STARPHARMA HOLDINGS LIMITED
ASX:SPL; OTCQX:SPHRY

Finance News Network

DR JACKIE FAIRLEY CEO

August 2017

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", 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.

Overview:
Starpharma Holdings Limited (ASX:SPL)

- **Melbourne-based ASX300 company; Market Cap ~A$330M**
- **Unique proprietary polymer (dendrimer) platform**
- **Deep portfolio of products in large, high-value markets**
- **Proven track record of commercialisation**
  - ü **VivaGel® BV – approved in Europe for treatment, awaiting launch and regulatory approval applications underway for prevention product following successful phase 3 trials**
  - ü **VivaGel® condom in-market (approved Australia & Canada)**
  - ü **Added significant value to Priostar® (Agrochemicals) portfolio, recently sold to Agrium Inc. for $35M**
- **Successful, longstanding global partnerships including with AstraZeneca, creating significant optionality, accelerating path to market & managing investment risk**
- **Well-funded, with estimated cash >$60M at 30 Jun 2017**

aspen AUSTRALIA

Ansell

SKY & LAND

Koushan Pharmed

okamoto

AstraZeneca

Starpharma's headquarters and laboratories Melbourne, Australia

Global Leader in Dendrimer Products

Starpharma's products, programs and commercial partnerships with leading companies

Starpharma's Dendrimer Platform
~104 granted patents

VivaGel® Portfolio

VivaGel® BV (bacterial vaginosis)

- **VivaGel® BV Treatment and Symptomatic Relief**
  - aspen AUSTRALIA
  - 

- **VivaGel® BV Prevention of Recurrence**
  - Global commercial deal process underway

VivaGel® condom

- DUAL Ansell
- SKY & LAND
- okamoto
- Koushan Pharmed

DEP® Drug Delivery

Internal DEP® programs

Including

- DEP® docetaxel
- DEP® cabazitaxel
- DEP® irinotecan
- Targeted-DEP®

Partnered DEP® programs

Companies including

AstraZeneca

Several undisclosed partnerships with leading Pharma companies

Starpharma Agrochemicals: sold to Agrium for $35M

Leading global producer and distributor of agricultural products

Listed on NYSE:AGU and TSX:AGU ~US$13B market cap

Annual revenue ~US$14B

1,500 ag-retail centres

>15,200 employees globally

Transaction completed in June 2017

- $35M cash consideration
- Sale amount is 4x book value of A$7.5M
- Reduces associated R&D expenditure
- No conditions precedent
- No FIRB
- No income tax payable
- Advised by Macquarie Capital

What was sold?	• Starpharma Agrochemicals comprised key Priostar® patents and know-how, and a small number of staff dedicated solely to agrochemicals • No impact on VivaGel® or DEP® IP
Strategic rationale	• Planned strategy to maximise the value of, and monetise Priostar® IP/technology • Enables Starpharma to focus on core pharmaceutical portfolios; cash will be re-invested into high-value pharmaceutical programs, including DEP®

Strong Financial Position: >$60M in cash

Key Financial Highlights FY 2017

- Sale of Agrochemicals business for A$35M cash consideration (closed 13 June 2017)
  - >4x carrying book value of ~$7.5M
  - No income tax payable
- Second AstraZeneca DEP® milestone US$2M
- Capex investment in scale-up facility $0.4M
- Cash est. >A$60M at 30 June 2017

- **Revenues expected to build with:**
  - Further DEP® Milestones
  - Receipts following VivaGel® BV launch, VivaGel® BV licence, sales
  - VivaGel® condom geographic expansion

- **Reduced R&D expenditure FY 2018:**
  - Phase 3 VivaGel® BV trials complete
  - Reduced spend on Agrochemicals

Key Financial Data	FY 2016 AUD $M	FY 2015 AUD $M
Total revenue & other income	4.6	1.7
R&D Tax Incentive	3.5	3.5
Net loss after tax	(22.7)	(19.0)
Net Cash Burn[1]	(17.5)	(13.7)
Closing Cash[2] (30 June)	46.0	30.8

Cash at 30 June 2017 $61.2M

[1] Net cash burn is considered a non-IFRS value and has not been audited in accordance with Australian Accounting Standards. Net cash burn is calculated by the movement in cash and cash equivalents at 30 June of the applicable year adjusted for net proceeds on the issue of any equity

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DEP® Drug Delivery

DEP® Drug Delivery Platform

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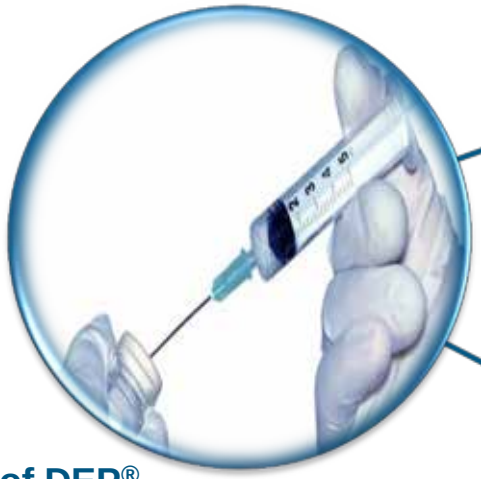
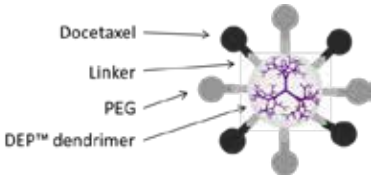
Dual Strategy

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



Internal Programs

- Application to established drugs
- New patents based on DEP® provide patent life extension
- Self funded
- Return through licensing milestones and royalties (e.g. DEP® docetaxel)



Partnered Programs

- Application to partners' drugs (typically proprietary)
- Platform with broad optionality
- New patents based on DEP® provide patent life extension (life-cycle management)
- Funded development
- Return through licensing milestones and royalties (e.g. AstraZeneca)

AstraZeneca

Benefits of DEP®

- Improved efficacy
- Reduced toxicity
- Improved pharmacokinetics
- Improved solubility
- New patents based on DEP®

