

# Starpharma's DEP<sup>™</sup> eliminates cabazitaxel neutropenia

**Melbourne, Australia; 25 May 2016:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced that Starpharma's DEP<sup>™</sup> cabazitaxel eliminated neutropenia typical of cabazitaxel (Jevtana<sup>®</sup>) in a preclinical study (see Figure 1). Neutropenia is a common and life-threatening side-effect of currently available chemotherapy drugs including Jevtana<sup>®</sup> (cabazitaxel). The data from this animal study follows on from similar findings with other DEP<sup>™</sup> candidates and recently announced findings demonstrating that Starpharma's DEP<sup>™</sup> cabazitaxel significantly outperformed Jevtana<sup>®</sup> with respect to the level and duration of anticancer activity, and overall survival (see Figure 2).

DEP<sup>™</sup> cabazitaxel is Starpharma's dendrimer-enhanced, detergent free version of the leading cancer drug, Jevtana<sup>®</sup> (cabazitaxel) which is currently registered for use in advanced prostate cancer and had 2015 sales of ~US\$430M. Jevtana<sup>®</sup>, like Taxotere<sup>®</sup> (docetaxel), is formulated using a detergent, polysorbate 80, due to its poor solubility and is associated with anaphylaxis and neutropenia. Jevtana<sup>®</sup> has a FDA "black box" warning regarding neutropenia and severe hypersensitivity to polysorbate 80. In contrast, Starpharma's DEP<sup>™</sup> cabazitaxel is water soluble and completely detergent (polysorbate 80) free.

Neutropenia, characterised by low neutrophil (white blood cell) levels in the blood, is a sign of bone marrow toxicity and the most important dose limiting toxicity (DLT) of Jevtana<sup>®</sup>. Severe neutropenia (extremely low circulating neutrophil numbers) is a life-threatening and potentially fatal toxicity that occurs in more than 80% of patients treated with Jevtana<sup>®</sup>. Neutropenia can necessitate anti-cancer treatment modification, interruption or discontinuation.

Jevtana<sup>®</sup> is currently used in the treatment of advanced prostate cancer that has worsened (progressed) after treatment with docetaxel, and is under clinical development for breast cancer and other cancers.

"These results are very pleasing for our DEP<sup>™</sup> cabazitaxel formulation, as they show the platform benefits of our DEP<sup>™</sup> dendrimers in enhancing the therapeutic window decreased bone marrow toxicity and enhanced efficacy - of drugs," said Starpharma Chief Executive Officer, Dr Jackie Fairley. "The combination of these benefits for DEP<sup>™</sup> cabazitaxel provide compelling commercial advantages. The fact that these results are similar to those seen previously with DEP<sup>™</sup> docetaxel and other classes of DEP<sup>™</sup> enhanced therapeutics demonstrates the platform nature of the DEP<sup>™</sup> technology." she added.

#### **Description of Study**

The relative toxicities of DEP<sup>™</sup> cabazitaxel and Jevtana<sup>®</sup> were compared in a preclinical study where equivalent doses (based on cabazitaxel - 2.5mg/kg) were administered to rats by intravenous injection. Blood samples were taken at day 0 prior to dosing, then at days 5, 7, 14 and 21 and cell counts undertaken. The neutrophil counts, expressed as the mean absolute count across all animals in the dose group (n=3 per group), at each time point are shown in Figure 1. These studies were conducted by an independent commercial laboratory which specializes in preclinical oncology services.



Figure 1: Neutrophil counts over 21 days (expressed as mean neutrophil counts) of animals treated with a single dose of either a vehicle control, Jevtana<sup>®</sup> or DEP<sup>™</sup> cabazitaxel, showing the lack of neutropenia in animals treated with DEP<sup>™</sup> cabazitaxel. In contrast, Jevtana<sup>®</sup>-treated rats exhibited severe neutropenia within the first week following drug treatment.



Figure 2. Efficacy of DEP<sup>™</sup> cabazitaxel vs. Jevtana<sup>®</sup> (cabazitaxel) and vehicle in preclinical model of human breast cancer. For full details refer to 4 April 2016 announcement, see <u>http://www.starpharma.com/news/277</u>

## ABOUT STARPHARMA

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has three core development programs: VivaGel<sup>®</sup> portfolio, DEP<sup>™</sup> drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead products are based on VivaGel<sup>®</sup> (SPL7013, astodrimer sodium), a proprietary dendrimer which has antimicrobial properties. VivaGel<sup>®</sup> formulated as a water based gel and delivered vaginally now has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and is under clinical development for the prevention of recurrent BV. Starpharma has signed a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel<sup>®</sup> BV in Australia and New Zealand. Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries. Inc., (TSE: JP3192800005) to market a value-added, VivaGel<sup>®</sup> condom. The VivaGel<sup>®</sup> condom is available for purchase in Australia under Ansell's Lifestyles<sup>®</sup> Dual Protect<sup>™</sup> brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles<sup>®</sup>, ZERO<sup>®</sup> and SKYN<sup>®</sup>. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

In the wider pharmaceutical field, Starpharma has both partnered and internal programs in Drug Delivery. A number of dendrimer-enhanced, or DEP<sup>®</sup> versions of existing drugs are under development. The most advanced of these is DEP<sup>®</sup> docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere<sup>®</sup>), which is in clinical development in patients with solid tumours. In preclinical studies DEP<sup>®</sup> docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere<sup>®</sup> (docetaxel). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP<sup>®</sup> drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound, with potential for follow on compounds directed at a defined family of targets.

In agrochemicals Starpharma has a series of partnerships with leading industry players including global leader Adama (formerly Makhteshim Agan) as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup<sup>®</sup>).

For more information please visit: www.starpharma.com

#### FOR FURTHER INFORMATION

#### Media:

Buchan Consulting Rebecca Wilson Mob: +61 417 382 391 rwilson@buchanwe.com.au

Arthur Chan +61 2 9237 2805 achan@buchanwe.com.au **Starpharma:** Dr Jackie Fairley, Chief Executive Officer Nigel Baade, CFO and Company Secretary

+61 3 8532 2704 investor.relations@starpharma.com www.starpharma.com

### Forward Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.