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Starpharma

DEP™ Drug Delivery

BioEurope, Munich, 2015

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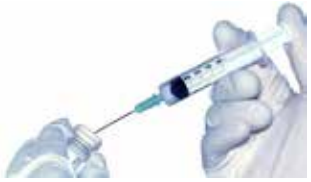
Starpharma – Snapshot

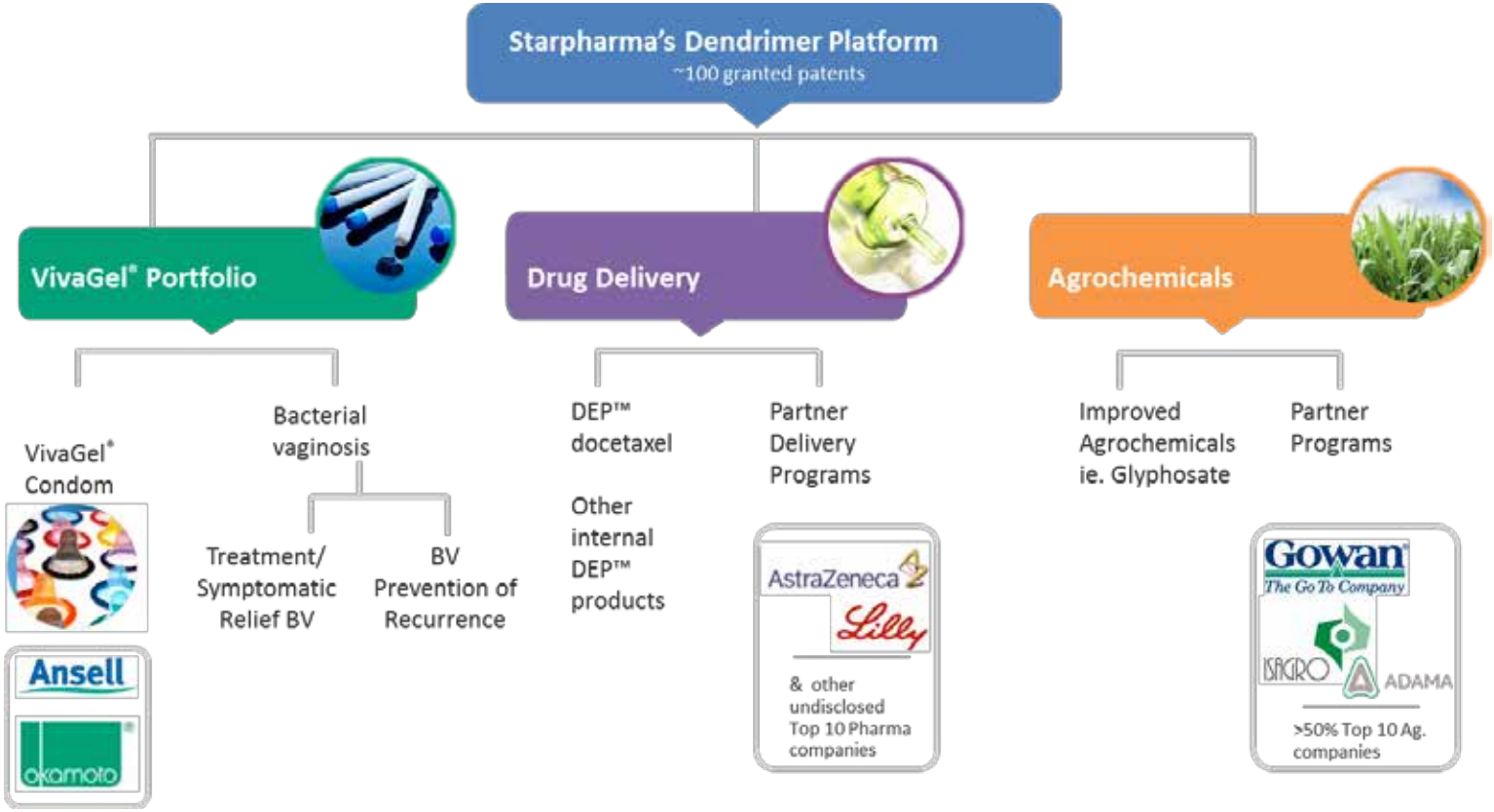
Starpharma headquarters in Melbourne, Australia

