



ASX:SPL OTC:SPHRY

Delivering improved outcomes - for COVID-19 and beyond

Bell Potter Healthcare Conference
25 November 2020

DR JACKIE FAIRLEY
CEO



Important notice and disclaimer



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Key Investment Data

ASX code	SPL
OTCQX code	SPHR
Share price	A\$1.39
Shares on issue	403.4M
Market capitalisation	~A\$550M
Daily average volume (shares)	~1.3M
Cash on hand - as at 30/10/20	>\$70M

Share register	Institutions ~55%
	Retail ~40%
	Staff & other ~5%

Share price & market cap at 20/11/2020

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 (>150 patents)
- Deep portfolio of high-value products on-market and clinical stage assets, with near term potential commercial and clinical milestones
- Products address clear unmet medical need for large markets
- Established supply chain and manufacturing
- Proven record of development & commercialisation including successful partnerships with leading global companies



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



VivaGel® condom – Approved in Japan, Europe, Australia & Canada



VIRALEZE™ COVID-19 preventative nasal spray – expedited product development & regulatory pathway; expected on market H1 2021

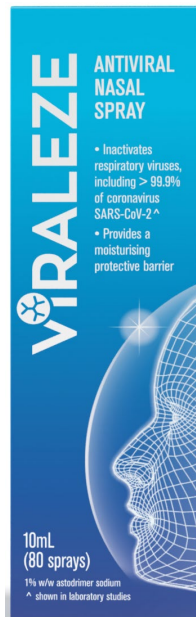


DEP® – a valuable proprietary nanoparticle drug delivery platform creating significant optionality, accelerates path to market and manages investment risk

VIRALEZE™ - preventative COVID nasal spray is virucidal, inactivating >99.9% of SARS-CoV-2 (coronavirus)

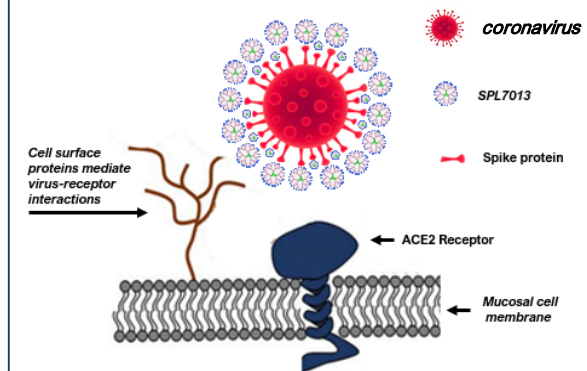
Broad spectrum antiviral activity against *multiple* important respiratory viruses including influenza and RSV

VIRALEZE™ ADVANTAGES



- SPL7013 is virucidal inactivating >99.9% SARS-CoV-2 with potent antiviral activity against SARS-CoV-2 if applied before, or after, exposure to virus)^
- Broad spectrum antiviral activity against *multiple* important respiratory viruses including coronavirus, influenza and Respiratory Syncytial Virus (RSV)
- VIRALEZE™ nasal spray has the potential to prevent infection and transmission of SARS-CoV-2
- The active in VIRALEZE™, SPL7013, has been shown to be well tolerated in multiple clinical studies and in products approved in 40 countries
- SPL7013's high selectivity index** (>2000) in SARS-CoV-2 - compares very favourably with remdesivir (279) and hydroxychloroquine (55)
- VIRALEZE™ nasal spray complements other prevention strategies like vaccines & PPE
- The broad antiviral activity of VIRALEZE™ creates potential in future pandemics
- To be available OTC (no prescription); Convenient room temperature storage

MECHANISM OF ACTION



SPL7013 acts by binding to “spike” proteins” blocking the ability of the virus to attach to ACE2 and enter nasal mucosal cells*

SPL7013 has also demonstrated activity in HIV, HSV, HPV, Adenovirus, HBV, Zika, H1N1 (influenza) and RSV

[^]Testing conducted at The Scripps Research Institute (US) and 360biolabs;

