Starpharma’s dendrimers improve efficacy of docetaxel in animals

- Starpharma’s dendrimer-docetaxel formulation significantly more effective than leading cancer drug docetaxel (Taxotere®) in breast cancer model

- More than half (60%) of animals treated with Starpharma’s dendrimer-docetaxel formulation had no evidence of tumour at 94 days whereas with docetaxel significant tumour regrowth was observed in all animals

- Starpharma’s dendrimer-docetaxel formulation improved water solubility by 5000-fold

Melbourne, Australia; 1 February 2012: Starpharma Holdings (ASX: SPL, OTCQX: SPHEY) today released animal data which demonstrated that its dendrimer-docetaxel formulation applying Starpharma’s dendrimer technology to the leading chemotherapy drug docetaxel was significantly more efficacious than docetaxel (Taxotere®) in a breast cancer model.

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.

Starpharma conducted the latest study, a breast cancer xenograft in mice, as part of its drug delivery program for docetaxel - having already demonstrated a marked improvement in the water solubility of docetaxel with its dendrimer formulation. This study was designed to assess the efficacy of Starpharma’s dendrimer-docetaxel formulations in treating cancer.

The results of this study show Starpharma’s dendrimer-docetaxel formulation demonstrated a significant enhancement of anticancer effect when compared to docetaxel/Taxotere® alone. Furthermore, 60% of animals treated with Starpharma’s preferred dendrimer-docetaxel formulation had no evidence of tumours at 94 days - whereas 100% of the docetaxel treated mice showed significant tumour re-growth or recurrence at the same time point.

Starpharma Chief Executive Officer, Dr Jackie Fairley said: “These initial results of our dendrimer-docetaxel program are extremely encouraging. To have a high proportion of animals with no evidence of tumours and a significant improvement in efficacy versus docetaxel is a great result. These findings together with the ability of Starpharma’s dendrimers to markedly improve water solubility represent a compelling product proposition.”

In the xenograft study mice were implanted with breast cancer cells which were allowed to grow to a predetermined tumour size (100 mm³) and then 10 mice per group were dosed with either dendrimer-docetaxel, docetaxel alone, or saline on days 1, 8 and 15. Tumour
volume was then assessed by manual measurement and the mean volume is plotted against time (days) in Figure 1.

![Mean Tumour Volume (MDA-MB-231)](image)

**Figure 1:** Mouse Xenograft – Breast Carcinoma (MDA-MB-231)
Mean tumour volume (mm³) v’s time (days); n=10 per group at commencement of study

For both actives the tumour volume decreased following dosing. However, by day 60 all tumours in the docetaxel group began to regrow. In contrast, in the dendrimer-docetaxel group there was no evidence of tumour regrowth up to day 94 (which is well beyond the typical duration of xenograft studies). Based on this and other data for dendrimer constructs it is believed that the improved efficacy of the dendrimer-docetaxel formulation is most likely due to a longer circulating half-life, the extended release of docetaxel from the dendrimer and the targeting of the dendrimer construct to tumour tissue.

The improvements in efficacy seen in this experiment are in addition to the benefit of improved water solubility (see below) with docetaxel announced in June 2011 which would also potentially allow the removal of formulation components in existing drugs thought to cause severe allergic reactions and fluid retention in some patients.
Starpharma’s docetaxel program will continue to run in parallel with its partnered drug-delivery programs which include a growing list of major pharmaceutical companies including GSK and Lilly. Further pre-clinical studies are now planned for the dendrimer-docetaxel formulation prior to clinical studies.

Detailed results of this study are expected to be presented at future scientific conferences.

### ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimers for pharmaceutical, drug delivery and other applications. Products based on SPL’s proprietary 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 microbicide designed to prevent the transmission of STIs, including genital herpes, HIV and treat bacterial vaginosis. Starpharma also has a licence agreement with Ansell Limited 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 commercial agreements in place with Lilly, Elanco, GSK, 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.

A dendrimer is a type of precisely-defined, highly branched nanoscale polymer.

**American Depositary 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). Starpharma’s ADRs are listed on International OTCQX, a premium market tier in the U.S. for international exchange-listed companies.

### FOR FURTHER INFORMATION

**Media:**

**Buchan Consulting**  
Rebecca Wilson  
Mob: +61 417 382 391  
rwilson@buchanwe.com.au

Haley Price  
Mob: +61 423 139 163  
hprice@buchanwe.com.au

**Starpharma:**

Dr Jackie Fairley, Chief Executive Officer  
+61 3 8532 2704

Ben Rogers, Company Secretary  
ben.rogers@starpharma.com

www.starpharma.com

**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.