- **ASX 300 company (ASX:SPL, OTCQX:SPHRY) located in Melbourne, Australia**
- **Market Cap ~ A$225M**
- **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 commercialization 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 (Jun 2015 - A$30.8M)**



A global leader in nanoscale polymers (dendrimers)

Potential for multiple and parallel revenue streams



Starpharma Pipeline

			Res	PC	PhI	PhII	PhIII	Reg.	Mkt
Antimicrobial / Antiviral (SPL7013)	VivaGel® BV	BV Symptomatic Relief							
	VivaGel® BV	BV Prevention of Recurrence							
	VivaGel® Condom	Ansell / okamoto							
Oncology (Internal)	Drug Delivery	DEP™ docetaxel (various cancers)							
	Drug Delivery	DEP™ oxaliplatin							
	Drug Delivery	Various Oncology DEP™							
Partnered programmes	Drug Delivery -	DEP™ Delivery – oncology, diabetes etc.			AstraZeneca				

Completed

Planned

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DEP™ Drug Delivery

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 licensed DEP ™ drug delivery platform in the development and commercialisation of a novel, proprietary AZ oncology compound**
- **SPL eligible to receive development, launch and sales milestones for the first AZ DEP™ product of USD$126 million (including a signature payment US$2m)**
- **Licence provides for application of DEP ™ to multiple AZ compounds directed at a defined family of targets**
- **Each subsequent qualifying product successfully developed and commercialised could yield USD$93m in milestone payments**
- **Tiered royalties on net sales**
- **AZ will fund all development and commercialisation costs**

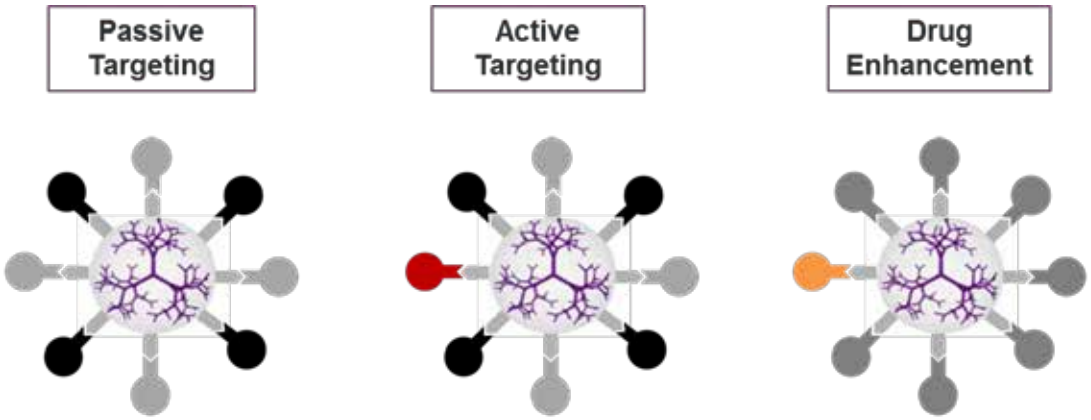
"SPL estimates that each product successfully commercialised under this agreement could be worth around US$450m to Starpharma and, depending on the range of indications and degree of commercial success in the market, potentially significantly more"

"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

AstraZeneca

Starpharma's DEP™ platform



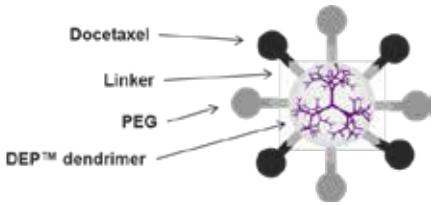
DEP™ dendimer	Precisely manufactured poly-lysine dendrimer (variable size) Manufactured using standard chemistry
Toxin/Drug/Payload	Small molecule, Cytotoxic, Ultratoxic
Targeting group	Whole antibody, fragment, mimetic, small molecule
PEG	Provides stealth; solubility; control clearance; flexibility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