^{**}Selectivity Index is a measure of relative safety or therapeutic index

* Based on data for SARS-CoV-2 and mechanistic data for other viruses

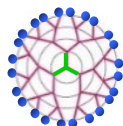
Starpharma is expediting the development of the VIRALEZE™ preventative COVID nasal spray

EXPECTED TO BE
READY FOR
MARKET 1H CY2021

Broad range of potential customers

- Front-line healthcare workers; staff in high-risk environments e.g. airlines, aged care, mining, abattoirs
- Broader population, including for use on airlines, public transport, in restaurants, bars, shopping etc

EXISTING APPROVALS & SUPPLY CHAIN FOR SPL7013 ALLOW FAST-TRACK DEVELOPMENT & LAUNCH



SPL7013 is the active included in other marketed VivaGel® products



- ✓ Reformulation completed
- ✓ Virucidal activity
- ✓ Pilot manufacture completed
- ✓ Labels developed; device components selected; building inventories
- ✓ Regulatory documentation compiled in preparation for submission
- ✓ Commercial preparations advancing well

Starpharma is currently developing and implementing its market entry strategy for VIRALEZE™ with input from Boston Consulting Group



- ➡ Direct to consumer (online)
- ➡ Business to Business
- ➡ Pharmacy (in-store and online)

Expected to be ready for market in 1H CY2021

SPL7013 is the active included in other VivaGel® products approved in 40 countries and is **already scaled up for commercial supply**

Existing stocks of SPL7013 will expedite launch of the VIRALEZE™, and Starpharma is building inventories in preparation.

Regulators have confirmed that **minimal re-development is required**, leading to an expedited program

VIRALEZE™ - preventative nasal spray for coronavirus & other respiratory viruses

VIRALEZE™ market research shows a high level of consumer interest

"Of course I would (be interested in a spray available for prevention), yeah!"

Consumer research, November 2020

"... You can use this and feel better about going to work. Not so anxious all the time."

Consumer research, November 2020

"...shopping malls, public transport; you use it because you're going to at risk areas.... then yes, why not."

Consumer research, November 2020

"It looks really, really useful. It really does. It would reduce the risk of developing Covid-19. Straightaway, that captures you."

Consumer research, November 2020



"So I think wearing gloves and a mask reduces the risk, but not enough... this would reduce it even more just an additional barrier"

Consumer research, November 2020

"Wow. I would take that... I'll take it before I go to work"

Consumer research, November 2020

"Yeah, I would use it definitely. It does make sense"

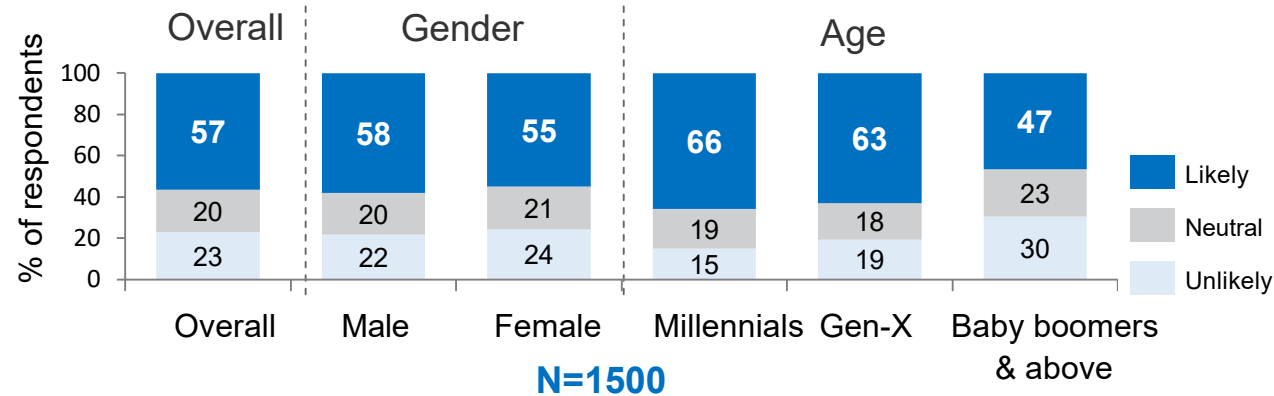
Consumer research, November 2020

"Buying online is not a problem for me. I buy virtually everything online"

Consumer research, November 2020

VIRALEZE™ EU consumer research: High likeability and high purchase intent

What is the likelihood of you buying VIRALEZE™?



