

DEP® gemcitabine outperforms Gemzar® in human pancreatic cancer model

- **Starpharma advances a new internal DEP® candidate, DEP® gemcitabine, into development**
- **DEP® gemcitabine demonstrated significantly enhanced anti-tumour activity compared with Gemzar® (gemcitabine), both alone and in combination with Nab-paclitaxel (Abraxane®), in a human pancreatic cancer model**
- **Gemzar® (gemcitabine), used alone or in combination with Abraxane®, is the current standard of care therapy for pancreatic cancer**
- **A patent has been filed for Starpharma's proprietary DEP® gemcitabine, providing coverage to 2040**

Melbourne, Australia; 31 October 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced results for its next internal development candidate, DEP® gemcitabine.

Starpharma's proprietary DEP® gemcitabine demonstrated significantly enhanced anti-tumour activity compared with Gemzar® (gemcitabine), both alone and in combination with Nab-paclitaxel (Abraxane®) in a preclinical human pancreatic cancer model. This data has formed the basis of a new patent application, which will provide coverage over DEP® gemcitabine to 2040. DEP® gemcitabine is one of several internal DEP® candidates under preclinical development by Starpharma.

DEP® gemcitabine is a DEP® version of Lilly's Gemzar® (gemcitabine) - a well-established anti-cancer drug, which had peak sales of US\$1.7 billion. Gemzar® (gemcitabine) is one of the leading chemotherapeutic drugs used to treat pancreatic cancer. It can be administered as a monotherapy or in combination with other therapies such as Abraxane®.

DEP® gemcitabine demonstrated significantly improved anti-tumour activity, compared to Gemzar®, the standard form of gemcitabine, in the human pancreatic cancer xenograft model ($p < 0.0001$). When used in combination with Abraxane®, DEP® gemcitabine significantly outperformed a combination of Gemzar® (gemcitabine) and Abraxane ($p < 0.005$).

Pancreatic cancer is a leading cause of cancer death, with a 1-yr survival rate of 20%, and a 5-yr survival rate of only 7%, with current therapeutic approaches (gemcitabine and Abraxane®) having significant bone marrow toxicities. An important attribute of DEP® products is a lack of bone marrow toxicities in both preclinical and clinical studies.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to be progressing yet another internal candidate through development and to have achieved such impressive results in this important cancer type with otherwise limited options for patients."

Study Results

DEP[®] gemcitabine vs Gemzar[®] alone

DEP[®] gemcitabine showed significantly enhanced tumour inhibition as compared to standard gemcitabine (Gemzar[®]) in this human pancreatic cancer (CAPAN-1) xenograft model ($p < 0.0001$; figure 1).

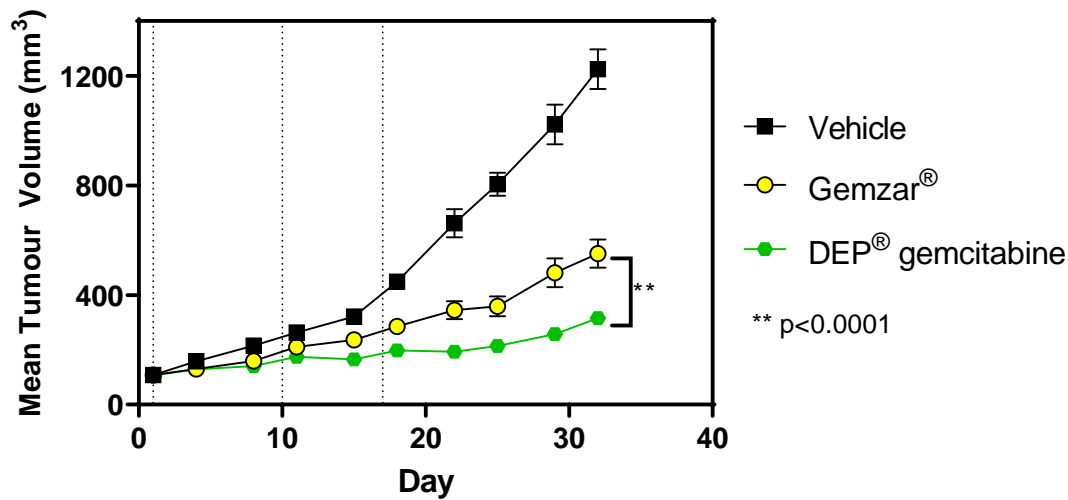


Figure 1: Enhanced efficacy of DEP[®] gemcitabine, compared to standard gemcitabine, in a human pancreatic cancer model (CAPAN-1)

DEP[®] gemcitabine + Abraxane[®] vs Gemzar[®] + Abraxane[®] combination

The anti-tumour effect of the DEP[®] gemcitabine + Abraxane[®] combination was significantly better than for the Gemzar[®] (gemcitabine) + Abraxane[®] combination ($P < 0.005$).