Extensive partner engagement to maximise commercial outcomes from DEP®

DEP® Platform: Consistent and significant benefits in efficacy and toxicity

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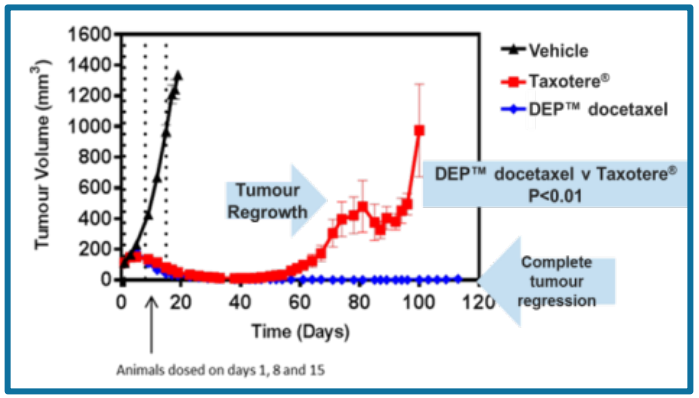
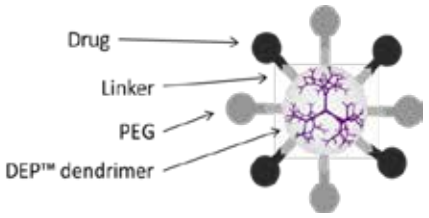
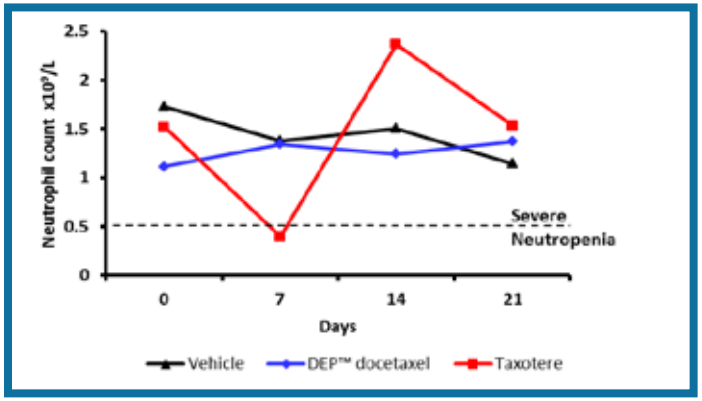


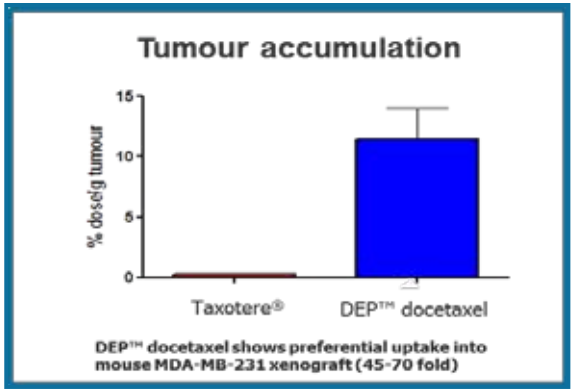
1.Improved efficacy vs. original drug
Breast Cancer Model (MBA-231 xenograft)



DEP® Drugs

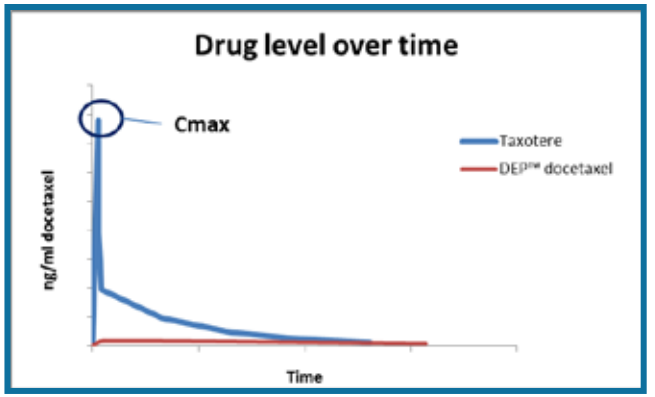


4. Improved safety vs. original drug
Reduced one marrow toxicity



2. Tumour targeting
45-70 times more drug vs. original drug

3. Improved Solubility
Detergent free formulations for improved safety



5. Improved PK vs. original drug
Longer half-life and lower Cmax

AstraZeneca multiproduct license and new program – Partnered DEP® momentum building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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.

"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."

