

SPL to present DEP radiotheranostics at Wilsons Conference

Melbourne, Australia; 26 October 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) today announces that it will present at the Wilsons Drug and Device Conference tomorrow, 27 October 2023, at 10:00 AM AEST.

The Wilsons Drug and Device Conference provides a forum for institutional investors to engage with ASX-listed healthcare companies through panel discussions, question-and-answer sessions, and 1 on 1 meetings.

Starpharma's CEO, Dr Jackie Fairley, will provide an overview of the Company, including recent clinical results from its Phase 2 trials of DEP[®] cabazitaxel and DEP[®] irinotecan, as well as recently released data on its novel DEP[®] radiotheranostics (radiodiagnostics and radiotherapeutics) programs.

At the conference, Dr Jackie Fairley will also participate in a panel discussion, **'Expanding the scope for theranostics and radioligand therapies'**, alongside Clarity Pharmaceuticals (ASX: CU6) and Telix Pharmaceuticals (ASX: TLX).

Dr Jackie Fairley, CEO, Starpharma, commented:

"Starpharma is delighted to present at the Wilsons Drug and Device Conference this week, highlighting our DEP[®] platform, including our DEP[®] radiotheranostics pipeline."

"Radiotheranostics is an innovative and rapidly growing area of cancer diagnosis and treatment, and Starpharma is pleased to participate in this panel, sharing recently reported data on Starpharma's targeted DEP[®] radiodiagnostic, DEP[®] HER2-zirconium."

Starpharma's conference presentation is appended.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ("DEP[®]") drug delivery technology, and marketed products, including VIRALEZE™ and VivaGel[®] BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP[®] drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP[®] programs, Starpharma has multiple DEP[®] partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP[®] platform, partnered DEP[®] programs have the potential to generate significant future milestones and royalties.

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 35 countries*, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel[®] BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on [LinkedIn](https://www.linkedin.com/company/starpharma).

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Disclosure

This ASX Announcement was authorised for release by the Chair, 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.



ASX: SPL
OTC: SPHRY

WILSONS

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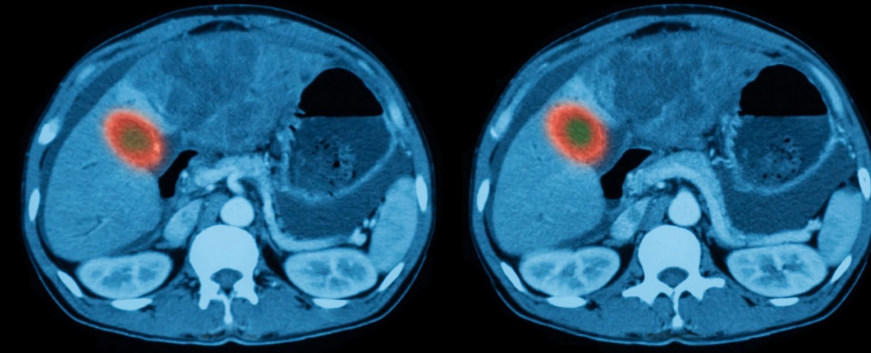
Expanding the scope for theranostics and radioligand therapies

Wilson's Drug and Device Conference

25 - 27 October 2023

Important notice and disclaimer

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Starpharma is an innovative biopharmaceutical company and leader in dendrimer technology



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 are under development: improved, patented versions of widely used cancer medications; and a strong pipeline of preclinical-stage assets, including radiotheranostics.

Multiple products on market.

Multiple global pharma partnerships

DEP® partnerships with three of the world's top 10 pharmaceutical companies: MSD, Genentech and AstraZeneca. Starpharma generates returns via research fees, milestones & royalties. Funded by large pharma partners. DEP® platform offers the ability to partner widely without Starpharma funding programs.

Strong financial position

Cash balance of \$35.2M (30 June 2023), excluding \$6.6 M received from Mundipharma in August 2023; \$7.2 M R&D tax incentive refund received in October 2023.

