



ASX ANNOUNCEMENT

DEP™ cabazitaxel shows complete and sustained tumour regression in breast cancer model

Melbourne, Australia; 4 April 2016: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced further efficacy results of its most recent DEP™ candidate, DEP™ cabazitaxel, in a human breast cancer model. These data will be presented along with an overview of Starpharma's DEP™ platform at the BioEurope Spring 2016 conference in Stockholm later this week.

DEP™ cabazitaxel is Starpharma's dendrimer-enhanced, water soluble (detergent free) version of the leading cancer drug, Jevtana® (cabazitaxel). Jevtana® is marketed by Sanofi-Aventis with 2015 sales of ~US\$430M growing at approximately 18% per annum. It is currently registered for use in advanced prostate cancer and is also under development for a number of other cancers, including breast cancer. Like docetaxel, Jevtana® (cabazitaxel) is formulated with a detergent (polysorbate 80) due to its poor solubility and can be associated with anaphylaxis and neutropenia. In contrast, DEP™ cabazitaxel is completely detergent free.

Starpharma's DEP™ cabazitaxel was compared with Jevtana® in a human breast cancer preclinical model (xenograft). DEP™ cabazitaxel significantly outperformed Jevtana® with respect to both level and duration of tumour regression (anticancer activity). Within four weeks of dosing, 100% of mice treated with Starpharma's DEP™ cabazitaxel were tumour-free and remained so for the duration of the extended study (150 days). In contrast, the Jevtana® treated group exhibited significant tumour regrowth from day 60 onwards (Figure 1). Tumour growth in both drug treated groups was significantly inhibited compared with the vehicle group ($P < 0.0001$)¹.

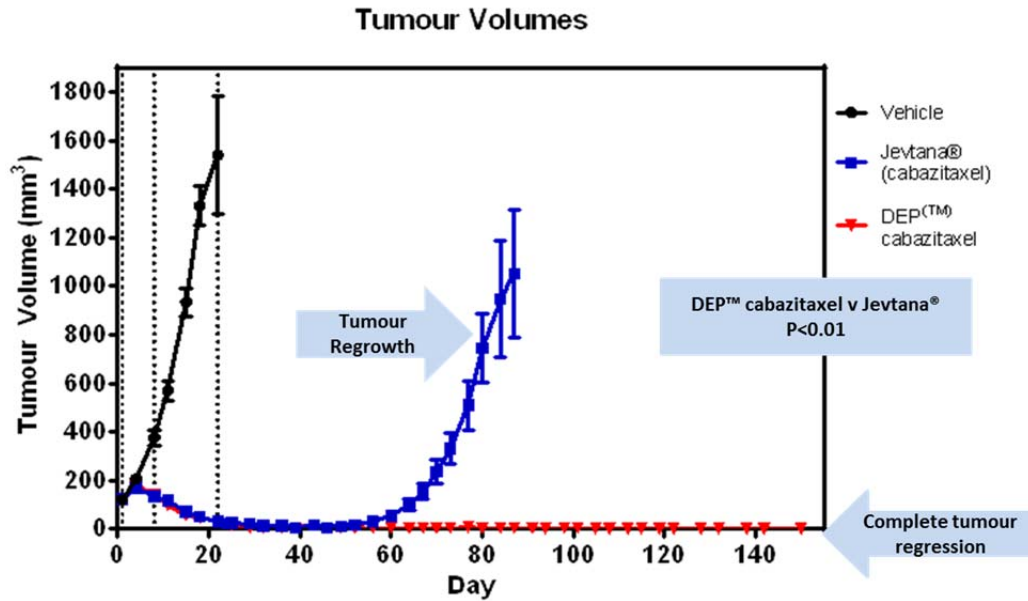


Figure 1. Efficacy of DEP™ cabazitaxel vs. Jevtana® (cabazitaxel) and vehicle in preclinical model of human breast cancer

DEP™ cabazitaxel also significantly outperformed Jevtana® in terms of survival in the model. DEP™ cabazitaxel treated animals showed 100% survival to the end of the experiment (150 days), and survival was significantly prolonged vs Jevtana® (Figure 2). The Jevtana® treatment group also had a significantly better survival outcome vs. vehicle group ($P < 0.0001$)ⁱⁱ.

