

DEP® docetaxel and gemcitabine combination trial commences

- Starpharma has commenced its DEP® docetaxel + gemcitabine combination study, to run in parallel with its phase 2 DEP® docetaxel trial
- Advancement of the combination study follows impressive data for DEP® docetaxel + gemcitabine in combination in preclinical human pancreatic cancer models
- Clinical data for DEP® docetaxel + gemcitabine will feed into commercial discussions and further enhance the commercial potential of DEP® docetaxel

Melbourne, Australia; 30 July 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has commenced its DEP® docetaxel + gemcitabine combination study for patients with advanced cancers, including pancreatic cancer. Recruitment into the study has commenced at the Christie in the UK, with two further sites expected to open in the coming weeks.

This study will recruit an initial cohort of approximately 10-12 patients and will run in parallel with the phase 2 DEP® docetaxel trial. The study will explore the potential benefits of DEP® docetaxel in combination with gemcitabine (Gemzar®) and builds on the impressive performance of DEP® docetaxel combined with gemcitabine in a preclinical human pancreatic cancer model, as [reported previously](#). In that study DEP® docetaxel in combination with gemcitabine resulted in complete tumour regression and 100% survival, significantly outperforming each standard treatment, gemcitabine and Abraxane® alone and in combination.

Pancreatic cancer is a leading cause of cancer deaths, with a one-year relative survival rate of 20%, and a five-year survival rate of only 7%. Gemcitabine is commonly used both alone and in combination with Abraxane® in pancreatic cancer as a first line treatment. Current therapeutic approaches for pancreatic cancer have significant bone marrow toxicities. An important feature of DEP® docetaxel is a significant reduction in bone marrow toxicity observed in both preclinical and clinical studies.

Gemzar® (gemcitabine) is one of the leading chemotherapeutics used to treat pancreatic cancer. It can be administered as a monotherapy or in combination with other therapies such as taxanes (e.g. Abraxane®). Annual sales of Abraxane® are approximately US\$1.2 billion. Gemcitabine, which is now generic, had peak sales prior to patent expiry of US\$1.7 billion.

Dr Jackie Fairley, Starpharma CEO, commented: “We have had enthusiastic feedback from clinicians for this combination given the bone marrow toxicities experienced with current pancreatic cancer therapies. Therefore, there is a significant unmet need in advanced pancreatic cancer and data from this study are expected to further enhance the commercial potential for DEP® docetaxel.”

This combination study will run in parallel with the phase 2 DEP® docetaxel trial program, which is currently recruiting at sites in the UK and continues to show encouraging efficacy signals including stable disease and substantial target tumour shrinkage in patients with cancers including lung, prostate, pancreatic, gastric and oesophageal.

About DEP[®] docetaxel and gemcitabine (Gemzar[®])

DEP[®] docetaxel is a detergent-free nanoparticle formulation of the widely used anti-cancer drug, docetaxel (Taxotere[®]), and is currently in phase 2. Docetaxel is one of the most widely used cancer drugs for treatment of a wide range of solid tumours including breast, lung and prostate. It is marketed by Sanofi Aventis as Taxotere[®] and generated peak global sales in excess of US\$3 billion. These products have US Food and Drug Administration (FDA)-mandated 'black box' warnings due to serious adverse events including neutropenia and anaphylaxis.

Gemcitabine is a major anti-cancer drug and Lilly's Gemzar[®] had peak sales prior to patent expiry of US\$1.7 billion. Gemcitabine is one of the leading chemotherapeutic drugs used to treat cancer of the pancreas, bladder, ovary and breast, and non-small cell lung cancer. Gemcitabine is used as a first-line treatment alone for pancreatic cancer, and in combination with other anti-cancer medicines, such as taxanes.

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 two core development programs: VivaGel[®] portfolio and DEP[®] drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel[®]: Starpharma's women's health product - VivaGel[®] BV is based on SPL7013, astodimer sodium, a proprietary dendrimer. VivaGel[®] BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem[®] BV Gel (UK), Betadine BV[™] (Europe), Betadine[™] BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel[®] BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel[®] condom (an antiviral condom which includes VivaGel[®] in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel[®] condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect[®] brand. The VivaGel[®] condom is approved in Europe.

DEP[®] - Dendrimer Enhanced Product[®]: Starpharma's DEP[®] drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP[®] programs, including improved efficacy, safety and survival. Starpharma has three internal DEP[®] products – DEP[®] docetaxel, DEP[®] cabazitaxel and DEP[®] irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP[®] programs include a multiproduct DEP[®] licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP[®] version of one of AstraZeneca's major marketed oncology medicines.

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Disclosure

This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

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.