- AZ multiproduct 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

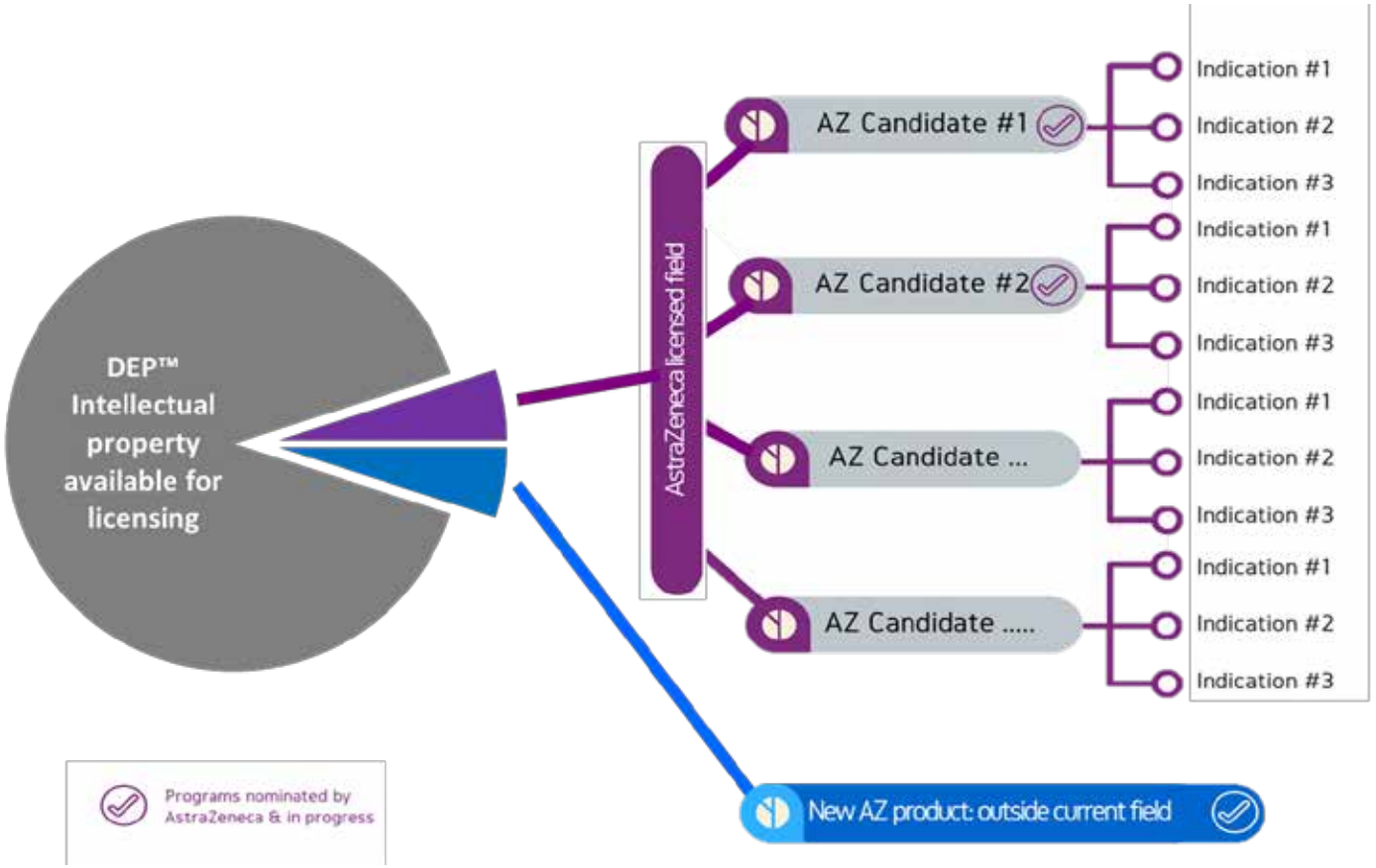
AstraZeneca

- Received US$2M in H1 FY2016
- Starpharma's internal products not impacted and agreement allows for multiple other DEP® licences
- Two new AZ programs added since signature

"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 multiproduct license and new program – Partnered DEP® momentum building



" AstraZeneca has a deep-rooted heritage in Oncology..
The Company is committed to advancing New Oncology as one of AstraZeneca's Growth Platforms…..

In addition to core capabilities, the Company is actively pursuing innovative collaborations and investments that accelerate the delivery of AstraZeneca's strategy…."

AstraZeneca
Q3 Results Presentation
November 2016

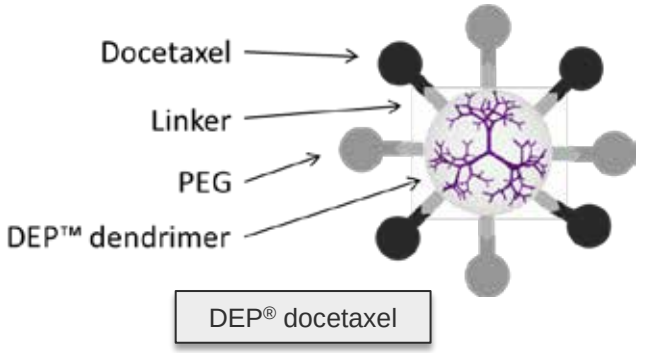
Starpharma's AstraZeneca deal structure provides for significant optionality – with multiple DEP® products in development and the potential for many other partnerships

DEP® Docetaxel: Multiple benefits

- Docetaxel (Taxotere®) is a blockbuster cancer drug **Sales: US$3.1B (2009)**
- Docetaxel is used in major cancer types including breast, prostate, lung and ovarian cancer
- Starpharma's patented DEP® docetaxel is a nanoparticle formulation with **multiple advantages compared to Taxotere®**
- **DEP® patents and applications provide coverage to 2032**
- **DEP® docetaxel Phase 1 trial – no neutropenia, no hair-loss, and promising efficacy signals in a range of tumour types**

DEP® docetaxel vs. Taxotere®

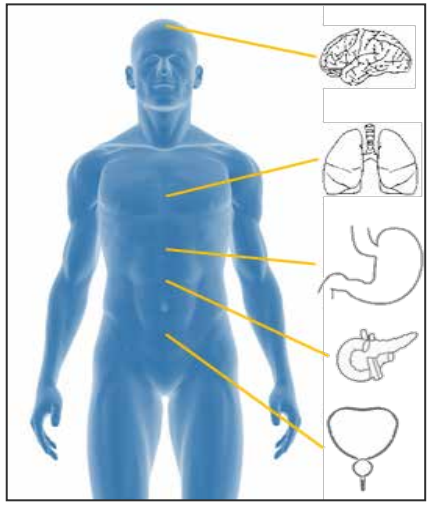
1. Elimination of major dose-limiting side effect (neutropenia)
2. Detergent-free formulation (less toxic)
3. Tumour-targeting (~70x more)
4. Extended duration (half-life)
5. Improved efficacy (breast, ovarian, prostate)



DEP® Docetaxel Clinical Program

Phase 1 Clinical Trial (open label study - 25-30 cancer patients - various solid tumours)
Phase 2 Clinical Trial (in advanced planning)

Current Status:
- Final expansion phase underway
- Large UK site recruiting to:
  - enrich final patient cohort with specific tumour types and
  - facilitate transition to Phase 2 via an adaptive design



Patients treated with DEP® docetaxel have exhibited:

- **No neutropenia** (docetaxel dose limiting toxicity)
- **No alopecia** (hair loss) reported in vast majority of patients
- **No hypersensitivity**
- **No standard steroid pre-treatment required**

Encouraging efficacy signals in a significant proportion of patients including:

- in **pancreatic** (SD*>20 wks), **oesophageal** (SD >18 wks), **prostate, lung, H&N and brain tumours**
- at low doses, **in cancers not responsive to docetaxel** and in a heavily pre-treated patient cohort

* Stable Disease

Phase 2:
- Planning now well advanced including CRO, trial design, KOLs and trial material manufacture

PROPOSED PHASE 2 STUDY (in advanced planning)

- Two-stage study design proposed
- Objective to establish anti-tumour activity and safety of DEP® docetaxel
- Open label, N=40 (e.g. 20+20)
- Two-stage approach:
  - Stage 1 – patients with cancer types based on docetaxel indications e.g. lung, prostate (taking account of Ph1 efficacy signals)
  - Stage 2 – select cancer type based on efficacy signals observed in Stage 1
- Standard efficacy endpoints
- Potential combinations also considered

DEP® Cabazitaxel: Multiple benefits

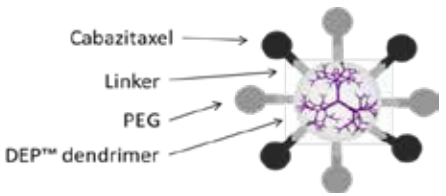
About cabazitaxel (Jevtana®)

