

DEP[®] irinotecan outperforms in pancreatic cancer model

- DEP[®] irinotecan alone showed complete tumour regression and 100% survival in a human pancreatic cancer model. This is compared with only very limited inhibition (and no regression) with standard irinotecan (Camptosar[®]) alone, and in combination with 5- fluorouracil (5-FU)
- The complete tumour regression induced by DEP[®] irinotecan was despite the fact that the human pancreatic cancer model used virtually did not respond to conventional irinotecan (Camptosar[®]) alone and in combination with 5-FU
- This efficacy study builds on previously announced excellent efficacy data for DEP[®] irinotecan in human colon cancer models
- Starpharma is currently completing final development activities and undertaking finished product manufacture and other trial preparations for the DEP[®] irinotecan phase 1 / 2 trial

Melbourne, Australia; 5 September 2018: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its proprietary DEP[®] irinotecan development candidate showed significant efficacy and safety benefits over standard irinotecan in combination with 5-FU in a mouse xenograft model of human pancreatic cancer (Figure 1 and 2). The human pancreatic tumour model used in this study virtually did not respond to the traditional irinotecan regimen (irinotecan + 5-FU), whereas complete tumour regression and 100% survival was achieved using Starpharma's DEP[®] irinotecan.

Pancreatic cancer is a leading cause of death among oncologic diseases, with a one-year relative survival rate of 20%, and a five-year survival rate of only 7%. Metastatic pancreatic cancer remains resistant to current chemotherapy and radiotherapy, where irinotecan containing combination therapies such as FOLFIRINOX (combination of 5-FU, leucovorin, irinotecan, and oxaliplatin) are used as a first line treatment.

Irinotecan was originally commercialised under the brand name Camptosar[®] and achieved peak annual sales of US\$1.1 billion. Irinotecan has a US FDA "Black Box" warning for both severe diarrhoea and myelosuppression (including neutropenia), making it an ideal candidate for Starpharma's DEP[®] technology.

These efficacy results build on previously announced significant efficacy and safety benefit data for DEP[®] irinotecan ([announced on 6 June 2017](#)) in a number of colon cancer models.

Dr Jackie Fairley, Starpharma CEO, commented: "These results for DEP[®] irinotecan of complete tumour regression and 100% survival are really impressive given the model used was virtually un-responsive to conventional irinotecan. Pancreatic cancer is known to have one of the lowest survival rates and remains an area of significant unmet medical need with substantial opportunity for better patient outcomes. These results provide additional validation of the DEP[®] platform's ability to significantly improve efficacy alone and in combination compared to relevant originator products."

DEP[®] irinotecan is expected to enter the clinic this financial year and will be Starpharma's third internal DEP[®] candidate to enter clinical development. In addition, Starpharma also has a number of partnerships, including a multiproduct licence with AstraZeneca for the application of the DEP[®] technology to selected oncology drug candidates. The first DEP[®] patent under this partnership was published on 31 August 2018 ([link to announcement](#)).

In this human pancreatic cancer model, conventional irinotecan (Camptosar®) alone or in combination with 5-FU displayed only limited tumour inhibition but no tumour regression whatsoever (Figure 1). In addition, conventional irinotecan alone or in combination with 5-FU showed no appreciable overall survival benefit compared to saline (Figure 2).

In contrast, Starpharma's DEP® irinotecan was significantly more efficacious than standard irinotecan alone and in combination with 5-FU, demonstrating significant anti-cancer efficacy with complete tumour regression ($P < 0.0001$) (Figure 1). These impressive findings are despite the fact that this human pancreatic cancer model virtually did not respond to irinotecan alone or in combination with 5-FU.