- ~60% of respondents liked VIRALEZE™
- Likeability translated to high purchase intent
- >60% likeability and purchase intent for VIRALEZE™ in both millennials and Gen-X



Top 4 features of VIRALEZE™ driving strong purchase intent

1. Activity against multiple viruses (coronavirus, RSV, influenza)
2. Inactivates >99.9% coronavirus
3. Preventative spray
4. Handy & convenient solution

- EU Quantitative Market Research n=1500
- November 2020

COVID-19: Experts agree that preventative measures will be critical even after an effective vaccine is widely adopted



A successful vaccine against COVID-19 would be a great lifesaving advance. But vaccines alone won't be enough to bring the crisis under control.



"...likely that Covid-19 would remain endemic — native and widespread — for years to come".

"I don't think it's going to be one and done people may be re-susceptible to infection from the virus".

The Financial Times, Dr Fauci

THE LANCET

*"It will be important to communicate to policy makers and the general public that **first-generation vaccines are only one tool in the overall public health response to COVID-19 and are unlikely to be the ultimate solution that many expect**"*

November 2020, Malik Peiris, Gabriel M Leung



Significant risk of future pandemics

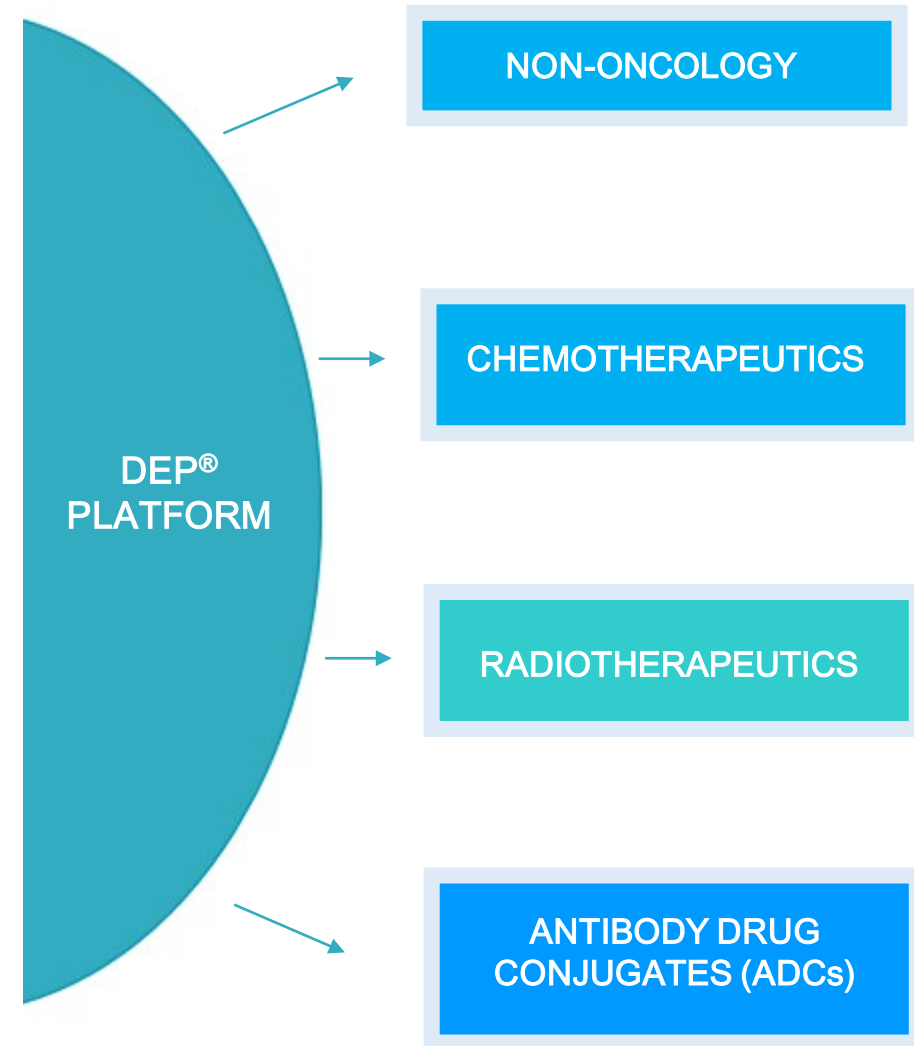
"It is highly likely that after SARS-CoV-2 there will be another pandemic. It might be another coronavirus, an influenza virus, a paramyxovirus, or a completely new disease.