Strong international institutional share register

Institutions include Allianz, Allan Gray, M&G, Fidelity, and UIL/ICM



Starpharma's portfolio: multiple clinical-stage assets, partnerships and products in market



DEP [®] pipeline				
Products	Target indication	Preclinical	Phase 1	Phase 2
DEP [®] cabazitaxel	Prostate and other cancers	Phase 2 complete & results reported		
DEP [®] irinotecan	Colorectal and other cancers	Phase 2 monotherapy complete		
DEP [®] docetaxel	Pancreatic and other cancers	Phase 2 monotherapy complete		
DEP [®] gemcitabine	Solid cancers	▶		
DEP [®] HER-2 ADC	Solid cancers	▶		
DEP [®] HER-2 radiotherapy	Solid cancers	▶		
DEP [®] HER-2 radiodiagnostic	Diagnostic	▶		
Partnerships	Various			

Commercialised products

VIRALEZE™ Antiviral Nasal Spray



VivaGel® BV



VivaGel® Condom



Partnered DEP[®] programs

Two DEP[®] ADC Research Agreements with MSD (Merck & Co., Inc.)



Two DEP[®] Research Agreements with Genentech



DEP[®] anti-infective research partnership with Chase Sun



Multi-product DEP[®] license with AstraZeneca



Starpharma's DEP[®] platform: highly versatile, enhancing the commercial and therapeutic value of a wide range of drugs

Improved Safety / Reduced side effects

Control release kinetics of drug to reduce C_{max} -related toxicities

Improved Efficacy / Performance

DEP[®] achieves drug targeting, improved PK and controlled release

New IP / Extended Patent Life

DEP[®] creates new intellectual property and extends patent life

Tumour Targeting

DEP[®] delivers 40-70x more drug in tumour cf. the original drug

Improved PK and Half-Life

Tuning of drug release and plasma half-life to improve performance

Improved Solubility

Highly water-soluble, removing the need for toxic excipients

DEP[®]
platform
benefits

Rx

Broad Applicability

Applicable to a wide range of therapeutic areas and treatment modalities (e.g., radiotheranostics, ADCs); DEP[®] is potentially applicable to ~70% of the top 200 pharmaceuticals (by sales)

Multiple DEP[®]
therapeutic areas
across partnered and
internal programs



Chemotherapeutics

Antibody-Drug Conjugates

Radiotheranostics

Non-oncology



Genentech
A Member of the Roche Group









红日药业集团
CHASE SUN

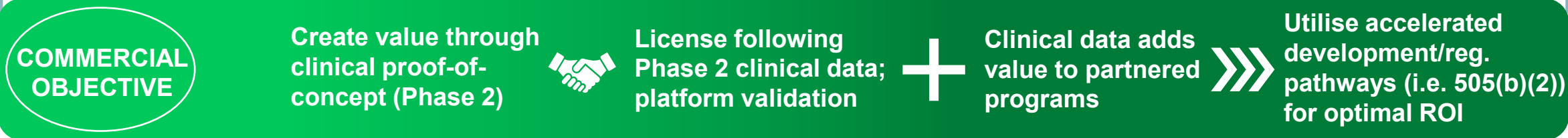


Starpharma's internal DEP[®] oncology portfolio

Multiple clinical-stage assets with high commercial value potential



DEP [®] Program	Original Drug Formulation	Advantages of DEP [®] Product ^{#*}
DEP[®] cabazitaxel (Phase 2)  	Dendrimer version of leading prostate cancer drug cabazitaxel (Jevtana [®]) Cabazitaxel (Jevtana [®]) – 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).
DEP[®] docetaxel (Phase 2)  	Dendrimer version of docetaxel (Taxotere [®]) – widely used for breast, lung & prostate cancer Docetaxel (Taxotere [®]) 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).
DEP[®] irinotecan (Phase 2)  	Dendrimer version of irinotecan (Camptosar [®]) - predominantly used for colorectal cancer Camptosar [®] had peak global sales of US\$1.1B despite having multiple US FDA “Black Box” warnings.	Tumour-targeting; irinotecan is a pro-drug converted to the active metabolite, SN38; DEP [®] 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).



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

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

DEP[®] cabazitaxel Ph2 trial: Positive results in multiple cancers; expanded market potential



Summary of Key Efficacy Results

- Heavily pre-treated, **advanced prostate cancer patients (mCRPC)** treated with DEP[®] cabazitaxel achieved a median progression-free survival (PFS) that was more than 50% longer and a median overall survival (OS) that was 10% longer than published data for Jevtana[®] at the same dose².
- In **advanced, platinum-resistant ovarian cancer patients** who were heavily pre-treated with an average of 4 prior lines of chemotherapy, DEP[®] cabazitaxel achieved a disease control rate (DCR) of 66.7% and an objective response rate (ORR) of 17.6%, which compares favourably to standard-of-care therapies that report ORRs ranging from ~9 to 16%^{4,5,6}.
- In **advanced gastro-oesophageal cancer patients**, DEP[®] cabazitaxel achieved a median progression-free survival and median overall survival that were 53.1% and 28.5% longer, respectively, than similar patient cohorts treated with standard-of-care paclitaxel⁷.