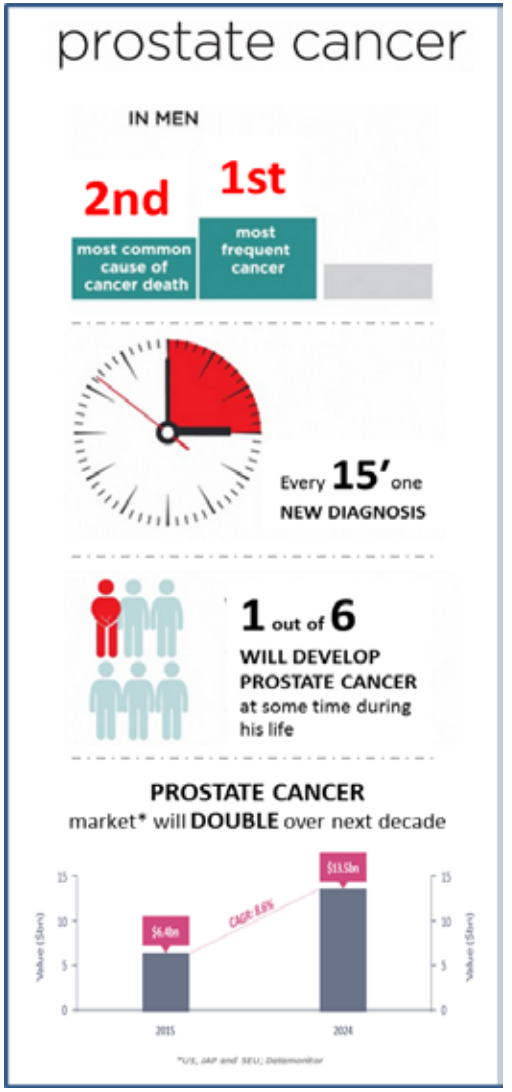
- **2016 sales approx. US$400m (est. US$500m by 2018)**
- **Primary indication – Prostate cancer**
- **In clinical development for other cancers including Breast, Bladder, Head & Neck**
- **Dose Limiting Toxicity – neutropenia (FDA "Black Box" warning)**
- **FDA "Black Box" warning due to anaphylaxis (polysorbate 80 detergent)**

DEP® cabazitaxel

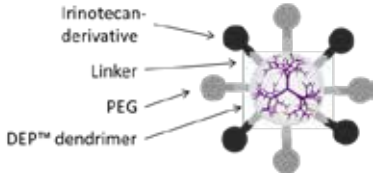
- ü **Significantly enhanced efficacy versus Jevtana® (cabazitaxel) in mouse xenograft models of breast and prostate cancer**
- ü **Detergent (polysorbate 80) free formulation**
- ü **Lack of neutropenia**
- ü **Final preparations underway for clinical trial commencement in 2017**

DEP® cabazitaxel





Starpharma's DEP® Irinotecan



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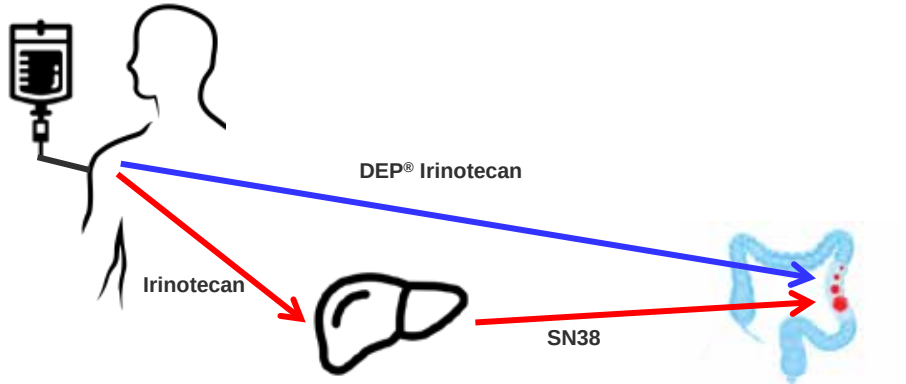
- **Irinotecan (Camptosar®) is a major cancer drug primarily used for the treatment of advanced colorectal cancer (peak sales US$1.1B)**
- **Colorectal cancer is one of the most common cancers and an area of significant unmet need with few treatment options**
- **Irinotecan has FDA "Black Box" warnings for - severe diarrhoea, myelosuppression and neutropenia** CAMPTOSAR® Irinotecan HCl Injection
- **DEP® Irinotecan incorporates the irinotecan derivative (SN-38) and shows enhanced tumour growth inhibition compared to Irinotecan and near-complete tumour regression**



Aspect	DEP® Irinotecan Benefit
Manufacture	SPL dendrimer manufacture is readily scalable and validated through extensive FDA input
Stability	Highly stable Important for drug approval, storage and subsequent shelf life
Particle Size	Nanoscale particles retained in tumour tissue more easily
Plasma Half life	DEP platform consistently delivers longer duration of effect – expect the same result with DEP® Irinotecan
Enhanced Solubility	Water soluble
Enhanced Efficacy	Significantly enhanced efficacy in all tumor models tested (v Irinotecan)

DEP® Irinotecan: Significantly enhanced efficacy and survival in colon cancer model

