
starpharma
Tony Eglezos
VP Business Development
STARPHARMA
DEP™ Drug Delivery
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Overview: Starpharma Holdings Limited (ASX:SPL)

- ASX 300 company (ASX:SPL, OTCQX:SPHRY) located in Melbourne, Australia
- Market Cap ~ A$250M
- Deep product portfolio of commercial and late stage products based on novel polymer (dendrimer) platform
- Developing first-in-class (new) therapies through a highly experienced in-house commercialisation team
- Established commercial partnerships with some of the world's leading companies - accelerates product development, shares development risk, and transfers development costs
- Strong cash position ($46M 30/6/16)

Starpharma's headquarters and laboratories
Melbourne, Australia

A global leader in dendrimer products

Starpharma's portfolio includes multiple commercial partnerships with leading companies

Starpharma's Dendrimer Platform
~120 granted patents

VivaGel® Portfolio

VivaGel® Condom

Ansell
okamoto
SKY & LAND

VivaGel® BV (bacterial vaginosis)

VivaGel® BV Treatment

aspen AUSTRALIA

VivaGel® BV Prevention of Recurrence

DEP™ Drug Delivery

Internal DEP™ Programs

DEP™ docetaxel

Other DEP™ cabazitaxel, oxaliplatin, targeted etc.