DEP[®] cabazitaxel: excellent efficacy responses in platinum-resistant ovarian cancer and advanced gastro-oesophageal cancers, both significant unmet medical needs.

Cancer Type	Gastro-oesophageal	Platinum-resistant Ovarian
Patients' Prior Anti-Cancer Therapy (Median)	1 line, 6 cycles	4 lines, 25 cycles
Disease Control Rate (DCR)	80.0%	66.7%
Objective Response Rate (ORR)	30.0%	17.6%
Median PFS	4.0 months	3.1 months

All efficacy response data reported are for evaluable patients that received ≥1 dose cycle of DEP[®] cabazitaxel and had a CT scan, or other efficacy assessment (e.g., PSA in prostate cancer) as applicable, to assess response to treatment at ≥~8 weeks after commencement of treatment with DEP[®] cabazitaxel. DCR comprises stable disease (SD), partial responses (PR) and complete responses (CR); ORR comprises PR and CR. PFS, OS and safety data are reported for all patients who received treatment. Results reported in Starpharma's ASX Announcement dated 18 October 2023. * Intend to treat (ITT) population; PFS = composite endpoint from date of randomisation to date of first tumour progression, PSA progression, or death (Jevtana[®] studies also included pain progression)

Longer progression-free survival and overall survival in advanced prostate cancer patients

Key Efficacy Measures	DEP [®] cabazitaxel (20 mg/m ²) (N=25*)	Jevtana ^{®2} (20 mg/m ²) (N=598*)
Median PFS	4.4 months	2.9 months
Median overall survival (OS)	14.7 months	13.4 months
PSA Reduction ≥50%	52.4%	29.5%

DEP[®] cabazitaxel had significantly fewer Grade 3/4 Treatment-Related Adverse Events (TRAEs) vs. Jevtana[®] in advanced prostate cancer patients

Safety Outcomes	DEP [®] cabazitaxel (20 mg/m ²) (N=25*)	Jevtana ^{®2} (20 mg/m ²) (N=580*)
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%

* Lab detected neutropenia or thrombocytopenia, regardless of whether the event was reported as an adverse event; † Safety population (received at least 1 dose)

² Eisenberger, M., et al., PROSELICA. *J Clin Oncol*, 2017, 35(28):3198-206

⁴ Taxol[®] (paclitaxel) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf.

⁵ Mutch, DG, et al., *J Clin Oncol*, 2007;25(19):2811-2818.

⁶ Pujade-Lauraine, E, et al., *J Clin Oncol*, 2014;32(13):1302-1308.

⁷ Stockton, S, et al., *The Oncologist*, 2023;28(9):827-e822.

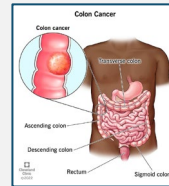
DEP[®] irinotecan Ph2 trial: Positive interim results in colorectal cancer and platinum-resistant/refractory ovarian cancer



Multiple patients have provided positive feedback about the better tolerability experienced with DEP[®] irinotecan compared to conventional irinotecan therapy.

Interim results in advanced colorectal cancer patients treated with DEP[®] irinotecan *monotherapy*

- Patients were heavily pre-treated with an average of 4 prior treatment regimens and 31 cycles; >97% progressed after prior treatment with conventional irinotecan.
- Despite this heavy pre-treatment, DEP[®] irinotecan monotherapy achieved durable efficacy responses for up to 72 weeks with a disease control rate (DCR) of 48% in evaluable patients.
- No severe diarrhoea or cholinergic syndrome.
- Significantly fewer severe treatment-related adverse events.