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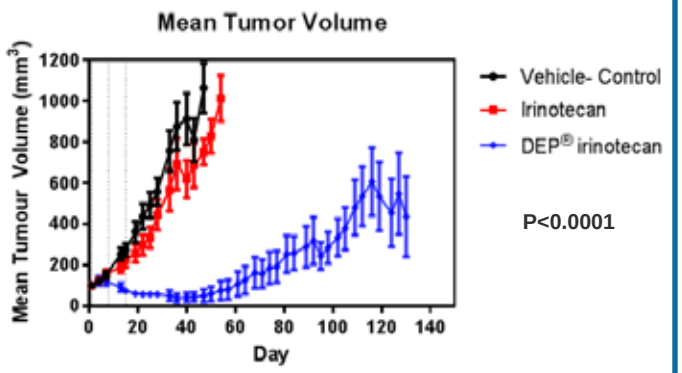
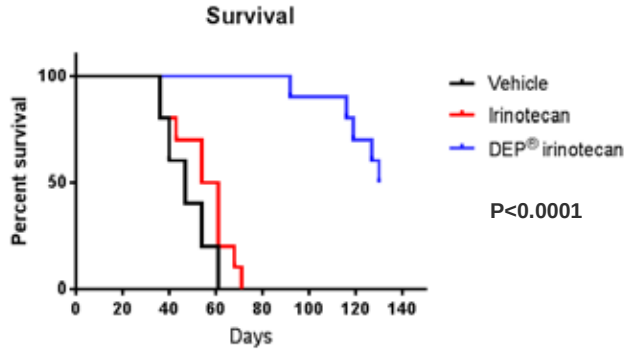
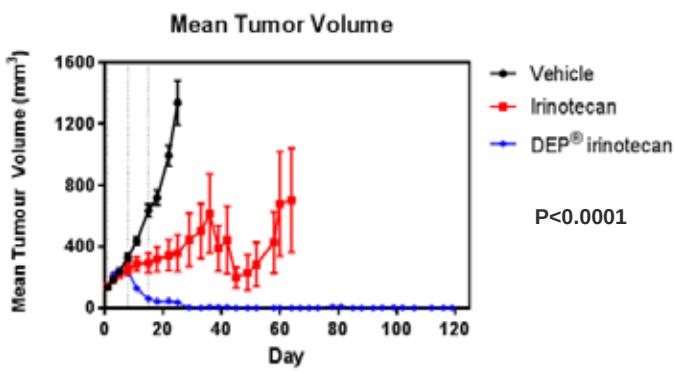
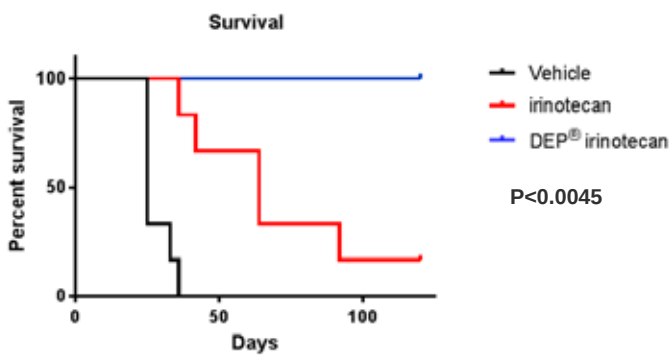
HT-29 (colon) Xenograft





SW620 (colon) Xenograft





- **Excellent efficacy demonstrated in two colon cancer models including (HT-29) known to be resistant to irinotecan**
- **Significant tumor regression with DEP® irinotecan (vs no regression with irinotecan)**
  - **62% regression in HT-29**
  - **100% regression in SW620**
- **Significant survival benefits: DEP® irinotecan resulted in 100% survival (SW-620) and >100 days in (HT-29).**

HT-29 (colon cancer) mouse xenograft Balb/c nude mice (n=10 /group). IV dosing with Vehicle, DEP® Irinotecan or Irinotecan on days 1, 8 and 15.

SW620 (colon cancer) mouse xenograft Balb/c nude mice (n=6 /group). IV dosing with Vehicle, DEP® Irinotecan or Irinotecan on days 1, 8 and 15.

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VivaGel® Portfolio

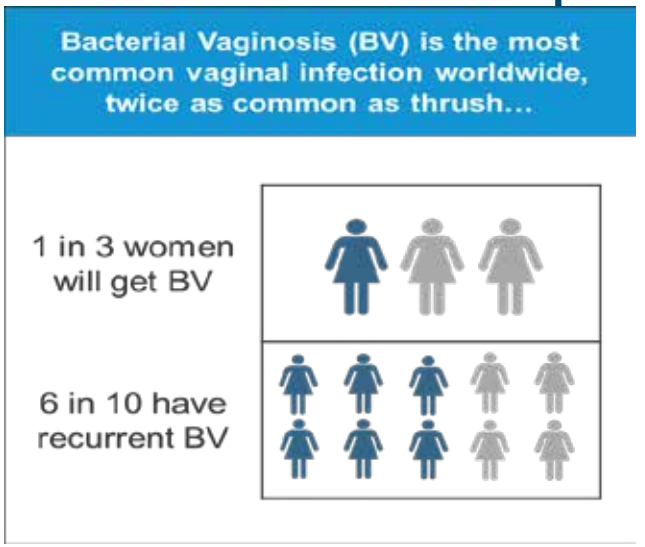
VivaGel® BV &
VivaGel® Condom

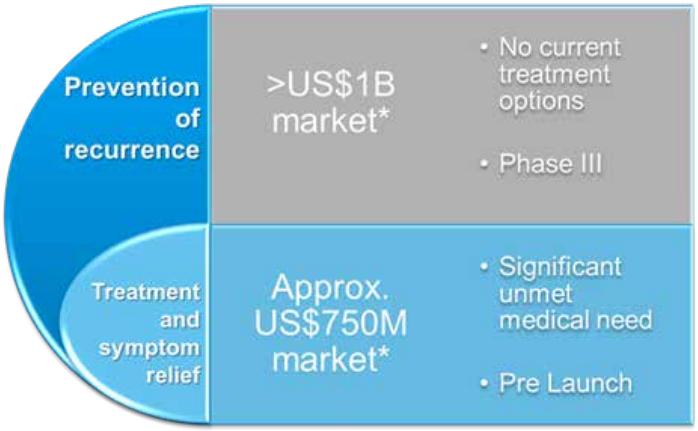
Bacterial Vaginosis and VivaGel® BV: Two Attractive Commercial Opportunities

Bacterial Vaginosis (BV):

- Most common vaginal infection worldwide
- ~29% women infected in US; up to 51% in some groups
- Serious medical consequences (PID, infertility, miscarriage, increased risk of HIV and other STIs)
- Current therapies have low cure rates and nasty side effects
- Recurrent BV (R-BV) occurs in 50-60% of BV sufferers
- No approved products for Recurrent BV (R-BV)

→ Large market opportunity for both prevention of R-BV and BV Treatment & Symptom Relief





* Estimate – Global Data, IMS, various Industry reports

VivaGel® BV: Product Proposition

- a non-antibiotic therapy
- treatment and management of BV symptoms *and* prevention of R-BV
- a selective antimicrobial effect for pathogens that cause BV
- a local effect and is not systemically absorbed
- bio-adhesive properties

VivaGel® BV: Two Attractive Commercial Opportunities

Jan 2017: FDA granted Fast Track & QIDP Designation

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VivaGel® BV Treatment & Symptom Relief

- Acute use product
- Global market est. >US$750M
- EU marketing approval achieved – Treatment of BV, including rapid relief of BV symptoms
- Regulatory approval underway in multiple regions
- Licensed to Aspen for ANZ
- Multiple, advanced partnering discussions underway (regional & global)
- Commercial manufacture underway and launch planned in the near future
- Recent FDA Guidance opens up a significant new market opportunity; NDA submission in preparation

VivaGel® BV Prevention of recurrence

- Chronic use product
- Unmet need: no approved products for R-BV
- Global market est. >US$1B
- ~60% BV sufferers experience recurrence
- SPA agreement with FDA in place
- Phase 3 program completed (Results Q3)
- Partnering discussions well advanced
- NDA well advanced

Benefits of VivaGel®

- Rapid resolution of symptoms
- Non-antibiotic
- Not systemically absorbed
- Selective antimicrobial effect
- Excellent tolerability

Advanced licence negotiations underway for multiple regions

VivaGel® BV – US Status

Treatment

— US: New guidance document released by FDA on BV treatment – July 2016

— US: NDA due for submission Q3 CY17

QIDP and Fast Track designation

- **Fast Track** designation
- **priority regulatory review** and
- an additional five years of **market exclusivity**.