Partnered DEP™ Programs

companies including

AstraZeneca

Agrochemicals

Priostar® Improved Agrochemicals Glyphosate, Gluphosinate ammonium & others

Partnered Priostar® Programs

companies including

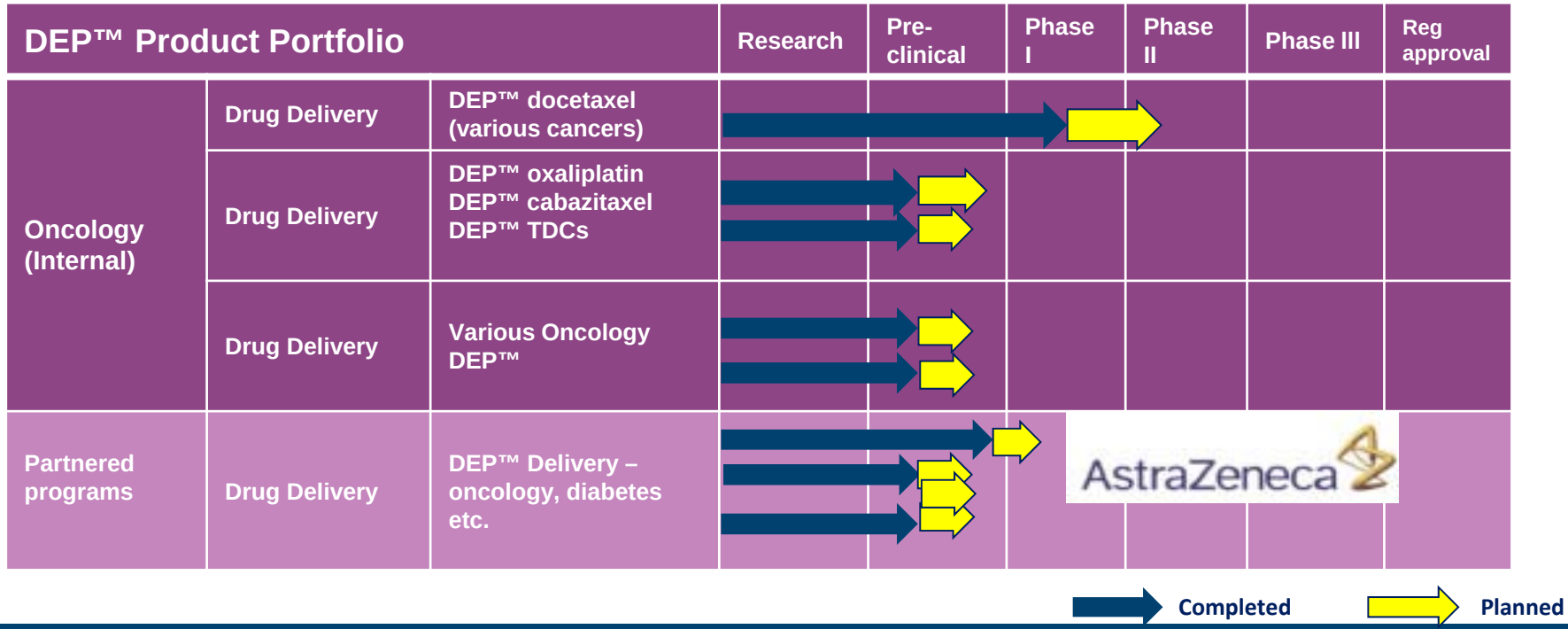
ADAMA

Gowan To Company

ISAGRO

DEP™ Drug Delivery Platform

- DEP™ dendrimer (nanoparticle) delivery technology shows broad commercial applicability
- Internal development and partnered program allows for accelerated development and increased returns
- Applicable to both currently marketed/generic and proprietary pharmaceuticals
- Potential across multiple diseases – cancer, inflammation, diabetes
- High commercial value opportunity, significant optionality via multi-product application



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DEP™ Drug Delivery

Starpharma's DEP™ Platform – Flexible, Scalable, Precise

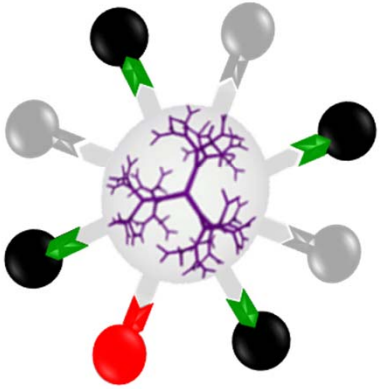
DEP™ dendrimer
- Clinically validated
- Easily scalable; precisely manufactured

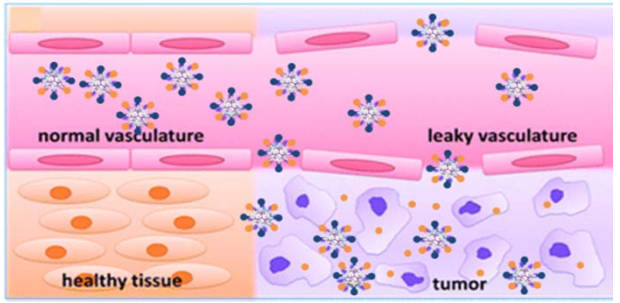
Drug/Payload
- Payload flexibility – type and number

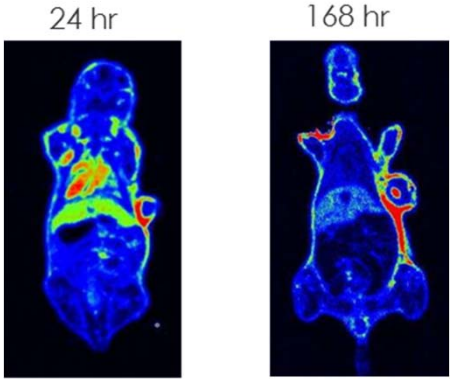
Linkers
- Tuneable to meet payload release requirements

PEG
- Provides stealth
- Controls clearance

Targeting (optional)
- Sites specific attachment
- Targeting moiety flexibility





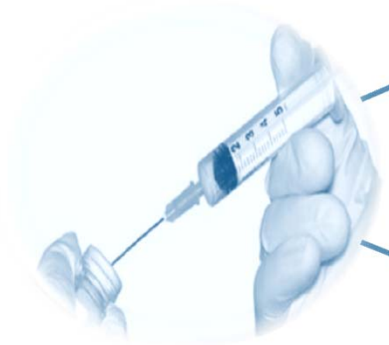


DEP™ docetaxel accumulation in tumour

DEP™ Drug Delivery

Dual Strategy

Provides technical, IP and financial leverage
Increases commercial opportunities
Reduces invested capital
De-risks



Internal Programs

- **Applies DEP™ to generics**
- **Creates new patented agents**
- **Self funded**
- **Return through licensing eg. DEP™ docetaxel**

Partnered Programs

- **Application DEP™ to partner drugs (existing or new)**
- **Creates new patented agents**
- **Funded by partner**
- **Platform with broad optionality**
- **Return through milestones and royalties eg. AstraZeneca**

General Benefits of DEP™ platform

- **Improved efficacy**
- **Reduced toxicity**
- **Improved pharmacokinetics**
- **Improved solubility**