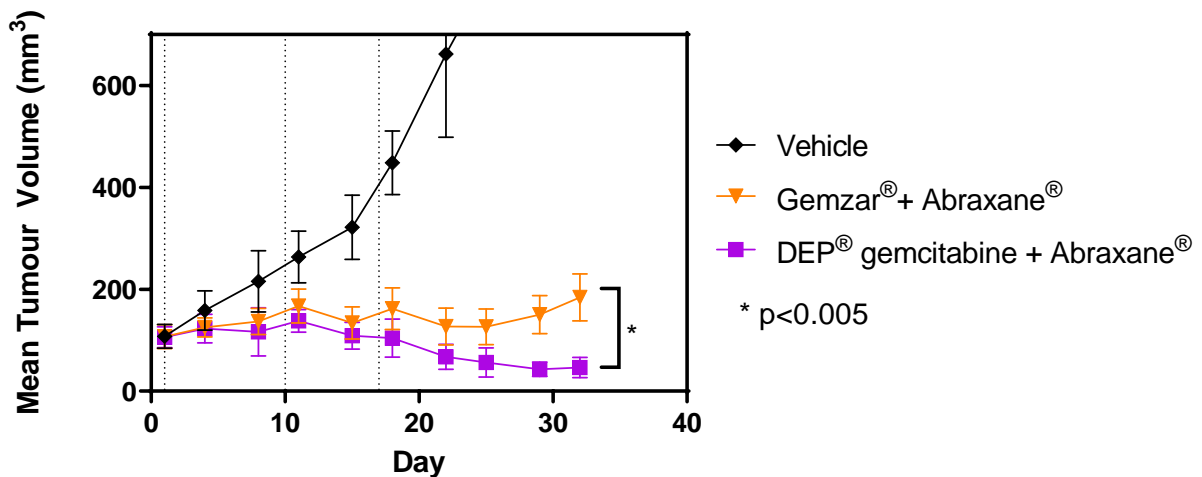


Figure 2: Enhanced efficacy of DEP[®] gemcitabine + Abraxane[®], compared to standard gemcitabine + Abraxane[®], in a human pancreatic cancer model (CAPAN-1)

Study Methods

The mouse xenograft study used CAPAN-1 human pancreatic cancer cells and was conducted for Starpharma by an internationally recognised translational cancer group. A xenograft study uses human cancer cells, which are then implanted in a mouse, and is a well-established means of assessing efficacy of anti-cancer therapies before clinical trials.

Balb/c mice were inoculated subcutaneously with the human pancreatic cancer (CAPAN-1) cells (10 mice/group). Mice were dosed with saline (vehicle), DEP[®] gemcitabine¹, standard gemcitabine (Gemzar[®]) (120 mg/kg) and Abraxane[®] (40mg/kg) IV on days 1, 10 and 18.

Tumours were measured twice weekly using electronic callipers. Tumour volume (mm³) was calculated as length (mm)/2 x width (mm)². Tumour growth inhibition data was analysed in GraphPad Prism and statistical analysis of treatment groups v vehicle control was one-way ANOVA with Dunnett's multiple comparison test. Statistical analysis between different groups was conducted via a one-way ANOVA with Sidak's multiple comparison test. The tumour volume data represent the mean ± standard error of the mean (SEM). Note: If error bars do not display on the graphs, they are not visible because they are shorter than the height of the symbol.

About Gemzar[®] (Gemcitabine)

Gemzar[®] (gemcitabine) is a chemotherapy drug 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 Abraxane[®] for the treatment of metastatic Adenocarcinoma of the pancreas. Gemcitabine also has a role in the treatment of metastatic bladder cancer, advanced or metastatic non-small cell lung cancer, ovarian cancer and breast cancer. Myelosuppression is the principal dose-limiting toxicity with gemcitabine.

About Starpharma's DEP[®] platform

Starpharma's internal pipeline includes a number of pre-clinical DEP[®] candidates, including DEP[®] gemcitabine, as well as three clinical stage assets - DEP[®] docetaxel, DEP[®] cabazitaxel and DEP[®] irinotecan. A fourth DEP[®] drug, DEP[®] AZD0466 (AstraZeneca's Bcl2/xL DEP[®] program), is expected to enter the clinic later this year.

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 name Betadine BV™ (Europe) and Fleurstat BVgel (Australia) 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.

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

¹ For intellectual property reasons, doses of DEP[®] gemcitabine are not disclosed

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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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.