Prevention of Recurrent BV

— Phase III data show statistically significant and sustained benefit for 1º and 2º endpoints

— Trials conducted under SPA

QIDP and Fast Track designation

- **Fast Track** designation
- **priority regulatory review** and
- an additional five years of **market exclusivity**.

— Expected rolling submission with Treatment NDA


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ASX ANNOUNCEMENT

VivaGel® BV granted QIDP and Fast Track designation by US FDA

Melbourne, Australia; 12 January 2017: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced it has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designation for VivaGel® BV by the US Food and Drug Administration (FDA).

QIDP and Fast Track designations were granted independently for both the VivaGel® BV treatment and prevention indications for bacterial vaginosis (BV). This positive development recognises the high unmet medical need in the management of BV and the potential of VivaGel® BV to address that need for both treatment and prevention of recurrent BV, markets estimated to be worth in excess of US$1 billion globally.

These two important designations are designed to make new therapeutics available to patients as rapidly as possible, carrying significant benefits for regulatory approval and commercialisation of VivaGel® BV.

QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act, and provides incentives for the development of new antimicrobial products. These incentives include priority regulatory review and an additional five years' of market exclusivity. The Fast Track designation enables more frequent interactions with the FDA and expedited review, leading to faster approval, and facilitates earlier market access for patients.


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ASX Announcement

Successful VivaGel® Phase 3 results and NDA planned for rBV

- VivaGel® BV demonstrated statistically significant efficacy in two pivotal phase 3 trials
- VivaGel® BV consistently resulted in reduced rates of BV recurrence by the primary efficacy endpoint and five secondary efficacy measures, and delayed time to first recurrence
- VivaGel® BV resulted in sustained benefits 3 months after cessation of treatment
- The majority of women who used VivaGel® BV in both studies remained BV-recurrence-free during the 16-week treatment phase
- VivaGel® BV demonstrated excellent safety and tolerability, including very low rates of candidiasis
- These trial results strongly support marketing applications to US FDA and other regulators for rBV indication and add significant commercial value to VivaGel® BV
- FDA QIDP and Fast Track designations already granted for VivaGel® BV, providing significant commercial and regulatory advantages
- VivaGel® BV New Drug Application (NDA) is well-advanced for both BV indications (treatment and prevention of rBV)
- Phase 3 trial data significantly enhances the commercial opportunity for VivaGel® BV through the ongoing licensing process, facilitated by a global healthcare investment bank

Melbourne, Australia; 7 August 2017: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its two phase 3 trials of VivaGel® BV for prevention of recurrent bacterial vaginosis (rBV) achieved their primary objective demonstrating statistically significant superiority compared to placebo in preventing rBV based on topline data

Overview of VivaGel® BV phase 3 results

VivaGel® BV demonstrated statistically significant efficacy in 2 pivotal phase 3 trials:

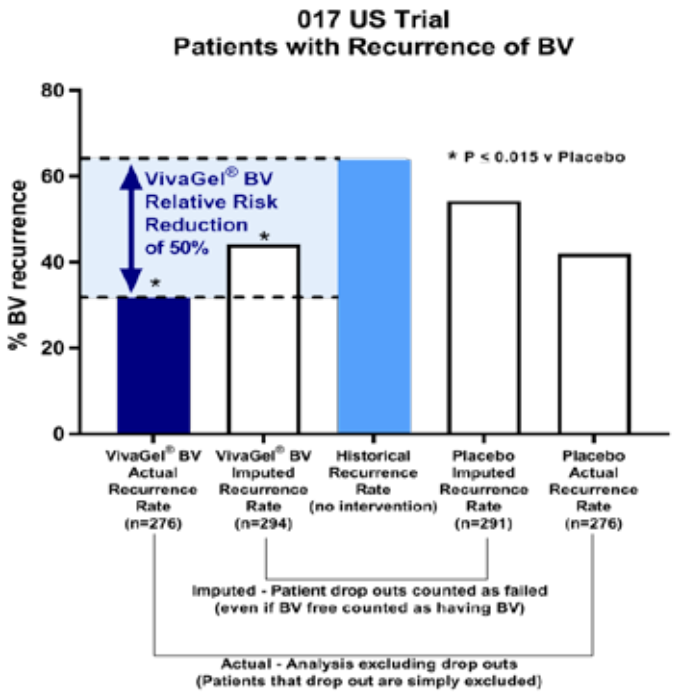
- Ø **consistently resulted in reduced rates of BV recurrence** by the **primary** efficacy endpoint ***and*** **all five secondary efficacy measures**
- Ø showed **sustained benefits - 3 months after cessation of treatment**
- Ø **excellent safety and tolerability, very low rates of candidiasis**

Phase 3 Trial results strongly support marketing applications to US FDA (and other regulators) and add **significant commercial value**

- Ø VivaGel® BV **New Drug Application (NDA) already well-advanced**
- Ø **Fast Track and QIDP status will be leveraged for rapid approval**
- Ø Phase 3 trial data **significantly enhances the commercial opportunity** for VivaGel® BV and feeds into licensing process, facilitated by global investment bank

VivaGel® BV: statistically significant efficacy in prevention of Recurrent BV

017 US Trial	VivaGel® BV	Placebo	P value
BV Recurrence Rate	N = 294	N = 291	
Imputed recurrence	44.2%	54.3%	0.015
	N = 276	N = 276	
Actual Recurrence	31.9%	42%	0.014



1º endpoint in SPA

- Rate of BV recurrence at or by week 16
- VivaGel® BV group (Imputed Recurrence Rate[1]) was 44.2% (statistically significant vs Placebo 54.3%; P=0.015).