We believe that learning from this experience is crucial so that we can meet a future pandemic threat..."

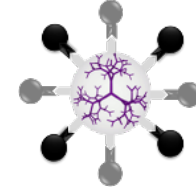
September 2020, Prof Eskild Petersen, MD et al

THE LANCET

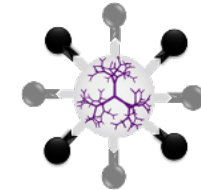
DEP® is a technology platform with multiple commercial opportunities in oncology and beyond



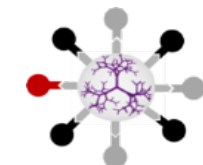
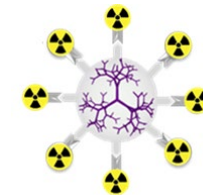
- Antiviral
e.g. DEP® remdesivir
- Anti-infective
- Endocrinology



- Franchise extension
- Generic differentiation
- New Chemical Entities
- Combinations including immuno-oncology



- Radiodiagnostic and radiotherapeutic applications
- Can use variety of radioisotopes



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

DEP[®] remdesivir

Slow release (long-acting) & soluble version of Gilead's remdesivir

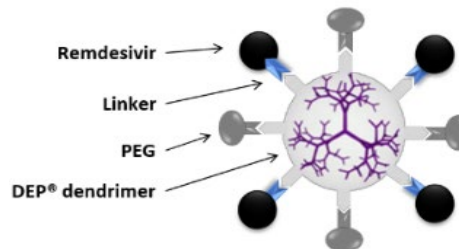
Gilead's antiviral drug, remdesivir, is an antiviral drug recently approved by the FDA for the treatment of COVID-19 patients with severe disease

DEP[®] remdesivir is a water-soluble nanoparticle incorporating remdesivir and PEG, providing a controlled release of remdesivir (longer half-life)

- Current remdesivir formulations are required to be administered IV, with each infusion taking up to 2 hours and requiring daily administration for 5 -10 days
- Remdesivir (Veklury) contains an excipient (a cyclodextrin, SBEDC) and is not recommended in patients with renal impairment¹
- DEP[®] remdesivir expands the potential application of remdesivir, by creating a long-acting version which doesn't require IV infusion;
- DEP[®] remdesivir could be administered ~2-3mls subcutaneously (out-patient setting) compared to large volume IV infusion (in hospital)



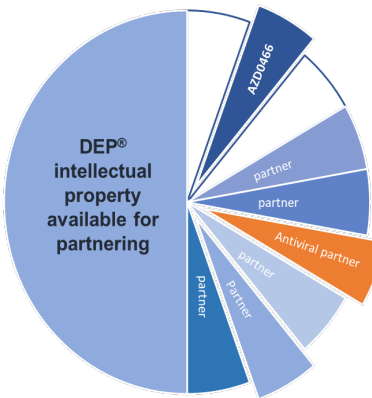
DEP[®] remdesivir has
>100-fold higher
solubility than
remdesivir and needs
no cyclodextrin