Starpharma's dendrimers are already in the clinic (Phases I-III)

- have been demonstrated to be well tolerated
- Current cGMP manufacture (30kg scale) provides dendrimers that are extremely pure
- Dendrimers are prepared by standard chemical synthetic methods: practical, easy to formulate and cost effective

Starpharma's DEP™ docetaxel

Multiple advantages - Better efficacy and less toxicity



$T_{1/2}$ and Targeting

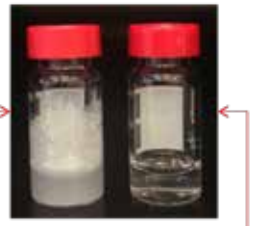
	Plasma Half Life (hours)*
DEP™– Docetaxel	39
Taxotere®	0.5

*n = 4 rats per group

DEP™ docetaxel formulation extends plasma t1/2 by >60-fold vs. Taxotere®

Safety

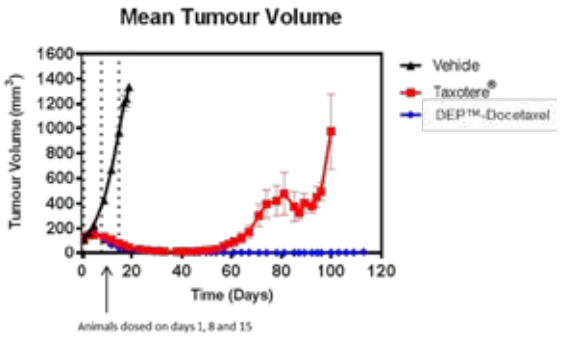
DEP™ docetaxel – Polysorbate 80-free and Water soluble



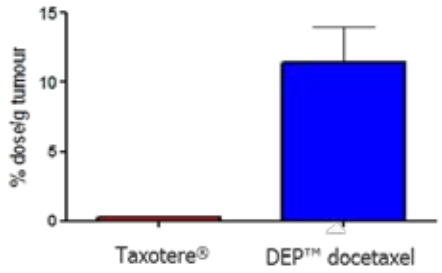
Docetaxel

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

Efficacy

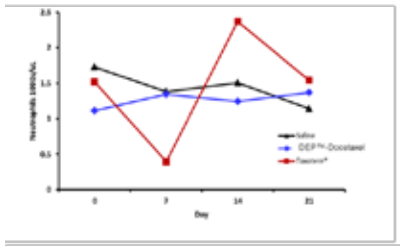


Mouse Xenograft (MDA- MB 231); N= 10/group; p< 0.0001

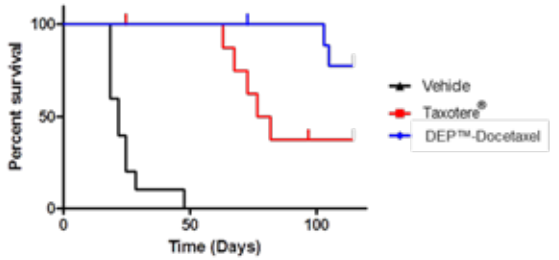


DEP™ docetaxel shows preferential uptake into mouse MDA-MB-231 xenograft (45-70 fold)

DEP™– Reduction of bone marrow toxicity and DLT's



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



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

Compelling product benefits for DEP™ docetaxel

Aspect	DEP™ docetaxel	Starpharma Benefit
Manufacture	Standard chemistry	SPL dendrimer manufacture is readily scalable and validated through extensive FDA input
Stability	Excellent stability	Important for drug approval, storage and subsequent shelf life
Drug loading w/w	25%	SPL delivers higher dose per mg of drug
Particle Size	10-15nm	Smaller particles enter tissues more easily
Tumour concentration of active	30-60x	Higher level of docetaxel delivery to tumour SPL - better efficacy & reduced toxicity
Plasma Half life	>50 hours	Longer duration of effect, less frequent dosing and greater anti-cancer effect
Enhanced Solubility?	water soluble; ~ 20,000 fold increase	Water soluble; safer formulation (see "polysorbate 80" below)
Neutropenia prevented	Yes	Avoids risks & need for expensive rescue therapies and hospitalisation
Polysorbate used	No - cortisone pre-treatment is not required	Avoids potentially fatal toxicities with polysorbate-containing formulations