Extensive partner engagement to maximise commercial outcomes

Starpharma's DEP™ Delivery License with AstraZeneca (LON:AZN)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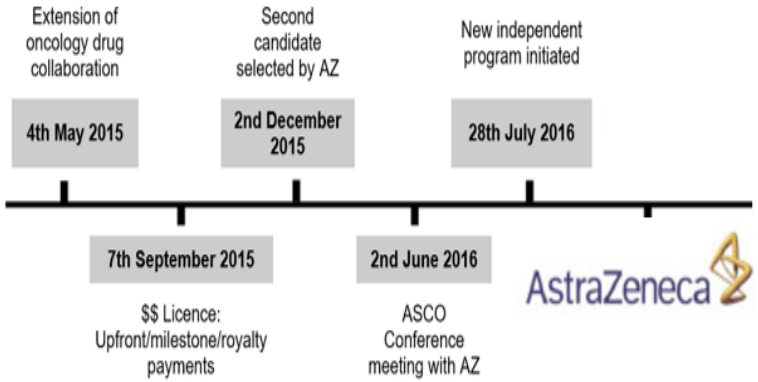
ASX ANNOUNCEMENT

Starpharma signs drug delivery license with AstraZeneca

- AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound on signature, and with potential for follow on compounds directed at a defined family of targets.
- Under the agreement Starpharma will receive a signature payment of US$2 million (A$2.9 million), and is also eligible to receive potential development, launch and sales milestones for the first AstraZeneca DEP® product of USD$124 million (A$177 million).
- Subsequent qualifying products successfully developed and commercialised to specified annual sales levels could yield up to USD$93.3 million (A$133 million) in milestone payments per product.
- In summary, signature and milestone payments could total USD$126 million (A$180 million) for the first AstraZeneca DEP® product and up to USD$93.3 million (A$133 million) for each subsequent qualifying product.
- Any AstraZeneca DEP® products would also attract tiered royalties on net sales.
- AstraZeneca will fund all development and commercialisation costs for AstraZeneca DEP® products under the agreement.

- **AZ multi-product license for use of DEP™ delivery platform for the development and commercialisation of proprietary AZ compounds directed at a defined family of targets**
- **SPL eligible to receive development, launch and sales milestones for the first AZ DEP™ product of up to USD$126m plus royalties & up to USD$93m in milestones for each subsequent qualifying AZ DEP™ products**
- **Tiered royalties on net sales**
- **AZ funds all development and commercialisation costs**
- **DEP™ docetaxel not impacted and agreement field allows for multiple other DEP™ licences**
- **Received US$2M in H1 FY2016**

"SPL estimates that each product successfully commercialised under this agreement could be worth around US$450m to Starpharma and, depending on the range of indications and degree of commercial success in the market, potentially significantly more"



"We already have a long-standing and successful working relationship with Starpharma. This license agreement will enable us to further harness the DEP™ technology and evaluate its potential across novel molecules within our oncology portfolio."

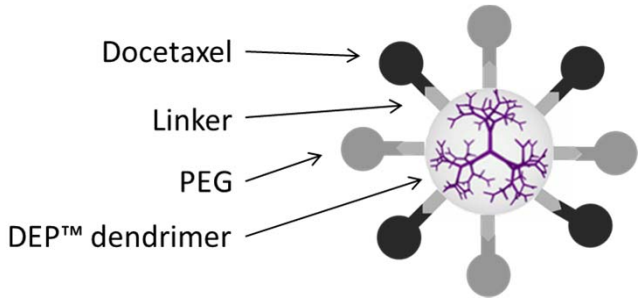
Dr Susan Galbraith,
Head of the Oncology Innovative Medicines Unit at AstraZeneca

Starpharma's DEP™ Docetaxel: Multiple Benefits

- Docetaxel (Taxotere®) is a blockbuster chemotherapeutic
- Docetaxel sales: US$3.1B (2012)
- Docetaxel is used in major cancer types including breast, prostate, lung and ovarian cancer
- Starpharma's DEP™ docetaxel has important advantages compared to Taxotere® #
- DEP™ docetaxel patents filed will offer coverage to 2032 (potential for further filings)
- DEP™ docetaxel Phase 1 trial - no neutropenia, hair-loss and promising efficacy signals