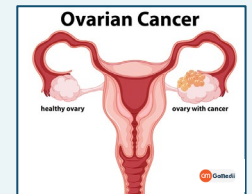


Interim clinical results in heavily pre-treated advanced colorectal cancer patients treated with DEP[®] irinotecan in *combination therapy* with 5-fluorouracil (5-FU) and leucovorin (LV) (ongoing)

- DCR is 100% and ORR of 20% (cf. published data in advanced CRC patients for conventional irinotecan plus 5-FU/LV (FOLFIRI) as second-line therapy. (i.e., in patients less heavily pre-treated than in the current study) reported an ORR of 4%¹).
- Clinicians reported significant clinical benefit in these heavily pre-treated patients, including durable responses for up to 35 weeks (SD and partial response [PR]) with very good tolerability.

Interim results in advanced, platinum-resistant ovarian cancer treated with DEP[®] irinotecan *monotherapy*

- Patients were heavily pre-treated, with an average of 6 prior treatment regimens and 30 cycles and disease that was resistant or refractory to platinum-based therapies (standard-of-care, SoC); patients had exhausted available SoC options.
- DEP[®] irinotecan monotherapy achieved a DCR of 100%, and an ORR of 43% in ovarian cancer patients dosed every 2 weeks (Q2W) (cf. standard-of-care single-agent therapies for platinum-resistant ovarian cancer, including paclitaxel, topotecan, gemcitabine or pegylated liposomal doxorubicin, which report ORRs ranging from ~9 to 16%^{4,5,6}).
- The DCR achieved in all ovarian cancer patients (Q2W and Q3W) is 72%, with several patients continuing to receive treatment and experiencing clinical benefit.
- Tumour shrinkage of up to 60%.
- Response durations of up to 45 weeks.
- Tumour biomarker reductions of up to 98% in more than 75% of patients.
- Clinical benefits reported by investigators in the study included complete resolution of a patient's debilitating tumour-related ascites and pleural effusion.

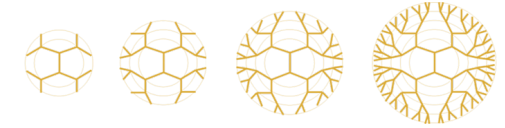


All efficacy response data reported are for evaluable patients. Evaluable patients are those that received ≥1 dose cycle of DEP[®] irinotecan and had a CT scan to assess response to treatment at ≥8 weeks after commencement of treatment with DEP[®] irinotecan. DCR comprises stable disease (SD), partial responses (PR) and complete responses (CR); ORR comprises PR and CR.

¹ Tournigand et al., FOLFIRI Followed by FOLFOX6 or the Reverse Sequence in Advanced Colorectal Cancer: A Randomized GERCOR Study, *Clinical Oncology*, 2023;41(19):3469-3477. <https://doi.org/10.1200/jco.22.02774>
⁴ Taxol® (paclitaxel) Injection label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020262s049lbl.pdf.
⁵ Mutch, DG, et al., *J Clin Oncol*, 2007;25(19):2811-2818.
⁶ Pujade-Lauraine, E, et al., *J Clin Oncol*, 2014;32(13):1302-1308.

