Starpharma advances leading cancer therapeutic in drug delivery program

- Starpharma’s dendrimers demonstrate improvements in multibillion dollar chemotherapy drug, docetaxel;
- Water solubility improved more than 2000-fold, potentially reducing serious side effects;
- Starpharma to advance a dendrimer-docetaxel formulation as a lead candidate in its drug delivery cancer program.

**Melbourne, Australia: 29 June 2011.** Starpharma Holdings (ASX: SPL, OTCQX: SPHRY) today announced the nomination of leading anti-cancer drug docetaxel as a lead candidate in its cancer drug delivery program following encouraging early results.

Docetaxel is an important chemotherapy drug to treat breast cancer, lung cancer and prostate cancer, and last year generated sales of €2.122 billion (US$3 billion).

Starpharma has been applying its dendrimer technology to the reformulation of existing cancer drugs, and following these latest results, will advance a dendrimer-docetaxel formulation to further pre-clinical studies as a lead candidate in its drug delivery cancer program.

Docetaxel reformulated with a suite of Starpharma’s dendrimers showed a 2000 to 8000-fold improvement in water solubility, potentially allowing for the development of a novel, improved formulation of this important cancer drug. It is hoped that the increased water solubility provided by Starpharma’s dendrimer technology will allow the development of a docetaxel formulation which would not require pre-medication with high doses of cortisone and would avoid the need for inclusion of formulation components thought to cause the severe allergic reactions and fluid retention experienced by some patients.

Starpharma’s strategy in advancing this candidate may be compared with that of American nano-pharmaceutical developer Abraxis with their highly successful water-soluble formulation of paclitaxel (a very similar molecule to docetaxel), Abraxane®. (Abraxis was acquired in 2010 for US$2.9 billion by Celgene.)

“The success seen with Abraxane® highlights the significant commercial opportunity of reformulated proprietary chemotherapy agents which can result in improved patient outcomes, significant product sales, and extended commercial life through new intellectual property filings,” said Starpharma CEO Dr Jackie Fairley.

“We believe a proprietary docetaxel-dendrimer formulation has a similar potential and as a result we are expanding our internal drug delivery program to fully explore this opportunity.”
Starpharma’s earlier work with other closely related cancer drugs demonstrated similar solubility improvements and other significant benefits including markedly reduced toxicities and lengthened half-life.

Starpharma’s internal program will run in parallel with its drug-delivery partnering program which includes a growing list of pharmaceutical companies including GSK and Lilly.

Starpharma has also filed a new patent application with the United States Patent and Trademark Office, incorporating recent Docetaxel data. This patent builds on extensive filings Starpharma currently holds and captures the potential uses of a class of dendrimers in a range of applications related to drug delivery, laying the groundwork to secure further intellectual property in this area.

ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimer technology for pharmaceutical, life-science and other applications. SPL has two operating companies, Starpharma Pty Ltd in Melbourne, Australia and DNT, Inc in the USA. Products based on SPL’s dendrimer technology are already on the market in the form of diagnostic elements and laboratory reagents through licence arrangements with partners including Siemens and Merck KGaA.

The Company’s lead pharmaceutical development product is VivaGel® (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV, genital herpes and bacterial vaginosis. Starpharma has a licence agreement with Durex® condom manufacturer Reckitt Benckiser to develop a VivaGel®-coated condom, and a licence agreement with Okamoto Industries Inc in relation to the VivaGel®-coated condom for the Japanese market. Okamoto is the market leader for condoms sold in Japan, the world’s second largest condom market.

Starpharma also has agreements in place with Lilly, Elanco, Stiefel Laboratories (a GSK Company), and Siemens Healthcare as well as many research collaborations with some of the world’s leading organisations in the fields of pharmaceuticals, drug delivery, cosmetics and agrochemicals.

**Dendrimer**: A type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

**American Depository Receipts (ADRs)**: Starpharma’s ADRs trade under the code SPHRY (CUSIP number 855563102). Each Starpharma ADR is equivalent to 10 ordinary shares of Starpharma as traded on the Australian Securities Exchange (ASX). The Bank of New York Mellon is the depositary bank. Starpharma’s
ADRIs are listed on International OTCQX, a premium market tier in the U.S. for international exchange-listed companies, operated by OTC Markets Group Inc. (www.otcmarkets.com).

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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 health authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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.

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1 Polyisorbate 80 in medical products and nonimmunologic anaphylactoid reactions.

Coors EA, Seybold H, Merk HF, Mahler

Polyisorbate 80 hypersensitivity reactions: a renewed call to action
LeAnn B. et al, Community Oncology, September 2010

Alternative drug formulations of docetaxel: a review.