ASX Announcement

Positive results with Targeted DEP® using antibody fragment in human ovarian cancer model

Melbourne, Australia; 29 August 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that treatment with a novel HER-2 Targeted DEP® conjugate from its internal Targeted DEP® program resulted in tumour regression and 100% survival in a preclinical human ovarian cancer model.

This finding builds on Starpharma's previously announced Targeted DEP® data with a full-length antibody and its work in this area with Targeted DEP® (antibody-drug conjugate) partner programs. This experiment used a novel antibody fragment, which, like a whole antibody, binds actively and selectively to a specific antigen. Using antibody fragments instead of full-sized antibodies has a number of commercial and technical benefits which stem from their small size, high potency, stability and ease of manufacture.

Starpharma's HER-2 Targeted DEP® conjugate in this experiment consisted of a dendrimer scaffold, a targeting group (in this case a novel HER-2 targeted antibody fragment) and a "payload" of anti-cancer drug.

Targeted DEP® conjugates, whether using whole antibodies or their fragments, have a number of important advantages over standard antibody-drug conjugates (ADCs) that include the potential for higher drug loading, new intellectual property, easier characterisation and manufacturing advantages.

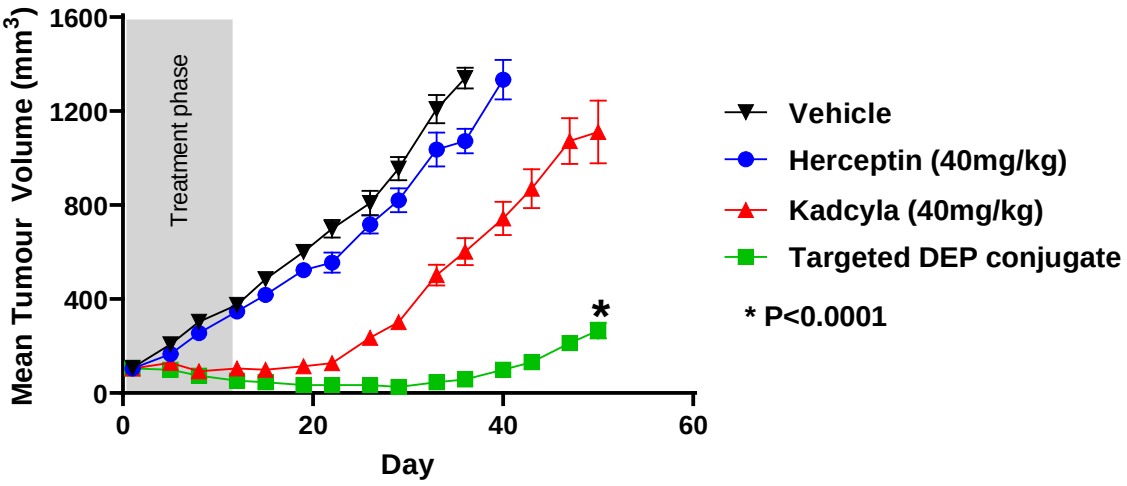
The use of ADCs in cancer therapy continues to grow, with 2018 sales of Roche's Kadcyla® now exceeding US$1 billion and Adcetris US$870 million[1]. Interest in the area also continues to grow with new ADC product launches planned. Corporate activity in the area is also strong as illustrated by the recent licensing deal between AstraZeneca and Daiichi Sankyo, with an announced value of up to US$6.9 billion for rights to a HER-2 targeted ADC[2].

Starpharma's novel HER-2 Targeted DEP® drug conjugate binds to the same target (HER-2) as the leading monoclonal antibody cancer therapy Herceptin® which had 2018 sales in excess of US$7 billion. In the study, Starpharma's novel HER-2 Targeted DEP® drug conjugate significantly outperformed both Kadcyla® (T-DM1), a HER-2 targeted antibody-drug conjugate (ADC), and Herceptin® (Trastuzumab) itself, in a human ovarian cancer model.

Anti-cancer efficacy and survival curves for Starpharma's novel HER-2 Targeted DEP® drug conjugate, Kadcyla® and Herceptin® in this human ovarian cancer model are illustrated in the graphs below.