DEP™ docetaxel vs. Taxotere® #

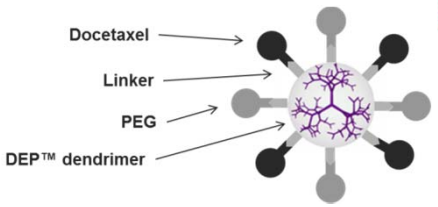
1. Elimination of major dose-limiting side effect (neutropenia)
2. Detergent-free formulation (less toxic)
3. Tumour targeting (40-70x more)
4. Extended duration (half-life)
5. Improved efficacy (breast, ovarian, prostate)



DEP™ docetaxel

DEP™ Docetaxel Preclinical Findings:

Multiple advantages - Better efficacy and less toxicity



$T_{1/2}$ and Targeting

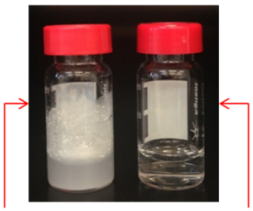
	Plasma Half Life (hours)*
DEP™– Docetaxel	39
Taxotere®	0.5

*n = 4 rats per group

- DEP™ docetaxel formulation extends plasma $t_{1/2}$ by >75-fold vs. Taxotere®

Safety

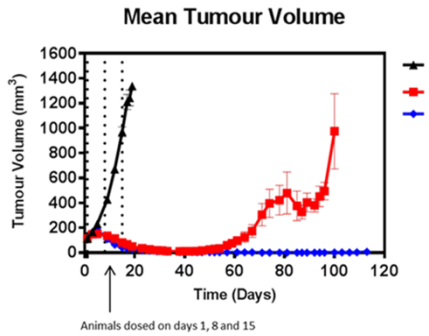
DEP™docetaxel
Polysorbate 80-free
and water soluble



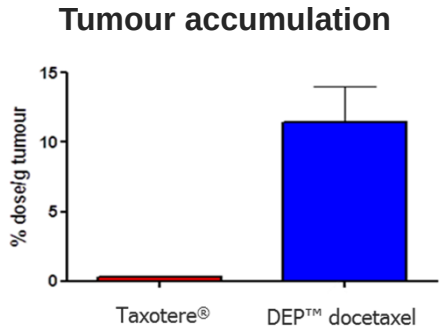
Docetaxel

Starpharma's water soluble DEP™ docetaxel:
- solubility >↑ 20,000x
- polysorbate 80-free

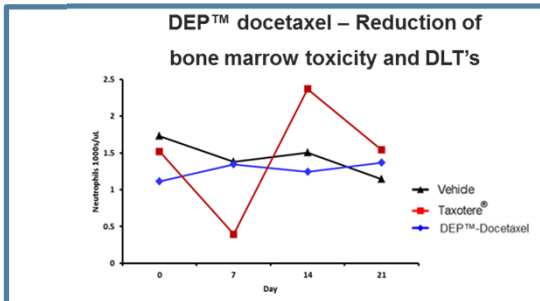
Efficacy



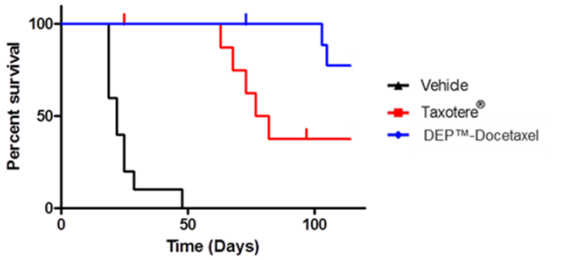
Mouse Xenograft (MDA- MB 231); N= 10/group; p< 0.0001



DEP™ docetaxel shows preferential uptake into mouse MDA-MB-231 xenograft (45-70 fold)



- Neutrophil levels are expressed as the mean absolute count across all animals (n=6)
- drug (equivalent amounts based on docetaxel) was administered to Sprague Dawley rats by iv injection.



Mantel-Cox log-rank test - Taxotere® vs DEP™ docetaxel (P=0.007).