DEP™ docetaxel: Phase 1 Clinical Trial

Encouraging initial clinical data

- Underway at 4 Australian sites;* Open label study - allowing progressive release of results
- Estimated sample: 25-30 cancer patients (various solid tumours)

Current Status

- DEP™ docetaxel administered every 3-4 weeks (*no steroid pre-treatment required)*
- Patients currently being enrolled in dose escalation phase with several dosed with multiple cycles (up to 6 cycles)
- dose-level exceeds commonly used Taxotere® dose 75mg/m^2

Interim Findings: DEP™ docetaxel well tolerated *with encouraging anticancer activity*

- ***No neutropenia*** (docetaxel DLT) observed so far (*c.f Taxotere® where published data indicates* ***severe neutropenia*** *will be suffered by* ***75% of patients given 60mg/m^2*** *)*
- ***No alopecia*** *reported*
- A sizable number of patients have exhibited **efficacy signals/anticancer activity** (one with pancreatic Ca. stable disease over > 20 weeks; prostate, lung, H&N)
- **Enhanced Pharmacokinetics** demonstrated (longer half-life, higher AUC and lower Cmax)

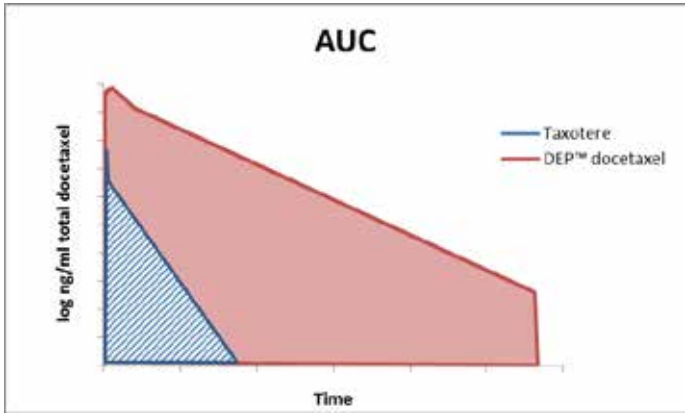
*Alfred, Austin Health/Olivia Newton John CC, Liverpool and Royal Brisbane & Women's Hospital

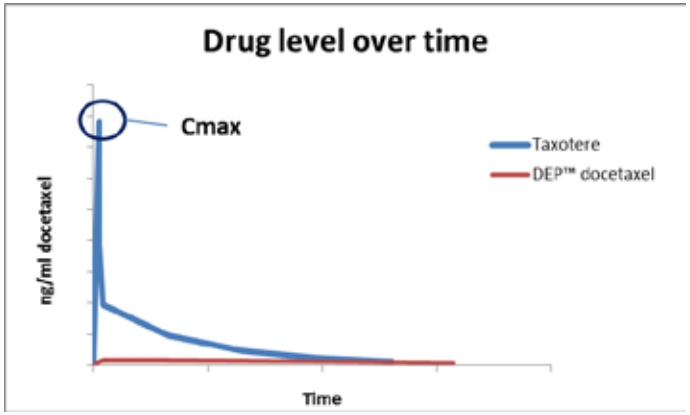
DEP™ docetaxel Pharmacokinetics (PK) in humans cf. Taxotere®^

1. **Extended duration of exposure with DEP™ docetaxel**
   - DEP™ docetaxel plasma half-life substantially longer (~8 x) than Taxotere® (~150x longer in the initial, rapid phases of plasma clearance)

2. **Increased extent of exposure with DEP™ docetaxel**
   - DEP™ docetaxel drug exposure (Area Under the Curve /AUC) for total docetaxel, is ~500-800x times greater than an equivalent dose of docetaxel administered as Taxotere®
   - reflects the gradual release of docetaxel (DEP™ docetaxel acts as a 'depot' of docetaxel)

