

DEP[®] irinotecan combination outperforms in refractory human colon cancer model

- DEP[®] irinotecan, a proprietary nanoparticle formulation, in combination with cetuximab (Erbix[®]) showed complete suppression of tumour growth and 100% survival in an irinotecan-refractory human colon cancer model
- The significant antitumor effect induced by DEP[®] irinotecan was despite the fact that leading colon cancer treatments, irinotecan (Camptosar[®]) and Erbix[®], showed limited activity in this human colon cancer model
- This study builds on previously announced promising efficacy data for DEP[®] irinotecan in human colon and pancreatic cancer models
- Starpharma is currently completing final trial preparations for the DEP[®] irinotecan phase 1/2 trial expected to start mid-year

Melbourne, Australia; 24 May 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its patented nanoparticle formulation, DEP[®] irinotecan, showed significant efficacy and safety benefits over leading colorectal cancer drugs irinotecan (Camptosar[®]) and cetuximab (Erbix[®]), in the irinotecan-refractory HT-29 human colon cancer model.

These impressive results were despite the fact that these standard colorectal cancer (CRC) treatments, Camptosar[®] and/or Erbix[®], showed limited activity in this preclinical model.

Irinotecan (Camptosar[®]) is used as a component of first line therapy for the treatment of CRC, which is one of the most common cancers in the world, affecting more than 1 million individuals annually and is the third-leading cause of cancer-related death. DEP[®] irinotecan is a novel nanoparticle formulation of SN-38, the active constituent of irinotecan (Camptosar[®]), delivered using Starpharma's patented DEP[®] platform.

Cetuximab (Erbix[®]) is marketed by Eli Lilly and Merck KGaA and is indicated for use in approximately 50% of CRC cases, with US\$1.6 billion in sales in 2018. Camptosar[®] achieved peak annual sales of US\$1.1 billion.

The results for DEP[®] irinotecan in this irinotecan-refractory human colon cancer model (see figures below) build on previously announced data for DEP[®] irinotecan in multiple human cancer models. These results also add further support to the growing body of data demonstrating that DEP[®] drugs perform better when used in combination (e.g. when used with Erbix[®]) than the originator product (e.g. Camptosar[®]) used in that same combination. These results are timely given the upcoming commencement of Starpharma's DEP[®] irinotecan phase 1/2 trial.

Dr Jackie Fairley, Starpharma CEO, commented: "These impressive results for DEP[®] irinotecan once again demonstrate the significant advantage conveyed by the DEP[®] platform. Combinations using DEP[®] drugs are consistently showing better performance than the same combinations using the originator products (e.g. Camptosar[®]). These results are particularly interesting given we have also previously shown the beneficial effect of using DEP[®] docetaxel, DEP[®] cabazitaxel and AZD0466 as part of a combination therapy approach."

Study Results

In this irinotecan-refractory human colon cancer model (HT-29 xenograft), the combination of cetuximab (Erbix[®]) and irinotecan (Camptosar[®]) displayed limited tumour inhibition (Figure 1a). In contrast, DEP[®] irinotecan in combination with cetuximab (Erbix[®]) resulted in significantly enhanced anti-cancer efficacy (Figure 1a) and survival (Figure 1b) despite the DEP[®] irinotecan doses being approximately one third (low dose) and approximately two thirds (high dose) of the maximum tolerated dose for this combination¹.