Real life benefit of VivaGel® BV

Actual Recurrence Rate[2], the rate of BV recurrence at or by week

- **VivaGel® BV group was lower at 31.9%** (significant; P=0.014 vs Placebo 42%)
- Using **Actual Recurrence Rate** the **Relative Risk Reduction (%)** for VivaGel® BV vs to the Historical Recurrence Rate[3] was **50%**
- **Actual Recurrence rate is more clinically relevant** and the way that clinicians will communicate **the benefit to patients**

"Our ability to prevent recurrent BV with current treatment regimes is abysmal"

"There is an enormous need for a safe and effective treatment to prevent recurrence of BV in women suffering BV"

Professor J Sobel
ID Physician & KOL
Dean, Wayne State University School of Medicine

1: Imputed Recurrence Rate (where patient drop-outs are counted as failures)
2: Actual Recurrence Rate (where dropouts are not included in the analysis)
3: 16 week Historical Recurrence Rate (rate of recurrence expected in this population in a 16 week period if they did not have a prevention therapy) in the 017 US Trial was 63.9%

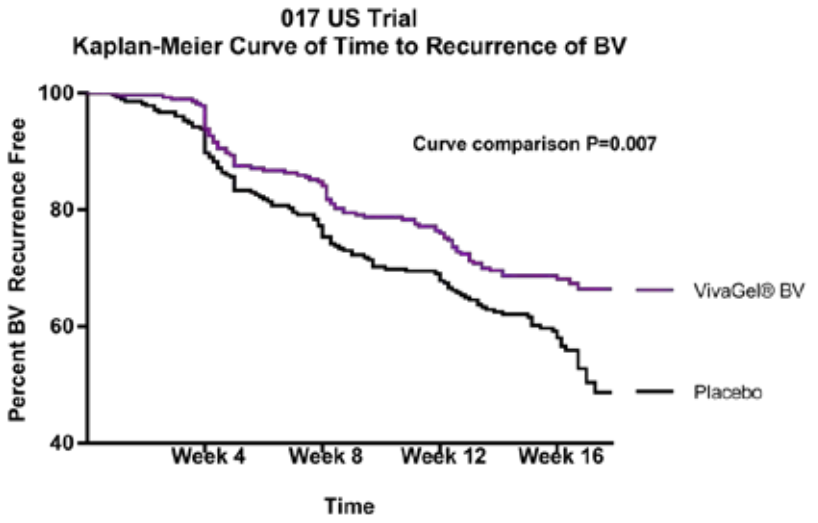
VivaGel® BV – Phase 3 Summary

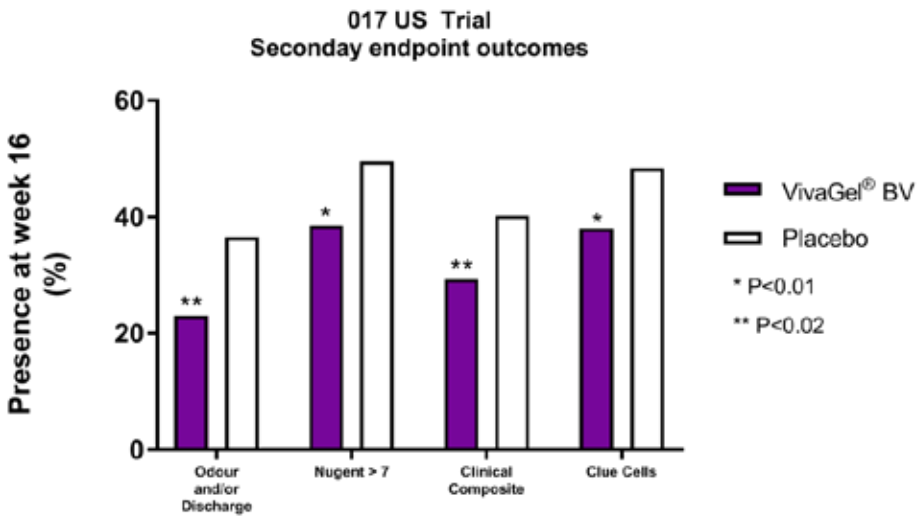
Significant benefit for Patients in Secondary efficacy endpoints

In addition to the **compelling benefits of VivaGel® BV** in the primary endpoint

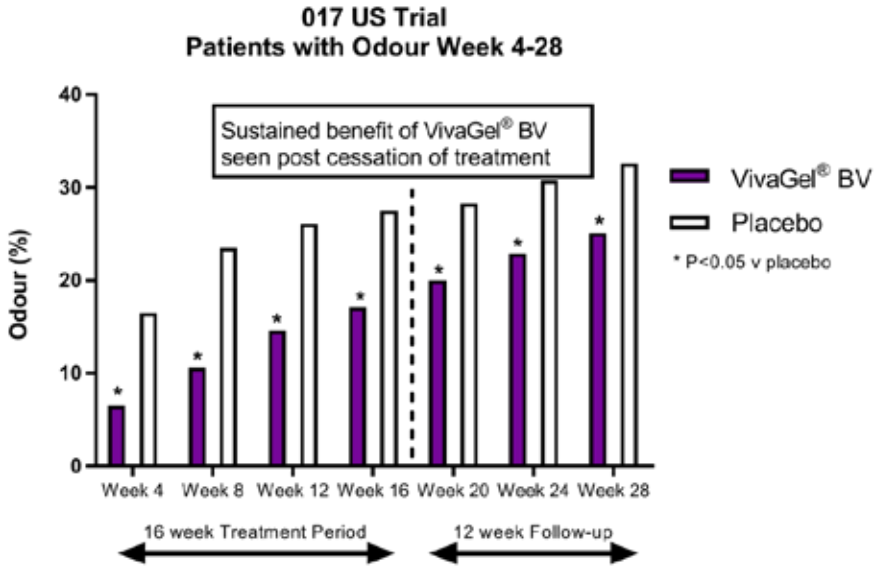
- VivaGel® BV demonstrated **statistically significant benefits in five secondary efficacy endpoints** compared with placebo

017 US Trial	VivaGel® BV	Placebo	P value
presence of Vaginal Odour and/or Discharge	23.0	36.5	<0.001
presence of Nugent Score 7-10	38.5	49.5	0.012
presence of Clinical Findings (3 of 4 Amsel criteria; Nugent Score ≥4)	29.3	40.2	0.008
presence of Amsel criterion for clue cells	38.0	48.4	0.014