Patents filed will offer coverage to 2032 (potential for further filings)

DEP™ Docetaxel Phase 1 Clinical Trial:

Encouraging anticancer activity and no neutropenia

- Ongoing open label study, approx. 25-30 cancer patients (various solid tumours)
- DEP™ docetaxel administered intravenously *(no steroid pre-treatment or anti-emetics required - unlike Taxotere®)*

Current status :

- Patients dosed up to & above commonly used Taxotere® dose of 75mg/m^2 multiple cycles (up to 6 cycles)
- Final phase of enrolment underway ; >80% recruited
- Large UK site recently opened will enrich final patient cohort with specific tumour types and facilitate transition to Phase 2

Findings:

- ***No neutropenia*** **(docetaxel dose limiting toxicity) or alopecia (hair loss) reported**
  - *Compared to Taxotere® where* ***severe neutropenia is*** *suffered by* ***75% of patients dosed 60mg/m^2^***
- **A significant proportion of DEP™ docetaxel** patients have exhibited **efficacy signals/anticancer activity**
- **Efficacy signals** for **DEP™ docetaxel** seen
  - **at low doses** and **in cancers not typically responsive to docetaxel**
  - in **pancreatic** (SD* > 20 wks), **oesophageal** (SD > 18wks), **prostate, lung, H&N, and brain tumours**

Phase 2:

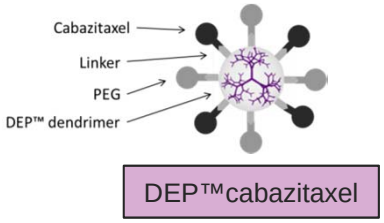
Planning and preparations now well advanced including CRO, trial design, KOLs, sites; clinical trial material manufacture underway

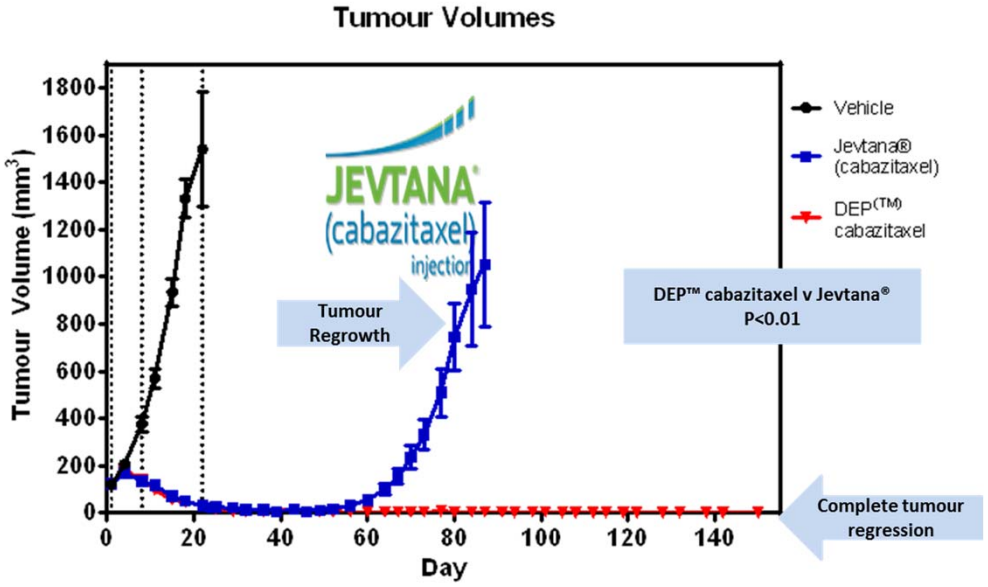
^ Taxotere PI
*stable disease

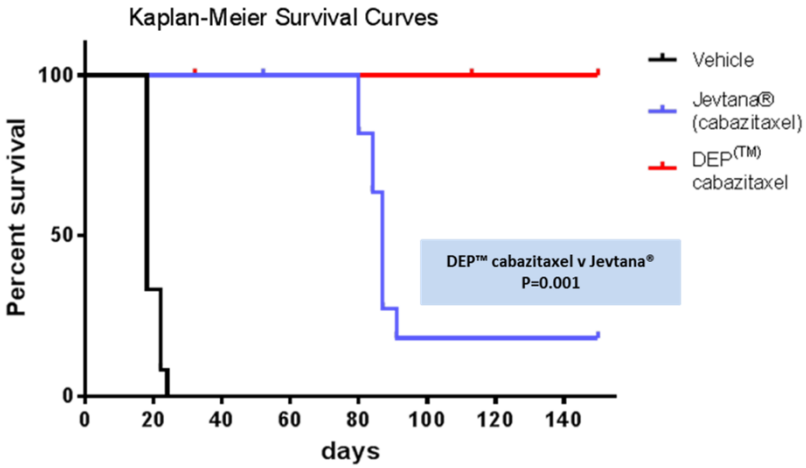
DEP™ cabazitaxel: significantly improved efficacy in breast cancer model*