DEP[®] partnering creates significant value and optionality

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

DEP[®] platform
optionality allows for
multiple partnerships



Starpharma has DEP[®] programs with large pharma companies incl. AstraZeneca, Chase Sun, and several undisclosed partnerships, including for ADCs



红日药业集团
CHASE SUN



DEP[®] can be used by partners to improve novel drugs

DEP[®] nanoparticles can be used to enhance novel drugs addressing issues such as toxicity or insolubility, which may limit their clinical use

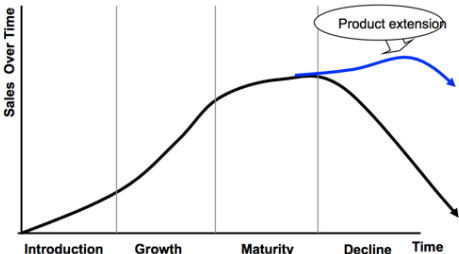


AstraZeneca describes AZD0466 as having the potential to be a “best-in-class” agent with a broad application in both solid and haematological tumours

AstraZeneca's novel DEP[®] nanoparticle AZD0466

- Dual Bcl2/xL inhibitor with DEP[®] significantly improving its therapeutic index
- Phase 1 trial recruiting at MD Anderson and other US sites
- US\$7M in milestones received to date; total AZD0466 deal up to US\$124M + royalties (est. up to A\$2.4B revenue to SPL)
- AZD0466 is the first candidate in Starpharma's multiproduct licence with AZ

DEP[®] can also be used to improve existing products for life-cycle management & create new IP



For example, AstraZeneca's third DEP[®] program (separate to the above multiproduct licence):

- AstraZeneca DEP[®] candidate is a major existing AZ oncology medicine
- US\$5M on option exercise (Development & Option Agreement), industry standard milestones, plus escalating royalties



AstraZeneca

Multiple clinical-stage assets with high commercial value potential

COMMERCIAL OBJECTIVE



Create value through clinical proof-of-concept in one or more cancer types – alone and/or in combination



License following proof-of-concept clinical data; platform validation



Utilise accelerated development / regulatory pathways (i.e. 505b2) for optimal ROI



DEP[®] DOCETAXEL:
Enhanced version of docetaxel (Taxotere[®]) – widely used for breast, lung & prostate cancer

PHASE 2

Docetaxel (Taxotere[®]) is a blockbuster cancer drug with peak global sales >US\$3B despite having multiple US FDA “Black Box” warnings

Advantages of DEP[®] docetaxel^{#}:*

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).



DEP[®] CABAZITAXEL:
Enhanced version of leading prostate cancer drug cabazitaxel (Jevtana[®])

PHASE 2

Cabazitaxel (Jevtana[®]) – global sales of ~US\$500M for 2019 despite having multiple US FDA “Black Box” warnings

Advantages of DEP[®] cabazitaxel^{}:*

Improved toxicity profile; detergent-free formulation; no steroid pre-treatment; tumour-targeting, improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



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

PHASE 2

Camptosar[®] had peak global sales of US\$1.1B despite having multiple US FDA “Black Box” warnings.

Advantages of DEP[®] irinotecan^{}:*

Irinotecan is a pro-drug that is converted to the more active metabolite, SN38; This conversion leads to variability between patients and toxicity. DEP[®] solubilises SN38 and allows direct dosing avoiding the need for liver conversion; improved efficacy; patent filings to 2039 (plus up to an additional ~5 years).



Starpharma’s deep preclinical pipeline includes DEP[®] chemotherapeutic candidates including DEP[®] gemcitabine, DEP[®] radiotherapeutic candidates & DEP[®] antibody drug conjugate (ADC) candidates & further therapeutic candidates

