces between the two negatively charged surfaces, from the vaginal environment.

ASTODIMER GEL

VAGINAL EPITHELIUM



**BREAKTHROUGH THERAPY FOR A SIGNIFICANT UNMET NEED**

-  Rapid relief of odour in 24 hours
-  Targets harmful BV-causing bacteria
-  Restores vaginal flora, normalises pH levels
-  Clinically proven to prevent recurrent BV
-  Clinically proven to treat BV
-  Non-antibiotic and not absorbed into the blood stream

# VivaGel® BV is licensed in >160 countries around the world and approved in >45 countries with multiple other submissions underway



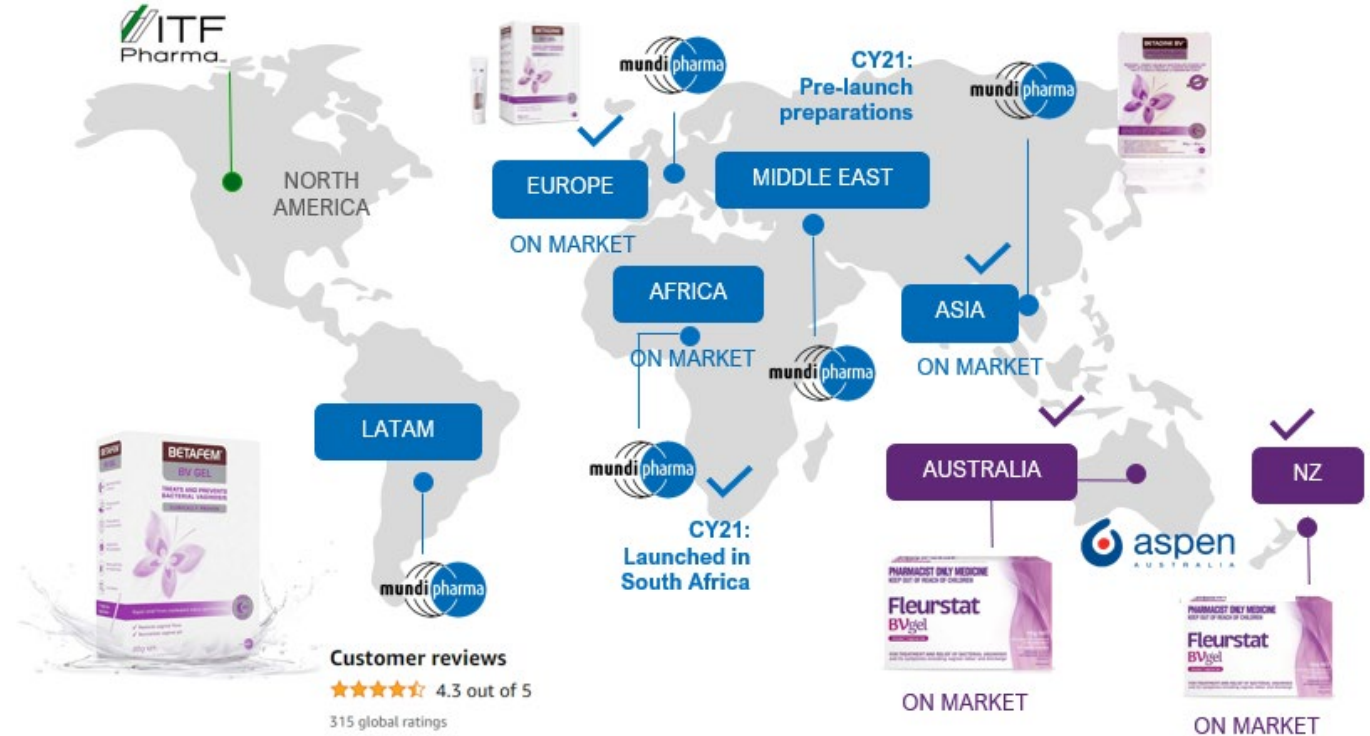
Launched in the UK, Europe, Asia, South Africa, Australia & NZ



Further launches and regulatory submissions progressing in multiple regions



Global market for BV treatment est. to be US\$750M and prevention est. to be US\$1B annually



Customer reviews  
 ★★★★★ 4.3 out of 5  
 315 global ratings



Left: Retail Pharmacy article featuring Fleurstat BVgel, September 2021.

In the US, a formal dispute resolution process is ongoing with the FDA as part of the regulatory process for VivaGel® BV, and COVID-19 has had an impact on timing. VivaGel® BV's Fast Track status & QIDP (qualified infectious disease status) remain on foot based on potential for VivaGel® BV to address a serious infection and significant unmet need in BV

- The VivaGel® condom incorporates SPL7013 antiviral, which has demonstrated activity in HIV, HSV-2, HPV
- Starpharma continues to support its marketing partners to progress registration and commercialisation of the VivaGel® condom
- Starpharma continues to progress regulatory activities in other regions



SPL7013



Okamoto launched an additional VivaGel® condom range in Japan, under the brand name *Pure Marguerite*, targeting youth and female segments of the market.

## DEP<sup>®</sup> Drug Delivery



### Internal DEP<sup>®</sup> Clinical-stage Assets

- Progress and complete Phase 2 trials
- Progress value-adding combination studies
- Licences for DEP<sup>®</sup> assets



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

- Progress existing partnerships with AstraZeneca, Merck & Co., Inc., Chase Sun, and Genentech
- Execute new and/or expand existing DEP<sup>®</sup> partnerships



### AZD0466 Clinical Program

- Clinical progress, including expansion of trial sites and recruitment
- Further milestones



### Preclinical DEP<sup>®</sup> Programs

- Advance DEP<sup>®</sup> radiotheranostics, DEP<sup>®</sup> ADCs and other DEP<sup>®</sup> candidates



## SPL7013 Products



### VIRALEZE<sup>™</sup> Nasal Spray

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



### VivaGel<sup>®</sup> BV

- Commercial rollout in other markets
- Further regulatory approvals and launches; milestones, product sales/royalties
- FDA review process



### VivaGel<sup>®</sup> Condom

- Approvals/launches in additional countries



### SPL7013

- Further development/co-development of other products
- Continued testing against important infectious pathogens

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



## ENVIRONMENT

Appropriate systems in place to comply with relevant Federal, State, and Local environment regulations



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

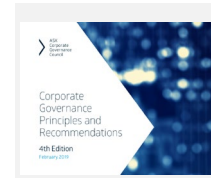
Starpharma has adopted documented procedures and processes to ensure all waste products are disposed of strictly in accordance with relevant



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

## GOVERNANCE

Compliance with



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

**DIRECTOR INDEPENDENCE**



BOARD 83%  
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.

## SOCIAL



>35% 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

Small, diverse workforce represented by 18 countries



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



[Download Report](#)

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



**For Investor Relations Queries Contact:**  
Dr Jackie Fairley, CEO  
+61 3 8532 2704  
[investor.relations@starpharma.com](mailto:investor.relations@starpharma.com)

---

4-6 Southampton Crescent  
Abbotsford Vic 3067  
[www.Starpharma.com](http://www.Starpharma.com)  
ASX:SPL | OTC:SPHRY