About Cabazitaxel (Jevtana®)

- 2015 sales: US$427m (+18%)
- Primary indication – Prostate cancer
- In development for various other cancer including breast, bladder, Head and Neck and others
- Dose Limiting Toxicity – neutropenia (FDA "Black box" warning)
- FDA "Black box" warning due to anaphylaxis (Polysorbate 80 detergent)



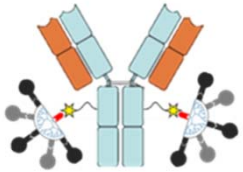




- *MDA-MB-231 (human breast tumour) xenograft model in Balb/c nude mice*

Targeted DEP™ Conjugates

A flexible approach to drug conjugate design and development



Diagrammatic representation of Herceptin targeted dendrimer conjugates

Starpharma's Ab TDC's provide;

- **Greater** homogeneity
- **Site specific** attachment of drug conjugate
- High **affinity**
- The delivery of **significantly higher payload** levels than conventional ADC's

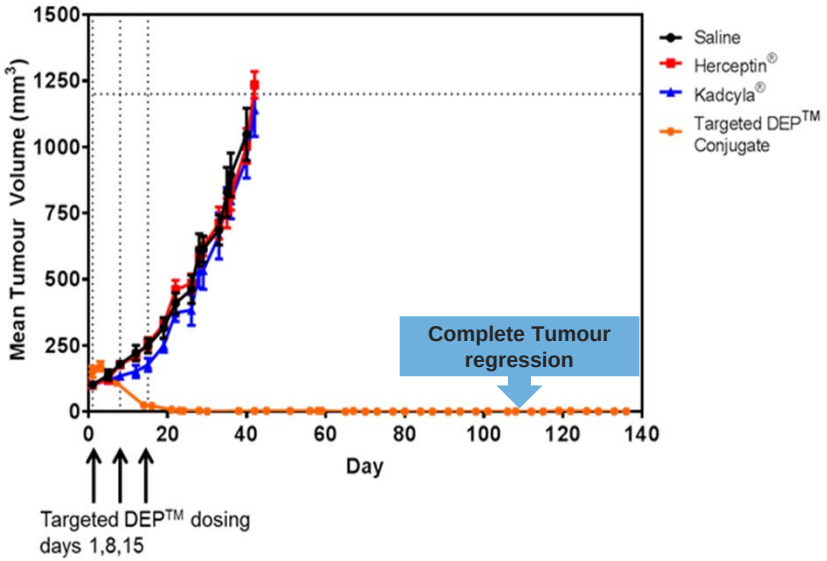
Pilot study to evaluate the efficacy of HER-2 TDC's against ovarian cancer xenografts

Method:

- **SKOV-3 tumour model in NOD SCID mice**
- **s.c. implantation**
- **Allow tumor to grow to >100mm^3**
- **Treatment groups**
  - Vehicle*,
  - Ab Targeted DEP™ drug conjugates
  - Kadcyla [10mg/kg*]
  - Herceptin [30mg/kg bi-weekly for 3 weeks]
- *** Weekly (days 1, 8 and 15) via iv route for 3 weeks at 0.1ml/10g body weight**
- **6 animals/group**
- **Measurement of tumour growth 2-3 times weekly**

Targeted DEP™ Conjugates

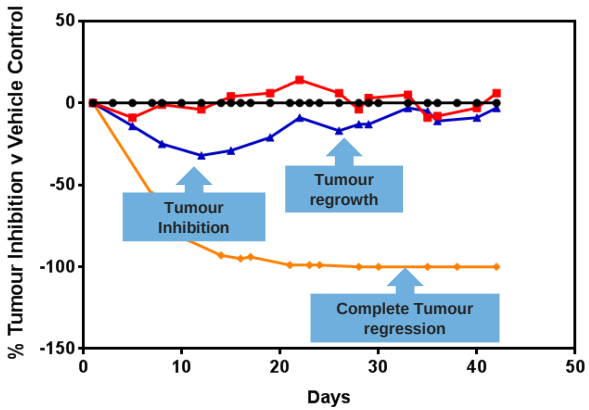
A flexible approach to drug conjugate design and development