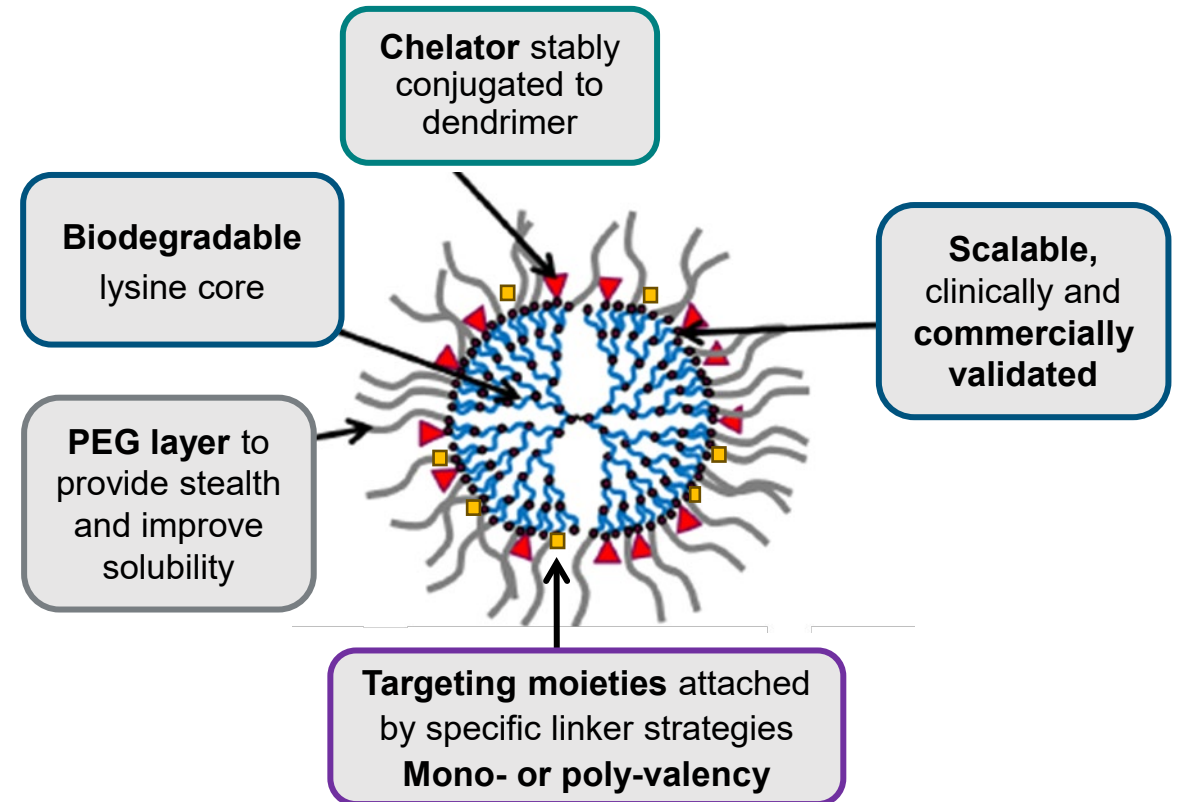
DEP[®] platform advantages in targeted radiotheranostics

- Can utilise a wide range of targeting moieties
- DEP[®] dendrimers deliver high chelator number (4, 8, 16) per conjugate
- Site specific attachment; precisely manufactured and easily scalable
- Drug-linker strategy can be easily tailored to meet drug release requirements
- Flexibility of payload choice – radioisotope, cytotoxic, ultra toxic, immunomodulator



DEP[®] dendrimers are constructed in concentric layers called generations

DEP[®] dendrimer	<ul style="list-style-type: none">• Clinically validated, safe, biodegradable• Easily scalable; precisely manufactured
Chelator / Isotope	<ul style="list-style-type: none">• Flexible – the type and number of chelators can be varied (e.g., DFO, NOTA, DOTA)
Pharmacokinetics	<ul style="list-style-type: none">• Plasma half-life can be tuned• Dendrimer size and charge can be altered to regulate kidney glomerular filtration
PEG	<ul style="list-style-type: none">• Provides stealth• Controls clearance
Tumour Targeting	<ul style="list-style-type: none">• Flexible targeting moiety (antibody, peptide, small molecule)• Poly-valency easily achieved



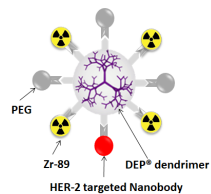
HER2-targeted DEP[®] radiodiagnostic and radiotherapeutic pair

- HER2 is overexpressed in ~20%-30% of breast (HER2^{hi}), gastric & gastro-oesophageal cancers (HER2^{hi}); also expressed at low levels (HER2^{lo}) in other carcinomas including colorectal, endometrial & lung
- HER2⁺ breast cancer treatment market was \$9.7 billion[^] in 2021 and is expected to increase to \$11.2 billion in 2025 (US, Japan, EU5)
- Global HER2⁺ gastric cancer market is currently valued at ~US\$ 1.3 billion in 2023

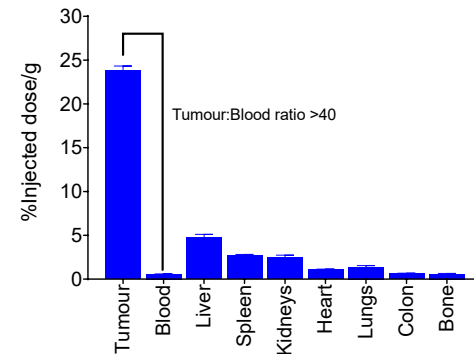
DEP[®] HER2-zirconium (radiodiagnostic)

DEP[®] HER2-zirconium has demonstrated imaging benefits in a HER2⁺ breast cancer model, including:

- More **rapid tumour accumulation and superior PK** than HER2 mAb, trastuzumab (Herceptin[®]), labelled with zirconium;
- Favourable biodistribution profile, with **excellent imaging contrast between tumour and normal tissues**;
- High **tumour-to-organ ratios, delivering excellent specificity** in imaging HER2⁺ tumours; and
- Highly desirable “fast-in”/“fast-out” kinetics, meaning it accumulates rapidly in the tumour and is cleared quickly from the bloodstream.