[1] Medtrack
[2] https://www.astrazeneca.com/media-centre/press-releases/2019/astrazeneca-and-daiichi-sankyo-enter-collaboration-for-novel-her-2-targeting-antibody-drug-conjugate.html

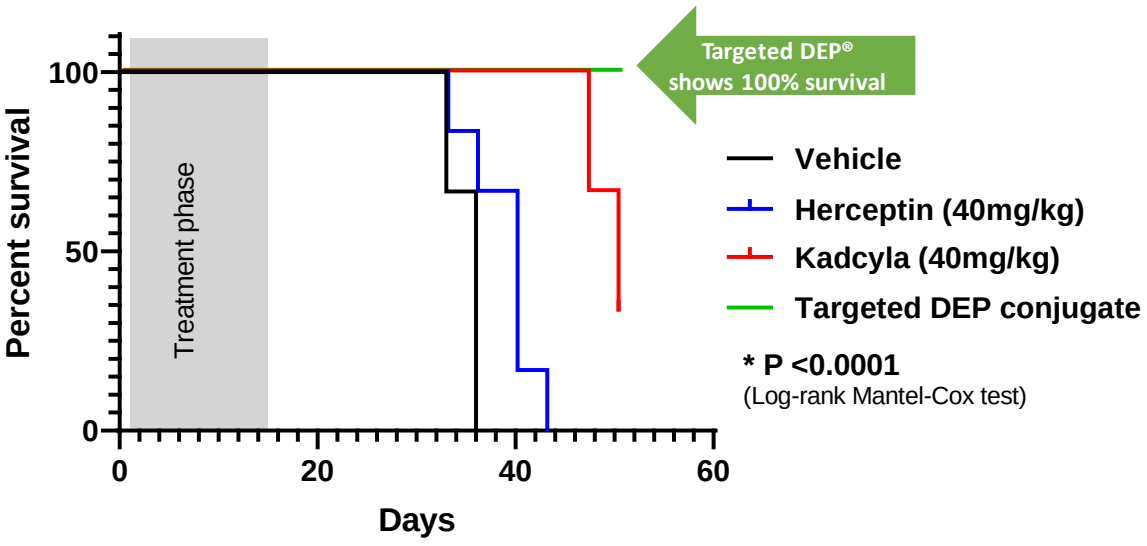
Efficacy of the novel HER-2 Targeted DEP® drug conjugate vs Kadcyla® and Herceptin® in human ovarian cancer model



The novel HER-2 Targeted DEP®-treated group[3] showed significantly improved anti-cancer effectiveness compared to both Kadcyla® (P<0.0001) and Herceptin® (P<0.0001), even after the first dose, with tumour regression seen in 100% of the novel HER-2 Targeted DEP® -treated group. In the Kadcyla® group, only tumour growth inhibition was seen and there was minimal response to Herceptin® in this xenograft model.

Kaplan Meier Survival Curve: Targeted DEP® Conjugate vs Kadcyla® and Herceptin®

Survival in the novel HER-2 Targeted DEP®-treated group was statistically significantly improved (P<0.0001), with 100% survival seen at day 50 (study still ongoing), whereas by day 50, only one third of the Kadcyla®-treated group had survived, and all of the Herceptin®-treated group had died. Survival results are presented below.



[3] For intellectual property reasons, doses of the HER-2 Targeted DEP® conjugate are not disclosed

Dr Jackie Fairley, Starpharma CEO, commented: "We're very pleased to present these impressive results for Starpharma's novel HER-2 Targeted DEP® conjugate which significantly outperforms the leading HER-2 ADC, Kadcyla®, and once again demonstrates the significant advantages conveyed by the DEP® platform. We're excited to be developing a DEP® product in such an innovative and cutting-edge area and will be exploring this and other Targeted DEP® candidates in a number of potential applications."

Starpharma is filing a patent application for this novel HER-2 Targeted DEP® conjugate.

Study Methods:

This experiment was conducted in a human ovarian cancer (SKOV-3) xenograft model in NOD SCID mice by an internationally recognised translational Cancer group. Groups of animals (6/group) were dosed once per week for 3 weeks with the novel HER-2 Targeted DEP® conjugate, Kadcyla®, or a saline control. Another group of animals was treated with Herceptin® twice a week for 3 weeks. The tumour volume data represent the mean ± standard error of the mean (SEM) and significance values determined using a Two-Way ANOVA (Tukey's post hoc). Survival analysis was carried out using Kaplan-Meier survival curves and the Log-rank test. (Note: If error bars do not display on the graphs, they are shorter than the height of the symbol and not visible.)

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, astodrimer 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 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.