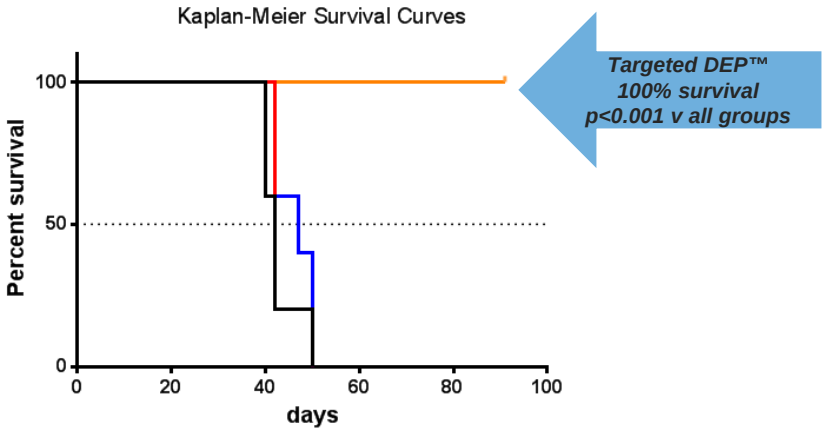


- **SPL's novel HER2-targeted DEP™ conjugate resulted in;**
  - **complete tumour regression and 100% survival in an ovarian cancer model**
  - **significantly outperformed both Roche's Kadcyla® (T-DM1) and the monoclonal antibody Herceptin® (Trastuzumab) alone**

    Statistical analysis at day 40. Kadcyla® vs Targeted DEP™; P <0.0001. (ANOVA followed by Tukey's post hoc test).

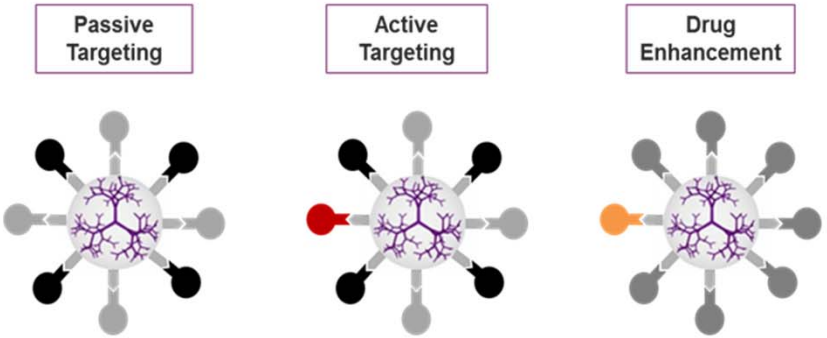
- **2 targeted DEP™ partnerships signed with major antibody-drug-conjugate players - August 2016**





Starpharma's DEP™ platform

A highly versatile platform with significant commercial and therapeutic benefits



DEP™ dendimer	Precisely manufactured poly-lysine dendrimer (variable size) Manufactured using standard chemistry
Toxin/Drug/Payload	Small molecule, Cytotoxic, Ultratoxic
Targeting group	Whole antibody, fragment, mimetic, small molecule
PEG	Provides stealth; solubility; control clearance; flexibility in size
Drug to be enhanced	Molecule requiring enhanced PK, PD, solubility or elimination of off target toxicities , expansion of therapeutic window

Commercial Benefits	Patent protection /extension	✓
	Innovative treatment options	✓
	Competitive product advantages	✓
	Robust, scalable manufacturing	✓
Therapeutic Benefits	Flexible platform with broad applicability in targeted therapies	✓
	Enhanced product properties – increased solubility; enhanced PK and efficacy; better side effect profile	✓
	Greater homogeneity with higher payload ratio than conventional ADC approaches	✓
	Enhanced therapeutic window	✓

Contact

Tony Eglezos
VP, Business Development
Starpharma Pty Ltd

4-6 Southampton Crescent,
Abbotsford, VIC 3067
AUSTRALIA

Email: tony.eglezos@starpharma.com
Web: www.starpharma.com

David Owen
VP, Research
Starpharma Pty Ltd

4-6 Southampton Crescent,
Abbotsford, VIC 3067
AUSTRALIA

Email: david.owen@starpharma.com
Web: www.starpharma.com