



ASX ANNOUNCEMENT

Starpharma commences Dendrimer-Docetaxel clinical trial

Melbourne, Australia; 23 January 2014: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has received the necessary approvals to commence a phase 1 human clinical trial for its dendrimer-enhanced docetaxel (Taxotere®) chemotherapeutic product, referred to as DEP™-Docetaxel.

The trial will be conducted exclusively in Australia, at Nucleus Network's clinical facility at the AMREP/Alfred Hospital initially, with the plan to add 1 to 2 additional sites in the near future. The study will enrol approximately thirty patients with solid tumours. The primary objective of the study is to establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT) of DEP™-Docetaxel, a new formulation of the major chemotherapeutic agent, docetaxel, which is marketed worldwide under the tradename, Taxotere®. The study will also include a preliminary assessment of the anti-cancer efficacy of DEP™-Docetaxel.

Earlier preclinical studies of Starpharma's DEP™-Docetaxel demonstrated the significantly superior anti-cancer effectiveness of the product compared to Taxotere® across a range of important cancer types including breast, prostate, lung and ovarian cancer. In addition, DEP™-Docetaxel exhibited a lack of the severe toxicity, neutropenia, which is the most important dose-limiting side effect of Taxotere®. Use of Starpharma's DEP™ technology also improved the water solubility and tissue targeting of docetaxel. This improvement means that unlike other marketed formulations of docetaxel, Starpharma's DEP™-Docetaxel is detergent (Polysorbate 80) free, delivering a number of potential patient tolerability and safety advantages compared to other formulations.

Starpharma Chief Executive, Dr Jackie Fairley said: "The commencement of this clinical trial of DEP™-Docetaxel represents a key development milestone for this product and follows very strong preclinical results, which have included both improved efficacy and the reduction in important dose limiting side effects."

"The multiple, clinically significant benefits of Starpharma's DEP™-Docetaxel will place the product in a very compelling competitive position. In addition, findings from this trial have potential flow-on benefit for Starpharma's dendrimer platform more broadly, particularly in oncology," said Dr Fairley.

DEP™-Docetaxel is the first clinical candidate using Starpharma's dendrimer based DEP™ technology. The features of these products allow them to access a streamlined development pathway compared to a completely novel product.

The primary objective of the clinical study is to establish the maximum tolerated dose (MTD) and dose limiting toxicities (DLT) of DEP™-Docetaxel given intravenously (IV), once every three weeks. The secondary objective is to identify the safety, pharmacokinetic and tolerability profile of DEP™-Docetaxel in patients with advanced cancer. Key outcomes of the study will be to define a recommended dose for future studies as well as to explore preliminary anti-tumour efficacy of the product.

Importantly, the study will also allow investigation of the impact of the improved dendrimer formulation on problematic side effects seen with Taxotere®, such as neutropenia, which was markedly reduced with the dendrimer formulation in preclinical studies, anaphylaxis and hair loss. The study will also employ a variety of imaging techniques and specific investigations aimed at exploring anti-tumour efficacy. These include CT scans and bone scans, as well as tumour markers.

Consultant Oncologist, Dr Jason Lickliter, MBBS, PhD, FRACP, Director, Phase 1 Cancer Trials Program, Southern Health and Monash Institute of Medical Research, and Medical Director, Nucleus Network, has been appointed as the study Principal Investigator.

Starpharma's dendrimer-based drug delivery DEP™ technology has been utilised to reformulate and improve a number of marketed cancer drugs including docetaxel (Taxotere®), oxaliplatin (Eloxatin®) and doxorubicin. Preclinical studies of the dendrimer-enhanced versions have shown these reformulated DEP™ versions of the drugs to be superior to the commercially available formulation, often in multiple ways including improved efficacy, reduced toxicity and lower side effects. Starpharma also has several partnered programs with leading pharma companies, including in oncology.

Expenditure on this trial will be eligible for the 45% refundable R&D tax incentive.

Docetaxel is a leading chemotherapy drug used to treat a wide range of solid tumours including breast, lung and prostate. It is marketed by Sanofi Aventis as Taxotere® and generated sales in excess of US\$3 billion in 2010.

For further detail on the clinical study, refer to the attached appendix.

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 uses. Starpharma has three core development programs: VivaGel® portfolio, drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead product is VivaGel® (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel® is under clinical development for the treatment and prevention of bacterial vaginosis (BV). Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries Inc (Tokyo Stock Exchange) to market a value-added, VivaGel®-coated condom. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, 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 Nufarm (ASX:NUF) and 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

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.

Appendix

Study Title: A phase I dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of DEP™-Docetaxel (a docetaxel (DTX)-dendrimer conjugate) in patients with advanced solid tumours.

Primary Objective: To establish the maximum tolerated dose (MTD) and dose-limiting toxicities (DLT) of DEP™-Docetaxel given intravenously once every 3 weeks.

Primary Endpoint: Maximum tolerated dose (MTD)

Secondary Objectives: To characterise the safety and tolerability profile of DEP™-Docetaxel in patients with advanced cancer
To characterise the pharmacokinetics (PK) of DEP™-Docetaxel
To define a recommended dose for phase 2 studies of DEP™-Docetaxel dosed IV once every 3 weeks
To explore preliminary anti-tumour efficacy

Study Design: Open-label, sequential dose-escalation study in two parts: (i) dose escalation and (ii) dose expansion. Approximately 30 patients.

Sites: Nucleus Network's clinical facility at the AMREP/Alfred Hospital; Potentially 1-2 further sites to be added.

Key Inclusion Criteria:

- Patients with histologically or cytologically confirmed advanced or metastatic cancer for which no standard or curative therapy exists.
- Life expectancy of greater than 12 weeks
- Measurable or evaluable disease by RECIST.