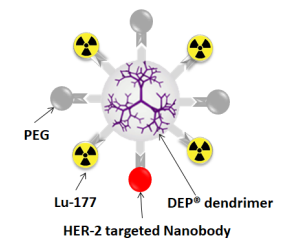
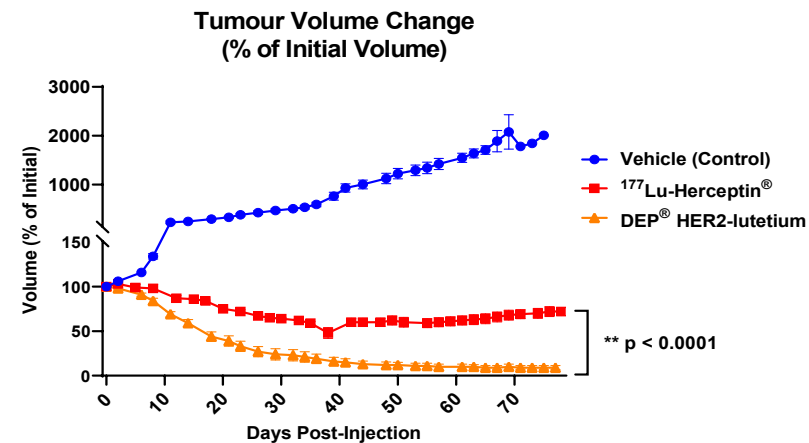
Tumour and normal tissue levels of DEP[®] HER2-zirconium at 120 hours.



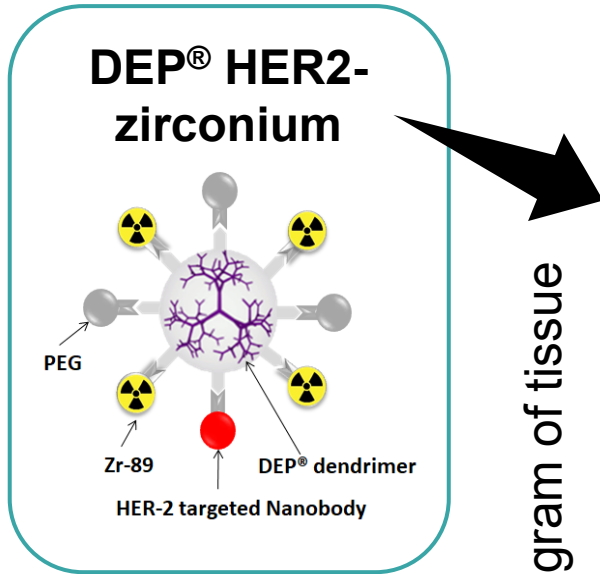
DEP[®] HER2-lutetium (radiotherapeutic)

DEP[®] HER2-lutetium has demonstrated therapeutic benefits in a breast cancer model.