3. **Reduced peak drug levels with DEP™ docetaxel**
   - Cmax (peak blood level) of docetaxel is substantially (~50-100 times) lower than the Cmax of an equivalent dose of docetaxel administered as Taxotere®



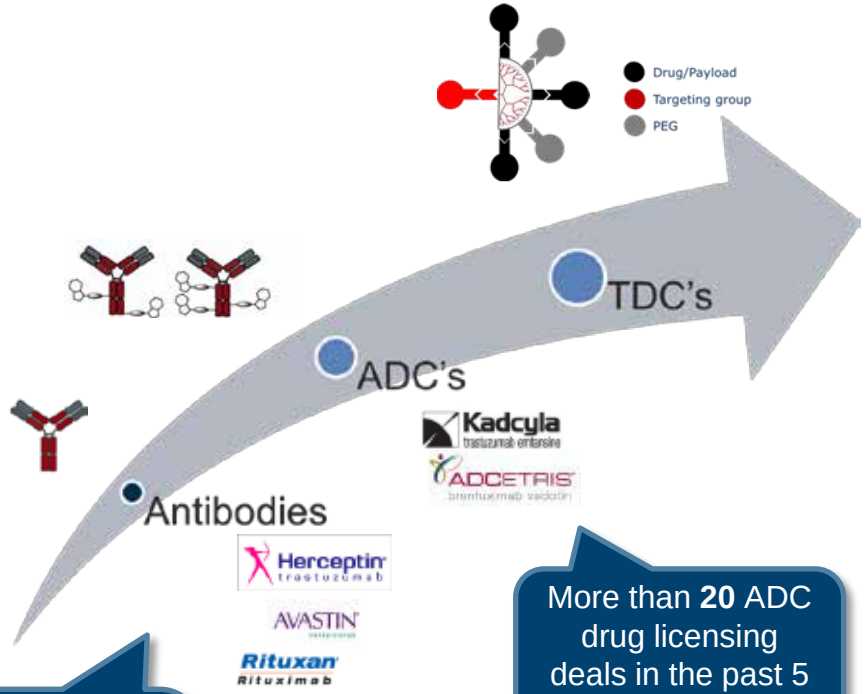


Example plasma drug levels over time DEP™ docetaxel vs.Taxotere®

^ Taxotere® parameters based on published data (Bruno et al, 1996)

Targeted DEP™ Conjugates (TDCs)

A new approach to drug conjugate design



50% of the top 10 products are antibodies with 2013 sales in excess of **$US38B**

More than **20** ADC drug licensing deals in the past 5 years

The top 3 oncology products are antibodies with combined sales of **US$20B**

Starpharmas Targeted DEP™ conjugates	
Can use small molecule, whole antibody, antibody fragments or antibody mimetics	ü
Bind with high affinity and specificity	ü
Highly efficacious in cancer model in vivo	ü
Flexible and tailored to suit clinical requirements	ü
Homogeneous	ü
Standard Chemistry yielding consistent, reproducible, stable molecules	ü
Platform already in the clinic and demonstrated to be safe and well tolerated	ü

Targeted DEP™ Conjugates

A flexible approach to drug conjugate design and development

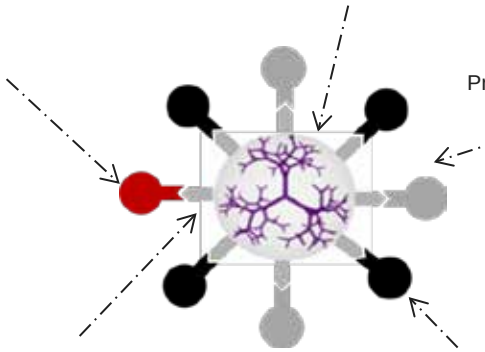
Dendrimer size easily scalable to deliver desired payload number

DEP™ dendrimer

- Precisely manufactured poly-lysine dendrimer
- Manufactured using standard chemistry

