



## ASX ANNOUNCEMENT

### **DEP™ Docetaxel Trial Dose Exceeds Common Taxotere® Dose Level**

**Melbourne, Australia; 30 April 2015:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHY) today released an update to the progress of its phase 1 clinical trial of DEP™ docetaxel for advanced solid cancers. The DEP™ docetaxel dose level now exceeds the most commonly used dose for Taxotere® of 75mg/m<sup>2</sup>, with no dose limiting toxicities (DLT), including neutropenia, having been observed to date.

Approximately 50% of the anticipated number of patients have been recruited into the study and dosed with DEP™ docetaxel. Several patients have received multiple (up to 6) cycles of DEP™ docetaxel.

Available data show that DEP™ docetaxel has been very well-tolerated, with no observations of neutropenia to date. According to the available product information for Taxotere® (currently marketed docetaxel formulation), neutropenia occurs in virtually all patients given 60mg/m<sup>2</sup> to 100mg/m<sup>2</sup> of Taxotere®, and the most severe (grade 4) neutropenia occurs in 75% of patients given 60mg/m<sup>2</sup> of the product. The clinical data for DEP™ docetaxel are in line with preclinical studies in animals that showed that DEP™ docetaxel eliminated the neutropenia seen with equivalent doses of docetaxel alone whilst enhancing anticancer efficacy.

There have also been no reports in the trial of vomiting or hair loss related to the DEP™ docetaxel treatment. By comparison these events occur in a significant proportion of patients receiving Taxotere® as monotherapy.

In contrast to therapy with Taxotere®, which is formulated in polysorbate-80, a detergent that can cause significant hypersensitivity reactions, patients receiving DEP™ docetaxel therapy do not need to receive pre-treatment with corticosteroids (cortisone) because DEP™ docetaxel is detergent free. Additionally, patients receiving DEP™ docetaxel therapy have not required prophylactic treatment with anti-emetics (to stop nausea/vomiting).

Available pharmacokinetic data show, as previously reported, that DEP™ docetaxel also has the benefits of longer half-life and reduced peak concentrations of docetaxel compared to when the drug is given in its native form.

Starpharma CEO, Dr Jackie Fairley, commented: "We are very pleased that the study is progressing so well. The fact that a number of patients have exhibited potential anti-cancer activity, across a range of tumor types, despite the absence of dose limiting toxicities (DLTs) and the maximum tolerated dose (MTD) for DEP™ docetaxel not yet being reached, is very encouraging."

Taxotere® is approved for treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric cancer and head and neck cancer. Patients with a range of advanced solid tumour types are enrolled in the current study. The study is being conducted across four Australian sites – Nucleus Network/Alfred Hospital, Austin Health/Olivia Newton John Cancer Centre, Liverpool Hospital and Royal Brisbane & Women's Hospital.

In recent weeks there has been significant recent media focus on Starpharma and its DEP™ platform technology, including a report on Starpharma's DEP™ docetaxel clinical trial on National Nine News, which is available [here](#).

*Starpharma uses its DEP™ technology to improve the performance of pharmaceuticals. Both pre-clinical and early clinical data have shown DEP™ versions of drugs to be superior in a variety of ways to the unmodified drugs. DEP™ docetaxel is wholly owned by Starpharma. The company also has a number of important partnered DEP™ programs underway where Starpharma's DEP™ technology is being applied to partners' drugs to improve their performance and formulation characteristics.*

#### 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® portfolio, DEP™ 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® (SPL7013, astodrimer sodium), a proprietary dendrimer which is a potent microbicidal agent. VivaGel® formulated as a water based gel and delivered vaginally is under clinical development for the management and prevention of bacterial vaginosis (BV). Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries. Inc., (TSE: JP3192800005) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia under Ansell's Lifestyles® Dual Protect™ brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Drug Delivery partners include GSK, Lilly and AstraZeneca. A number of dendrimer-enhanced, or DEP™ versions of existing drugs are under development. The most advanced of these is DEP™ docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®), which is in clinical development. In preclinical studies DEP™ 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® (docetaxel).

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®).

## FOR FURTHER INFORMATION

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### Forward Looking Statements

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