Starpharma’s docetaxel demonstrates targeted tumour delivery

Melbourne, Australia; 29th October 2012: Starpharma Holdings Ltd (ASX:SPL; OTCQX: SPHRY) today reported significant tumour-targeting results with its proprietary dendrimer-docetaxel formulation.

In recent animal studies Starpharma’s docetaxel formulation resulted in levels of the cancer drug docetaxel in tumour tissue more than 40 times greater than levels seen with the conventional formulation of docetaxel (Taxotere®). This far greater accumulation of the drug in the tumour tissue compared to the current Taxotere® formulation is evidence of the significant tumour-targeting effect of Starpharma’s dendrimer formulation.

Docetaxel is a leading chemotherapy drug used to treat a wide range of tumours including breast, lung and prostate. The original formulation is commercially registered as Taxotere® and marketed by Sanofi Aventis with sales in excess of US$1 billion in 2011.

Starpharma’s proprietary formulation, which the company plans to take into the clinic in 2013, has now demonstrated the following key benefits compared with docetaxel:

1. Improved tumour targeting;
2. significantly improved efficacy in a breast cancer model;
3. extended half-life; and
4. water-soluble formulation (removing the need for certain toxic excipients).

Starpharma’s dendrimer-docetaxel formulation also showed a 60 fold increase in the plasma half-life compared to Taxotere®. A lengthened half-life (or how long it lasts in the blood) enables sustained exposure of the chemotherapy drug to the tumour tissue which helps to fight the cancer more effectively.

Dr Jackie Fairley, Chief Executive Officer of Starpharma said: “These latest results showing such significant tumour-targeting with Starpharma’s proprietary formulation are really impressive. This tumour targeting finding is relevant not only to Starpharma’s docetaxel product, but also more broadly to the potential application of the delivery technology for anticancer agents in general.”

“In July we announced that Starpharma’s dendrimer-docetaxel formulation demonstrated significantly extended plasma circulation. When combined with the recent findings of targeted delivery and greater accumulation in cancer tissue, these features make for a powerful combination and viable explanation for the significantly improved efficacy we reported in February 2012.” Dr Fairley said.
Further studies are also underway with the dendrimer-docetaxel formulation including investigation of efficacy in various cancer types. These studies together with production scale up and additional investigations of various pharmacological parameters will support preparations for the Phase I human clinical study, planned for 2013.

Many of the leading cancer drugs are very compatible with dendrimer technology and the potential benefits for other anticancer drugs include increased half-life, solubility enhancement, reduced toxicity, and enhanced efficacy. Starpharma has already successfully formulated dendrimers with several other chemotherapeutic agents including gemcitabine, platinums, paclitaxel and doxorubicin, as well as various proprietary drugs from Partners.

“Dendrimers loaded with chemotherapeutic drugs can also be conjugated to therapeutic antibodies, thus opening up the potential of the very exciting field of antibody–drug conjugates,” Dr Fairley added.

Antibody-drug conjugates enable additional targeting to specific cancer cell populations in organs and metastases with potential improved efficacy and reduced toxicity.

* Experimental Methods – Mouse Biodistribution:

In this experiment mice (n=5 per group) were implanted with breast cancer cells which were allowed to grow to a predetermined size to simulate a tumour. Mice were dosed with either dendrimer-docetaxel or Taxotere® (docetaxel). Tumour tissue was collected at 3 days after dosing and assessed for docetaxel levels.
Starpharma Holdings Limited (ASX:SPL, OTCQX:SHPRY), 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) and also as a vaginal microbicide to prevent the transmission of sexually transmitted infections including HIV and genital herpes. 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. Most recently Starpharma announced pre-clinical results in its Docetaxel (Taxotere®) program demonstrating significant improvements in that agent’s anticancer efficacy and the enhancement of solubility offering potential safety benefits as well. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships with leading industry players including AstraZeneca and Nufarm (ASX:NUF) as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

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Forward Looking Statements
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