Flexibility in targeting molecule
Ab; Ab fragment; Non-Ab ligand; Small molecule

Targeting
Whole antibody, fragment, mimetic, small molecule



PEG
Provides stealth; control clearance; flexibility in size

PEG size to meet requirements

Linker
Variable linkers to suit clinical need

Drug / Payload
Small molecule, Cytotoxic, Ultratoxic

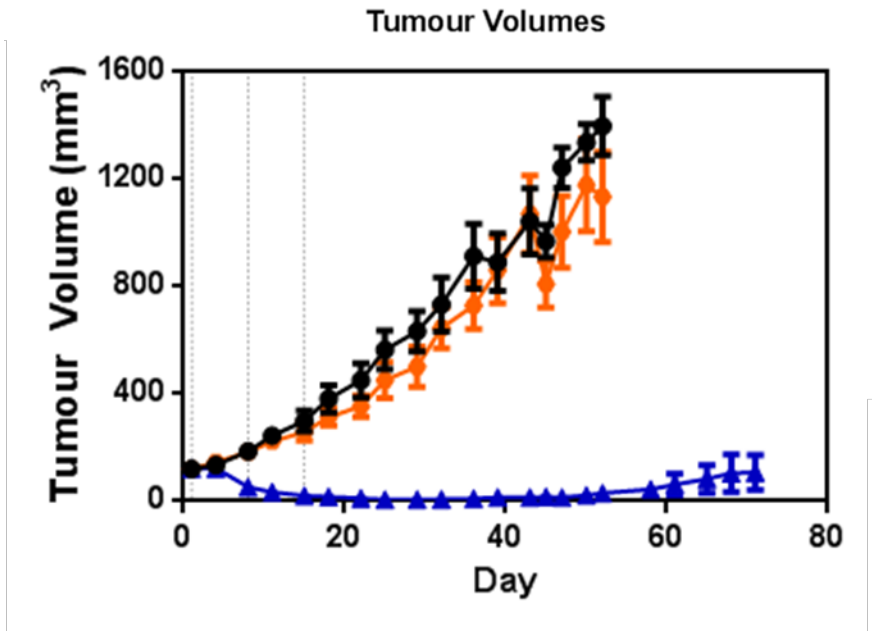
Linker strategy tailored to meet drug release requirements
- **Enzymatic; protease; pH; reducing; stable etc**

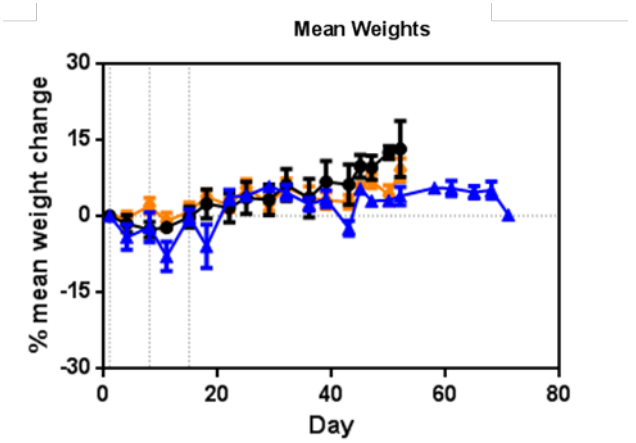
Can deliver any type of payload Cytotoxic or Ultratoxic (number of payload molecules per DEP™ molecule can be scaled based on size of dendrimer)