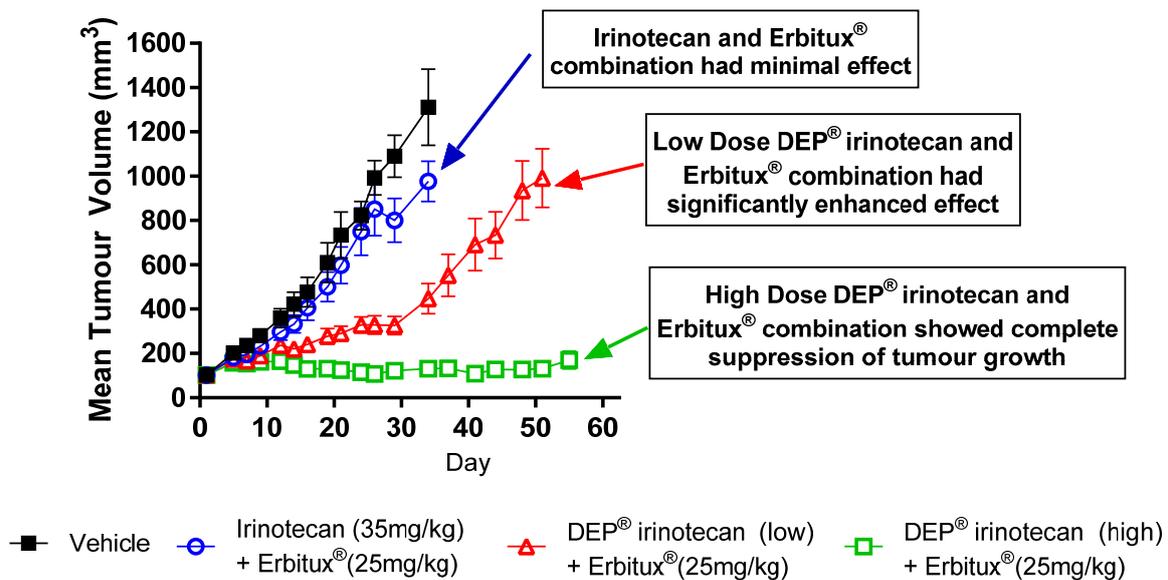


Figure 1a: Tumour volume vs time: DEP[®] irinotecan + Erbix[®] compared with irinotecan (Camptosar[®]) and Erbix[®] in combination in a mouse xenograft (human colon cancer model) ($p < 0.001$)²

¹ Doses of DEP[®] irinotecan are not disclosed for intellectual property reasons.

² Irinotecan (Camptosar[®]) and DEP[®] irinotecan dosed IV weekly, Erbix[®] dosed twice weekly IP.

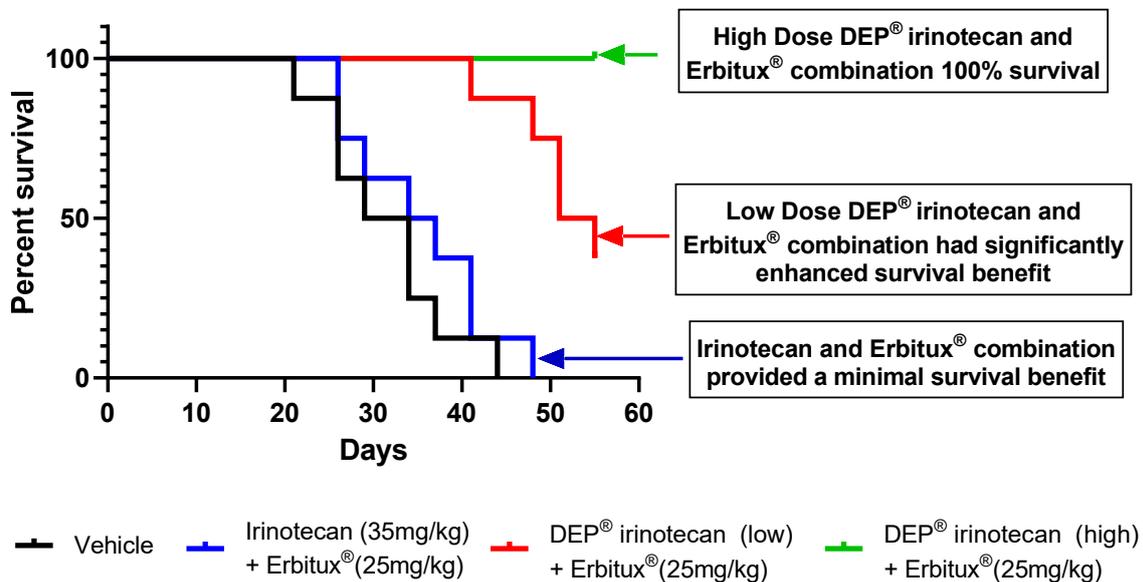


Figure 1b: Kaplan-Meier survival curve: DEP[®] irinotecan + Erbitux[®] compared with irinotecan (Camptosar[®]) + Erbitux[®] in combination in a mouse xenograft (human colon cancer model). Survival curves for both high and low doses of DEP[®] irinotecan in combination with Erbitux[®] were significantly different to irinotecan (Camptosar[®]) + Erbitux[®] (p<0.001)

Study Methods

The xenograft study used an HT-29 cell line (irinotecan-refractory human colon cancer) and was conducted for Starpharma by an internationally recognized translational cancer group as part of a wider program of studies to assess DEP[®] conjugates in combination with other leading cancer drugs. 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.

Balb/c mice were inoculated subcutaneously with the colon (HT-29) cell line (8 mice/group). Mice were dosed with saline (vehicle), DEP[®] irinotecan (low and high dose), and irinotecan (Camptosar[®]) (35 mg/kg) IV once per week and cetuximab (Erbitux[®] 25 mg/kg) IP twice per week. Irinotecan (Camptosar[®]) and cetuximab (Erbitux[®]) were dosed at the pre-determined maximum tolerated dose for the combination; however, DEP[®] irinotecan doses were approximately one third (low dose) and approximately two thirds (high dose) of the maximum tolerated dose for this combination.

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. (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 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 available for sale in Australia for bacterial vaginosis (BV) 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 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, with DEP® irinotecan due to commence clinical trials shortly. 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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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.