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

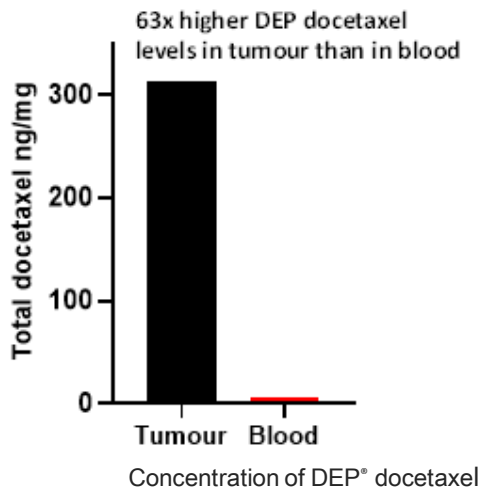
* Multiple preclinical studies have established improved efficacy, survival and safety with DEP[®] with many different drugs



72-year-old woman: extensive intrahepatic cholangiocarcinoma, an often-fatal cancer that affects the bile ducts

Cholangiocarcinoma is a rare but aggressive form of cancer. The 5-year survival rate for intrahepatic cholangiocarcinoma is very low (8%).

- Patient was heavily pre-treated having progressed following 8 cycles of prior anti-cancer therapy
- Patient received 4 cycles of DEP[®] docetaxel and achieved **>28 weeks stable disease**



A tumour biopsy from the patient after dosing with DEP[®] docetaxel showed 63x more DEP[®] docetaxel in the tumour tissue than in blood



66-year-old man: stage IV oesophageal cancer with liver metastases

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

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



48% reduction in size of tumour lesion

DEP[®] cabazitaxel case studies



65-year-old man with late-stage (metastatic) gastro-oesophageal cancer

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

- Heavily pre-treated patient with >15 cycles & three different kinds of anti-cancer treatment and cancer progressed
- Response to DEP[®] cabazitaxel: Patient received 6 cycles of DEP[®] cabazitaxel and achieved a 50% reduction in total tumour size maintained for >27 weeks

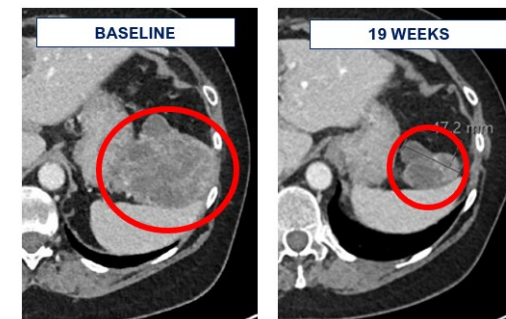


60-year-old woman with advanced (metastatic) ovarian cancer

Ovarian cancer has the lowest survival rate of women's cancer* and is the eighth most commonly occurring cancer in women

- Heavily pre-treated; cancer progressed on 3 other anti-cancer therapies including paclitaxel (another taxane); Previously had 14 cycles of treatment and multiple surgeries
- Response to DEP[®] cabazitaxel: Patient received 6 cycles of DEP[®] cabazitaxel - response seen after 3 cycles of treatment with overall response:
 - 40% reduction in total tumour burden
 - 50% reduction in biomarkers

CT scans



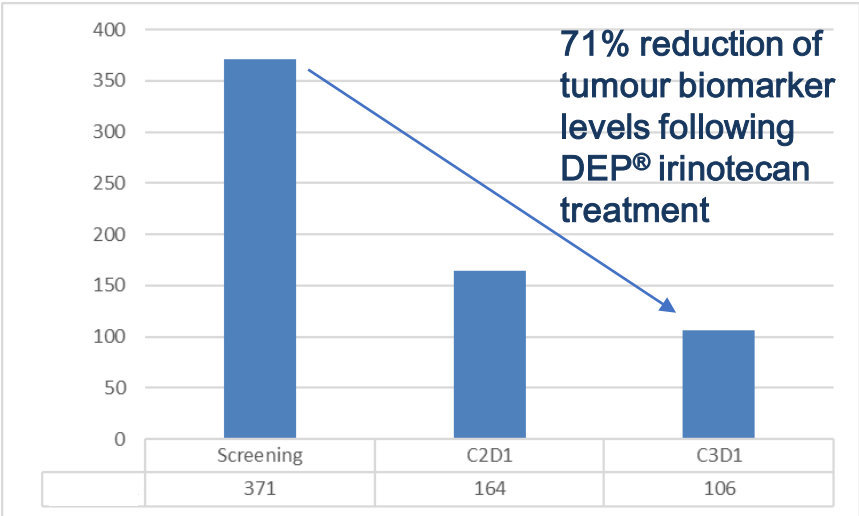
43% reduction in size of abdominal tumour lesion