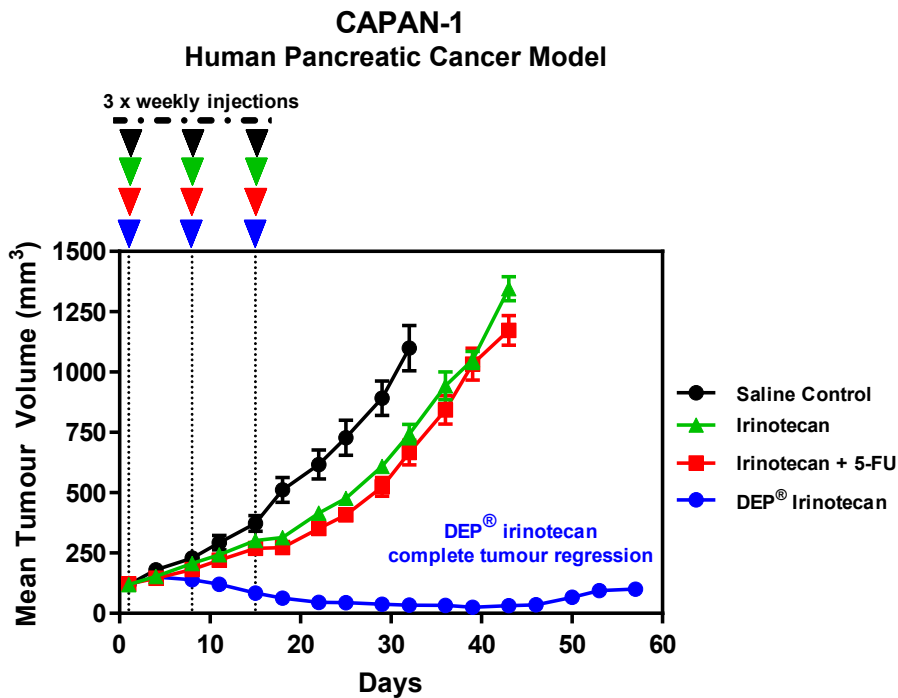


Figure 1: Mean Tumour Volume

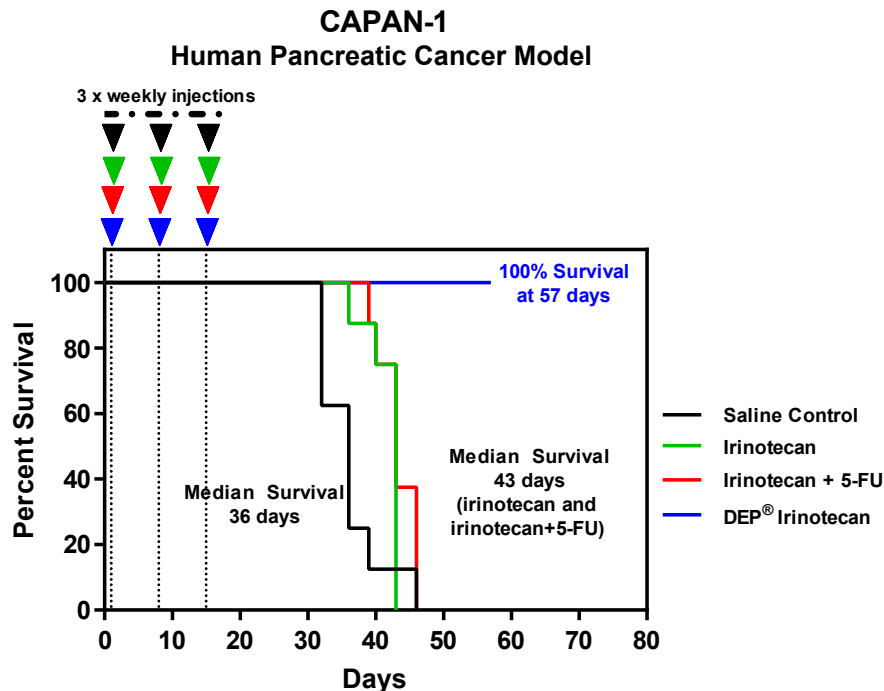


Figure 2: Kaplan Meier Survival Curve comparing DEP® irinotecan versus all other groups (P<0.0001 Log-rank Mantel Cox)

Study Methods

This study was conducted for Starpharma by a leading international cancer research institution. The NOD-scid Interleukin 2 receptor gamma chain null mice were inoculated subcutaneously with CAPAN-1 (8 mice/group, respectively). Mice were dosed with saline vehicle, DEP® irinotecan (Maximum Tolerated Dose¹), irinotecan (40mg/kg) or irinotecan + 5FU (40 and 50 mg/kg) on days 1, 8 and 15 (all drug groups). Tumour growth data were analysed in GraphPad Prism for ANOVA followed by Dunnett’s post-hoc test. The tumour volume data represent the mean ± standard error of the mean (SEM). Kaplan-Meier survival curves were analysed using the Log-rank (Mantel-Cox) test.

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 is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application is under Fast Track review by the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to 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 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 two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. 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.

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¹ Dose not disclosed pending intellectual property filings

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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.