VivaGel® BV: Significant and sustained benefits in what matters to patients – Odour



*"**It is absolutely horrible**... I can smell myself, it is the most embarrassing thing ever."*

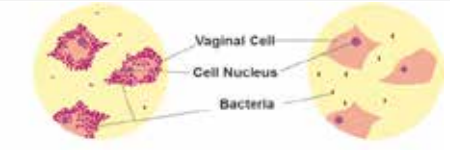
*"I don't like it. I don't like the way it feels because I feel like **I'm not normal**."*

Verbatim comments from BV sufferers in VivaGel® BV clinical trials

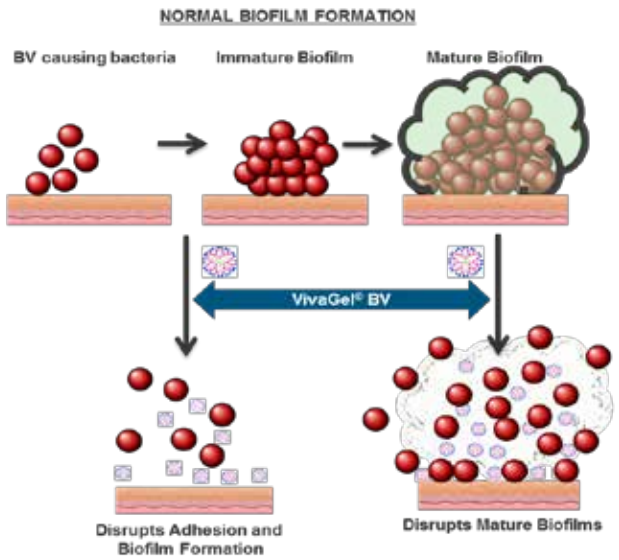
- Odour is the most concerning and distressing symptom women with BV describe
- VivaGel® BV resulted in statistically significant benefits in suppressing odour throughout the treatment period
- The **benefit was sustained with a significant benefit seen to the end of the trial - 12 weeks post cessation of treatment** at 28 weeks P<0.05 vs placebo)

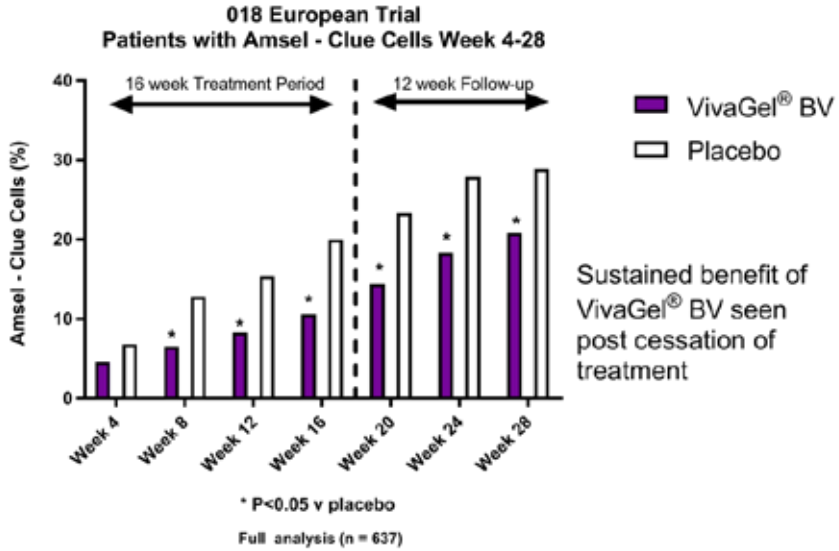
VivaGel® BV: Effect on bacterial biofilm/adhesion

Compelling clinical data supporting biofilm mechanism of action



Graphical representation of Clue cells





It is certain that ***BV involves the presence of a thick vaginal multi-species biofilm,*** *where G.vaginalis is the predominant species ….* ***standard antibiotics, like metronidazole, are unable to fully eradicate the vaginal biofilm,*** *which can explain the high recurrence rates of BV*[1]

Studies have shown that SPL7013 has the ability to inhibit formation of biofilms, and to physically disrupt preformed biofilms

- Clue cells are vaginal epithelial cells coated with bacteria and are one of the diagnostic criteria (Amsel) for a clinical diagnosis of BV
- VivaGel® BV treatment had a significant impact on Clue Cells v Placebo (P<0.05) – and benefit that was sustained post cessation of treatment at week 28

1: Machado et al. 2016. Bacterial Vaginosis Biofilms: Challenges to Current Therapies and Emerging Solutions. Frontiers in Microbiology, vol 6.
2: Scott et al. 1987. In vitro adhesiveness and biotype of Gardnerella vaginalis strains in relation to the occurrence of clue cells in vaginal discharges. Genitourin Med. Feb; 63(1): 47–53.

VivaGel® BV: a highly attractive commercial proposition

- Successful phase 3 trial results
  - VivaGel® BV has demonstrated compelling efficacy in all six primary and secondary efficacy measures
  - Seen consistently in both trials
- VivaGel® BV represents a highly attractive commercial proposition especially:
  - given it will be first in class for the prevention of recurrent BV and also proven clinically for the Treatment of BV
  - offers an alternative to conventional antibiotic therapies for BV with a novel mechanism of action on biofilm
- NDA for VivaGel® BV for both treatment and recurrent BV is well-advanced, and this data is highly supportive of marketing applications and will be used to complete the clinical package for submission
  - leverage the SPA, QIDP designation and Fast Track status
  - package for submission to the FDA and other regulatory authorities

Outlook

VivaGel® Portfolio

- NDA for VivaGel® BV – treatment and prevention
- Launch of VivaGel® BV in Australia, Europe and elsewhere
- Further regulatory approvals for VivaGel® BV
- Further licenses for VivaGel® BV marketing (multiple territories)
- Launch of VivaGel® condom in Europe, Japan, China and elsewhere
- Further regulatory approvals and geographic roll-out of the VivaGel® condom

DEP® Drug Delivery

- Completion of DEP® docetaxel Phase 1 clinical trial and commencement of Phase 2 for DEP® docetaxel
- AstraZeneca program developments – milestones, further compounds advanced and expanded licences
- DEP® cabazitaxel Phase 1 trial commencement
- Other DEP® candidates developed and advanced to the clinic (e.g. DEP® irinotecan)
- Targeted DEP® program developments and licences
- Other partnered DEP® deals

Deep portfolio of products targeting large, high-value markets

VivaGel® Portfolio

DEP® Drug Delivery

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