60-year old male with stage IV oesophageal adenocarcinoma (metastatic)

Oesophageal cancer is the seventh most commonly occurring cancer in men. The estimated 5-year survival rate for stage IV disease is only 10% to 15%.

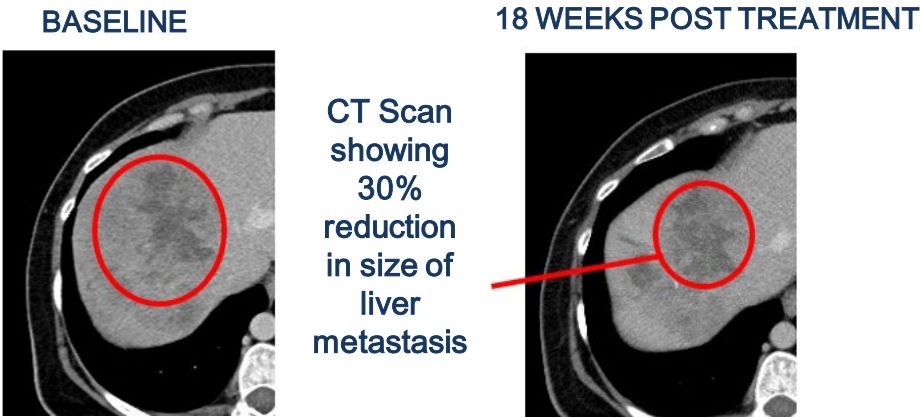
- Previously with 6 cycles with 3 different agents
- Response to DEP[®] irinotecan seen after 3 cycles of treatment; 4 cycles of DEP[®] irinotecan treatment to date
- **Stable disease >9 weeks; 71% reduction in tumour biomarkers (CA 19-9); well tolerated, minimal side effects**



45-year old woman with stage IV breast cancer with extensive liver metastases

Breast cancer is the most common cancer affecting women and is the second leading cause of cancer-related death in Australian women, accounting for 14.9% of all female cancer deaths

- Extensive metastases including in the liver
- **Very heavily pre-treated with >100 cycles of 11 different treatment regimens**
- Response to DEP[®] irinotecan seen after 3 cycles of treatment
- **20 cycles of DEP[®] irinotecan treatment to date; well tolerated**
- **Prolonged stable disease >54 weeks; 21% reduction in target tumours**



DEP[®] Antibody Drug Conjugates (ADC)

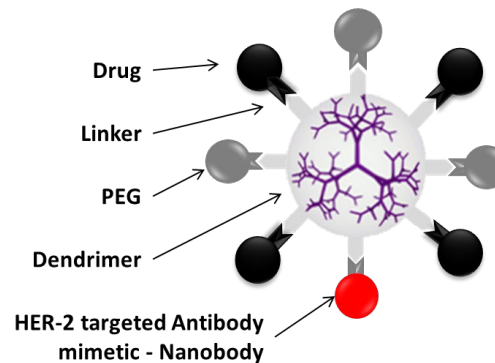
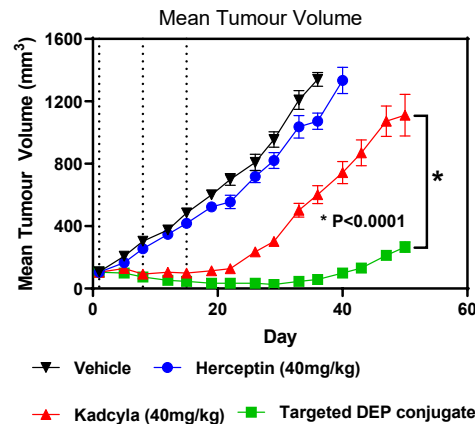
DEP[®] ADCs further build the value of the DEP[®] platform