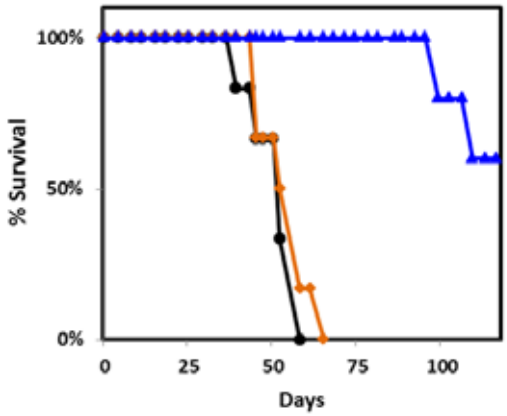
Targeted DEP™ Conjugates

A flexible approach to drug conjugate design and development

Small molecular weight (anti-HER-2 targeting) molecule





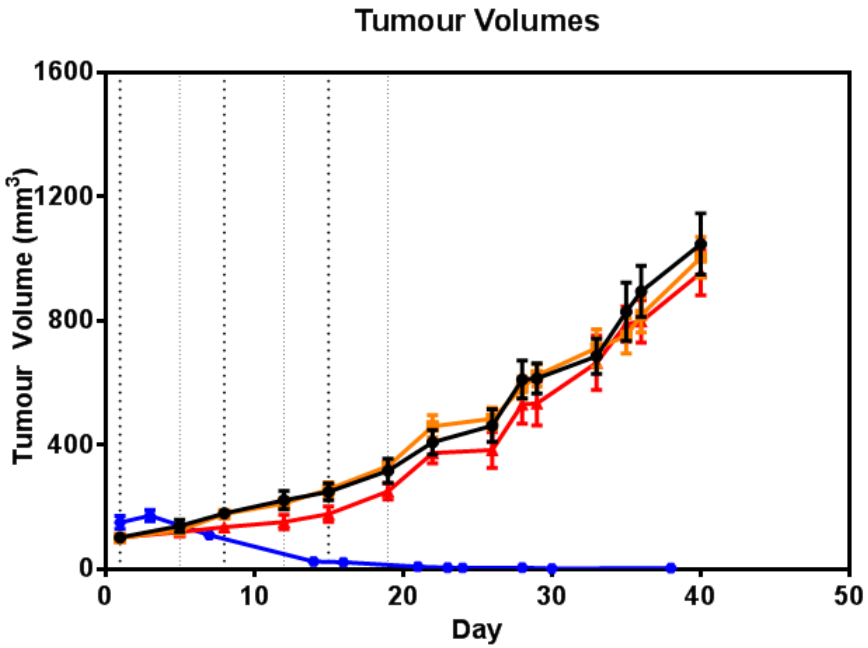


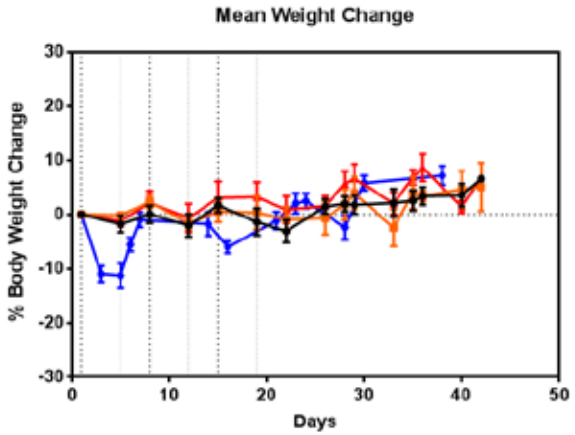
- **SKOV-3 tumour model in NOD SCID mice**
- **6 animals/group**
- **All groups dosed once weekly for 3 weeks**

Targeted DEP™ Conjugates

A flexible approach to drug conjugate design and development

Full length Ab (Herceptin) molecule





- **SKOV-3 tumour model in NOD SCID mice**
- **5 animals/group**
- **Vehicle, Kadcyla and Targeted DEP™ conjugate groups dosed once weekly for 3 weeks**
- **Herceptin group dosed twice weekly for 3 weeks**

Treatment	Efficacy				Toxicity	
	% Inhibition		% Regression		%	
	Last Measurement Day (40)	% Inhibition Maximum (Day)	Last Measurement Day (40)	% Regression Maximum (Day)	mean weight change Last Measurement Day (40)	Mortality
Vehicle	NA	NA	NA	NA	3.5	4/5
Herceptin®	4	10 (5)			4.6	4/5
Kadcyla®	9	32 (12)			1.4	3/5
Targeted DEP™ conjugate	>100	>100	99.6	99.6 (38)	7.1	0/6

DEP™ platform in drug delivery

Maximising commercial opportunity through differentiation and value add

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

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