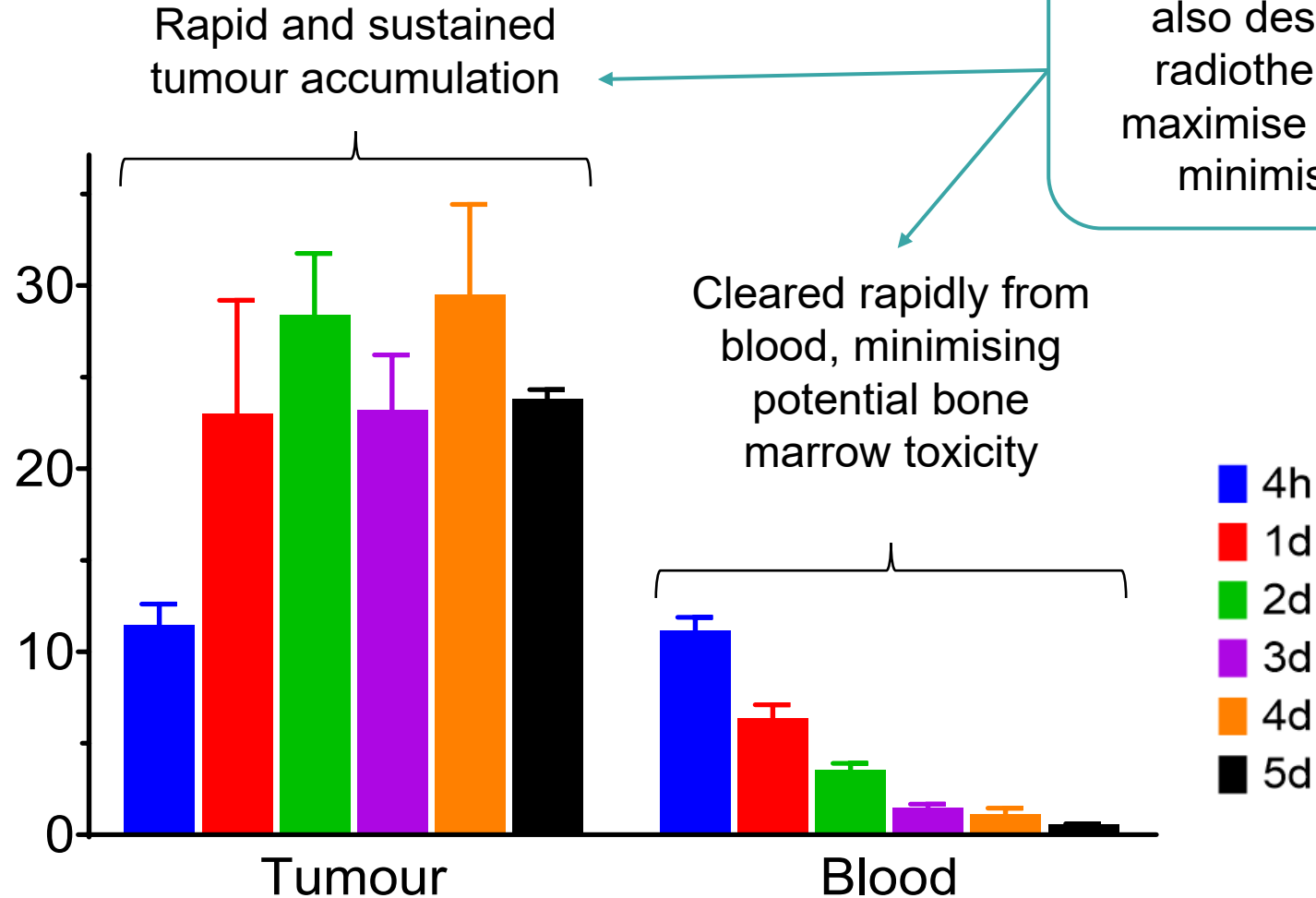
- **Achieved complete tumour regression**; well-tolerated;
- Anti-tumour effect was radiation dose-dependent;
- 100% survival throughout the experiment.



DEP[®] HER2-zirconium (radiodiagnostic): favourable imaging characteristics in a HER2⁺ breast cancer model



% injected dose / gram of tissue



DEP® Drug Delivery



Internal DEP® Clinical-stage Assets

- Complete and report results from Phase 2 DEP® trials, including value-adding combination arms
- Licensing discussions continuing in parallel



Partnered/Funded DEP® Programs

- Progress existing partnerships with MSD, Genentech, AstraZeneca, and Chase Sun
- New and/or expanded DEP® partnerships, increasing optionality of potential revenue streams



Preclinical DEP® Programs

- Advance/partner DEP® radiotheranostics
 - DEP® HER2-zirconium (radiodiagnostic)
 - DEP® HER2-lutetium (radiotherapeutic)
- Advance/partner DEP® ADCs
- Other DEP® candidates

SPL7013 Products



VIRALEZE™ Antiviral Nasal Spray

- Further commercial roll-out, registrations and product launches
- Complete recruitment and report UK post-market study
- Further distribution arrangements with commercial partners
- Continue to generate clinical and antiviral data to support and expand commercialisation



VivaGel® BV

- Execute new marketing and distribution arrangements
- Further regulatory approvals and commercial launches
- FDA review process



VivaGel® Condom

- Approvals/launches in additional countries



SPL7013

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



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