Starpharma's DEP[®] technology provides enhanced therapeutic benefits to ADCs including greater homogeneity, site specific attachment, and higher drug antibody ratio (DAR), than conventional ADC approaches



DEP[®] demonstrated significant tumour regression and 100% survival, **outperforming Herceptin & Kadcylla** in a human ovarian cancer model,

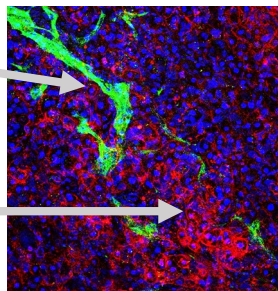
DEP[®] HER-2 ADC:



2019 sales of Roche's Kadcyla[®] US\$1.62B and Adcetris >US\$1B

Green – Blood Vessel

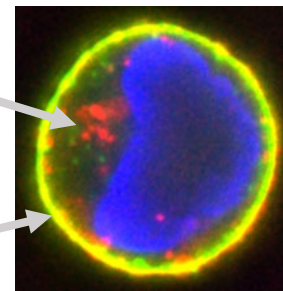
Red dots – Targeted DEP conjugate



Targeted DEP[®] penetrates deep into the tumour (left) and then binds and is internalised into tumour cells (right) for antitumour effect

Dendrimer inside cell in vesicles

Dendrimer on cell surface



Recent deals – growing interest in ADC therapeutics

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

July 2020



Gilead acquired Immunomedics in a transaction valued at approximately **US\$21 billion** – a deal that includes the ADC Trodelvy that was granted accelerated approval by the U.S. FDA

Sep 2020



Seattle Genetics and Merck signed an agreement for a phase 2 ADC - Seattle Genetics will receive **\$600 million** upfront payment, eligible for up to **\$2.6 billion** in milestone payments. Merck will also make a **\$1.0 billion** equity investment.

Sep 2020



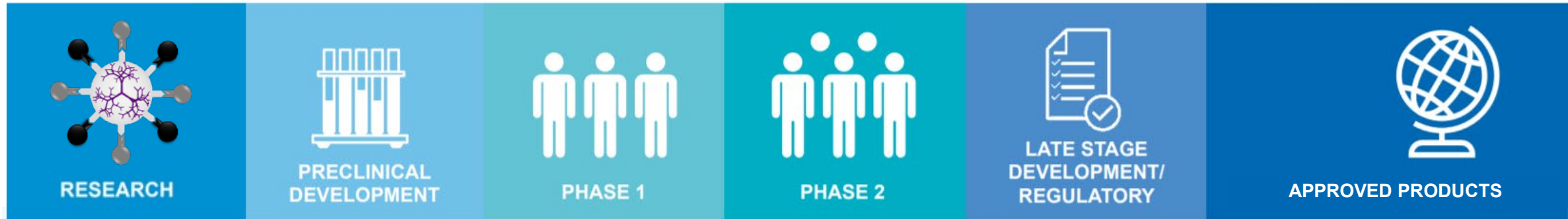
Starpharma's portfolio

High-value assets including VivaGel[®] products on market, SPL7013 antivirals and multiple DEP[®] clinical assets

Extensive & growing pipeline of proprietary assets

Multiple clinical stage assets

Multiple approved products



INTERNAL & PARTNERED

INTERNAL

LICENSED

LICENCE AFTER PROOF OF CONCEPT

FURTHER APPROVALS

FURTHER APPROVALS

FURTHER APPROVALS

FURTHER APPROVALS

AstraZeneca

红白药业集团
CHASE SUN

starpharma



**FOR INVESTOR RELATIONS
ENQUIRIES CONTACT:**

Dr Jackie Fairley, CEO

+61 3 8532 2704

investor.relations@starpharma.com

4-6 Southampton Crescent
Abbotsford Vic 3067

WWW.STARPHARMA.COM

ASX:SPL OTC:SPHRY

