

DRUG DELIVERY UPDATE

Starpharma reports rapid advancement of drug delivery program

Key Points:

- Dendrimer-docetaxel program advancing rapidly; clinical trial expected to commence in 2013
- Successful application of dendrimers to a number of important classes of drugs including small molecules, antibodies and proteins
- Analysis shows Starpharma's dendrimers applicable to more than 50% of top-selling pharmaceuticals - highlighting versatility and potential to develop improved formulations

Melbourne, Australia; 3 July 2012: Starpharma Holdings Ltd (ASX:SPL;OTCQX: SPHRY) today provided an update on the developments within its substantial drug delivery program.

Starpharma's program to enhance the blockbuster cancer drug docetaxel is advancing rapidly and plans are underway for clinical trials to commence in 2013.

Starpharma has also demonstrated its dendrimer technology's applicability to hormones such as insulin, and antibodies, further diversifying drug delivery product potential into these high-growth segments of the market.

In addition, Starpharma continues to expand its partnered delivery programs with major pharmaceutical companies' proprietary drugs.

Docetaxel program advances towards clinic following positive preclinical results

The strong preclinical data produced by Starpharma's docetaxel formulation supports the advancement toward clinical trials. As part of this preparation Starpharma is currently scaling-up its dendrimer-docetaxel synthesis to support both further development studies and clinical trials.

Earlier this year Starpharma reported its docetaxel-dendrimer formulation had showed a substantial increase in efficacy in a breast cancer model compared to treatment with docetaxel alone. In that study 60% of animals treated with the dendrimer-docetaxel formulation had *no evidence of tumours* at 94 days into the study, whereas by that timepoint all of the Taxotere® (docetaxel) treated mice showed significant tumour regrowth or recurrence. Following these extremely positive findings the company commenced additional efficacy studies to explore the activity of Starpharma's dendrimer formulation in various cancer types and at different dose levels. These studies are ongoing and continue to progress well.

The company has recently demonstrated that the plasma half-life of its dendrimer-docetaxel formulation is 60 times longer (30 hours for the dendrimer formulation compared to 30 minutes for Taxotere[®]). This observation supports the potential for less frequent dosing and is in line with Starpharma's target product profile for the dendrimer-improved formulation.

Therefore Starpharma's dendrimer-docetaxel formulation has already demonstrated at least three important advantages over conventional docetaxel:

- Improved efficacy (demonstrated in breast cancer model)
- Longer plasma half-life, and
- Solubilisation and removal of toxic excipients (i.e. detergent) from the formulation

Dendrimer technology provides significant potential to improve a wide range of drugs

Whilst Starpharma's primary internal drug delivery program focuses on docetaxel the technology is also valuable more broadly as it can be applied to a wide variety of drugs (including proteins, antibodies, hormones) in addition to being particularly valuable in cancer treatments. The company has successfully formulated its dendrimers with several chemotherapeutic drugs including platinum compounds gemcitabine, paclitaxel (Taxol®), methotrexate and doxorubicin.

Starpharma's rapid advancement of its drug delivery program has been facilitated by running parallel internal and big pharma-partnered development projects. With many leading drugs either off-patent or nearing the end of patent lifetimes, Starpharma's technology offers a significant opportunity to develop a range of new and improved formulations which can be the basis for new patents. This potentially rich source of new products is very attractive to companies seeking to expand and manage the life-cycle of their portfolios. This strategy is also attractive as it carries lower development risk than developing completely new products.

"Based on recent successes of our anti-cancer drug delivery projects and positive developments with partners, Starpharma is investigating additional opportunities to broaden its program and target high value, market leading drugs. The evidence supports a high likelihood of Starpharma being able to enhance their properties, or widen their areas of application though the use of dendrimers," said Starpharma Chief Executive Officer Dr Jackie Fairley.

"Other priority targets - apart from docetaxel - include the major chemotherapeutics including a class of widely used, but highly toxic platinum anticancer drugs, which include carboplatin and oxaliplatin. We have also successfully formulated the leading oncology drug gemcitabine with our dendrimers.

"In addition, Starpharma has recently demonstrated the ability of dendrimers to conjugate to certain therapeutic antibodies, thus opening up the possibility of entering the very exciting field of antibody–drug conjugates."

Applying dendrimers to antibodies

Antibodies belong to a class of drug called biologics, which include some of the most targeted and effective drugs on the market today, such as Roche's highly publicised Herceptin® for the treatment of breast cancer. The area of biologics is a major growth area for modern medicine, and the commercial potential for a technology that enhances antibody activity and functionality is theoretically enormous.

"We are in a period of rapid progress with advancement in multiple areas within our drug delivery program and we continue to make good progress toward clinically validating this technology," said Dr Fairley.

Testosterone and other reformulation opportunities

The potential applications for Starpharma's dendrimers go beyond drugs to include hormones such as insulin and testosterone. Starpharma's chemistry team has recently applied its dendrimer delivery technology to create an improved formulation of testosterone. This highly water-soluble dendrimer form of testosterone would potentially permit the use of much narrower, therefore less painful, needles and may also offer other delivery benefits such as extended duration of activity.

"Whilst the USD\$1.5 billion global testosterone replacement market is dominated by transdermal products, injectable products do not suffer from concerns with secondary exposure and are therefore still important in certain settings and geographies. This example together with antibodies and cancer drugs illustrate the extraordinary versatility of Starpharma's platform technology," said Dr Fairley.

"Perhaps the best way of illustrating the potential of our drug delivery program is by considering its potential application to the world's best-selling pharmaceutical products. We recently reviewed the chemistry of the top 200 pharmaceuticals worldwide and found that more than 50% would be amenable to dendrimer conjugation. This exciting result underlines the potential value and breadth of our technology," Dr Fairley concluded.

Summary

Starpharma continues to advance its internal docetaxel program towards the clinic and to investigate a number of other actives, including antibodies. Further updates regarding Starpharma's drug delivery program will be reported in coming months.

Significant value in Starpharma's dendrimer technology is derived from both its versatility and its ability to deliver a number of important and valuable benefits for pharmaceuticals:

Feature	Potential Benefits for Patients and/or Manufacturers
Improved Drug Efficacy	More effective treatments or lower doses
Reduced Toxicity of Actives	Reduced side-effects
Improved Drug Solubilisation	Less toxic formulations (allowing removal of toxic excipients) Less painful injection formulations
Improved Pharmacokinetics	Less frequent dosing and less severe side effects
Targeted Drug Delivery	More effective treatments with reduced side effects

ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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. In addition, products for diagnostics and laboratory reagents are already on market through licence arrangements with partners including Siemens Healthcare and Merck KGaA.

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 as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

Starpharma's headquarters and research facilities are located in Melbourne, Australia

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