



ASX ANNOUNCEMENT

DEP™ docetaxel shows intended longer duration and increased exposure

Melbourne, Australia; 20 October 2014: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced it has completed preliminary analyses of the pharmacokinetics (PK) of DEP™ docetaxel from the ongoing Phase 1 human clinical trial using results from the first cycle of dosing for several patients.

The preliminary PK findings confirm in humans a number of beneficial product features that were also seen in earlier preclinical studies. These beneficial features of DEP™ docetaxel, when compared with the reference drug, Taxotere®, include a very substantially extended duration of exposure, greatly increased extent of total exposure to drug, and reduced peak levels of drug.

DEP™ docetaxel is Starpharma's patented formulation of the widely used cancer drug docetaxel and utilises the Company's proprietary dendrimers to improve its delivery. In preclinical studies DEP™ docetaxel demonstrated significantly improved anti-cancer efficacy and reduced toxicity and the current clinical trial is being conducted to assess DEP™ docetaxel in cancer patients.

Starpharma CEO, Dr Jackie Fairley, said:

"The PK profile seen with DEP™ docetaxel in humans is very pleasing. It fits very well with our preclinical data and these findings also support the likely explanations for the improved efficacy and improved tolerability previously seen with DEP™ docetaxel in animal models. It's really pleasing to see the PK results in humans lining up so well in this respect.

To date in the trial, there have been no reports of drug-induced nausea, hair loss, fluid retention, or indeed neutropenia, which is the most important dose-limiting toxicity for Taxotere®."

These PK data indicate that when equivalent¹ doses of Taxotere® and DEP™ docetaxel are intravenously administered to patients, DEP™ docetaxel results in a much greater exposure to the cancer drug, docetaxel. This outcome could be expected to result in higher levels of exposure of cancer tissue to the drug. This increased drug exposure is in addition to the significant cancer-tissue targeting observed with DEP™ docetaxel in preclinical studies.

In addition, the peak level (or C_{max} ²) of docetaxel achieved with DEP™ docetaxel administration is lower, as intended, and exposure to docetaxel occurs over a much longer period of time, due to release of docetaxel from the dendrimer occurring gradually. This gradual release PK profile afforded by DEP™ docetaxel indicates that the dendrimer is

¹ Equivalent with respect to dose (mg/m^2) of docetaxel.

² C_{max} is the maximum plasma concentration of the drug.

acting as a depot for docetaxel, avoiding the initial excessive spike in plasma docetaxel levels observed following dosing with Taxotere[®].

Key findings of the pharmacokinetic analyses include:

Extended duration of exposure with DEP[™] docetaxel

The plasma half-life³ of docetaxel when administered as DEP[™] docetaxel is substantially longer (~8 times on average) than the plasma half-life of the equivalent dose of the approved form of docetaxel, Taxotere[®].⁴ When compared with the initial rapid phases of docetaxel (Taxotere[®]) plasma clearance, the current data show that the plasma half-life of DEP[™] docetaxel is approximately 150 times longer. Plasma half-life is a parameter used to evaluate the duration of drug level in the blood.

The extended plasma half-life of docetaxel when administered as DEP[™] docetaxel reflects the gradual release of docetaxel from the dendrimer and indicates that there is an extended duration of exposure to docetaxel compared with Taxotere[®].

Increased extent of exposure with DEP[™] docetaxel

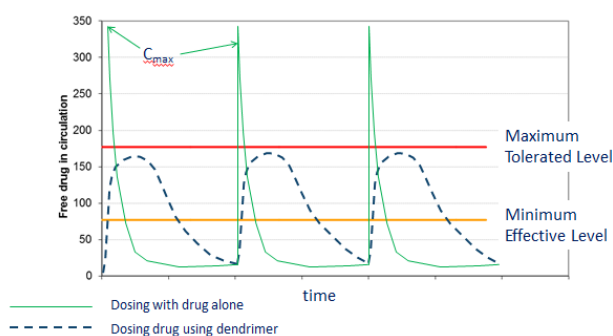
For a given dose of DEP[™] docetaxel, the extent of drug exposure, measured as the Area Under the Curve⁵ for total docetaxel, is ~500-800 times higher for DEP[™] docetaxel than the extent of drug of exposure (AUC) for an equivalent dose of docetaxel administered as Taxotere[®].

This finding reflects the gradual release of docetaxel from the dendrimer and indicates that the DEP[™] docetaxel molecule is a 'depot' of docetaxel (i.e., dendrimer-bound docetaxel) circulating for an extended period of time.

Reduced peak drug levels with DEP[™] docetaxel

For a given dose of DEP[™] docetaxel, the peak blood level (or C_{max}) of docetaxel is substantially (~50-100 times) lower than the C_{max} of an equivalent dose of docetaxel administered as Taxotere[®]. The lower C_{max} for docetaxel administered as DEP[™] docetaxel compared to an equivalent dose of docetaxel administered as Taxotere[®] avoids the sometimes problematic "spike" in drug levels (see schematic representation below). The lower C_{max} is due to the gradual release of docetaxel from the dendrimer).

Schematic Illustration: Drug levels over time with a dendrimer version (e.g. DEP[™] docetaxel) and reference drug alone (ie. Taxotere[®])



³ **Plasma half-life** for the purposes of these analyses is defined as the time required for the concentration of the drug to fall to half of its concentration in the blood after reaching a steady-state.

⁴ Taxotere[®] parameters based on published data (Bruno et al, 1996).

⁵ **Area under the curve, or AUC**, is a measure of total drug exposure. It is derived from plasma drug concentration and time so reflects how much and for how long a drug stays in a body.

Docetaxel is a leading cancer 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.

In earlier preclinical studies, Starpharma's DEP™ docetaxel demonstrated the significantly superior anti-cancer effectiveness 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 Taxotere® and other marketed formulations of docetaxel, Starpharma's DEP™ docetaxel is also detergent (polysorbate 80) free, delivering a number of potential patient tolerability and safety advantages compared to other formulations.

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, 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, astodimer 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. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, ZERO® and SKYN®.

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

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.