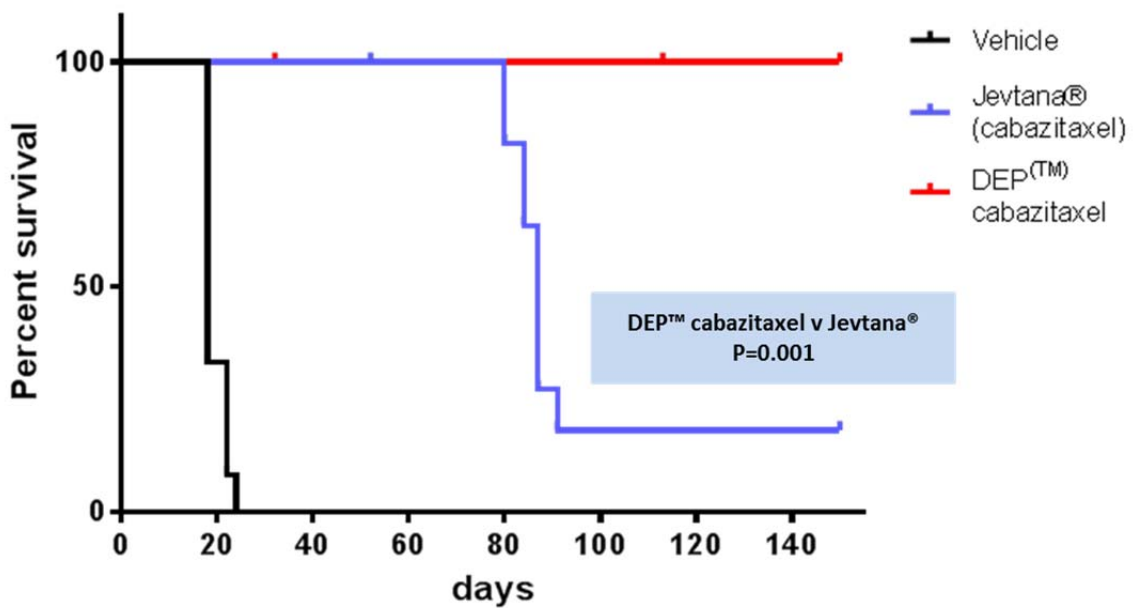


Figure 2. Kaplan Meier Survival Curve: DEP™ cabazitaxel vs. Jevtana® (cabazitaxel) and vehicle

Starpharma Chief Executive, Dr Jackie Fairley, commented, “We are very encouraged by these results for DEP™ cabazitaxel, our latest development candidate. The growing body of evidence of both efficacy-enhancement and survival benefits with DEP™ formulations is very positive and illustrates the utility and platform nature of Starpharma’s DEP™ technology.

“Early indications for DEP™ cabazitaxel are that it also demonstrates similar safety benefits to what we have seen with DEP™ docetaxel and other DEP™ conjugates in terms of reduced bone marrow toxicity. Additional benefits may also be seen as the DEP™ formulation is polysorbate 80 (detergent) free. The results from this study clearly demonstrate sustained efficacy and survival benefits for DEP™ cabazitaxel compared to Jevtana®, and follow recently-announced impressive sustained efficacy results with our HER2-targeted DEP™ conjugate.”

About Jevtana®

Jevtana® is an oncology product marketed by Sanofi-Aventis with 2015 sales of ~US\$430M growing at approximately 18% per annum. Jevtana® is currently marketed for the treatment of hormone refractory metastatic prostate cancer and is also in clinical development for a variety of cancers including breast, bladder, head and neck, and others. Jevtana® often works in docetaxel resistant cancer types, but is generally associated with greater toxicity than docetaxel. Jevtana® has a ‘Black Box’ warning for the dose-limiting toxicity, neutropenia, and warnings due to anaphylaxis from polysorbate 80.

Study Methods

This human breast cancer cell line (MDA-MB-231) xenograft study was conducted for Starpharma by an internationally recognised translational cancer group as part of a wider program of studies to assess various DEP™ conjugates. A xenograft uses human breast cancer tissue in a mouse and is a well-established means of assessing efficacy of anticancer therapies including the Taxanes (docetaxel, cabazitaxel, etc.). Balb/c mice were inoculated subcutaneously with MDA-MB-231 breast cancer tissue (12 mice/group). Mice were dosed with Saline (Vehicle), DEP™ cabazitaxel or Jevtana® on days 1, 8 and 22. The drug treated groups were dosed at the maximum tolerated dose for each agent in the species. Tumour growth data were analysed by analysis of variance (ANOVA) followed by Dunnett’s post-hoc test. Survival curves were analysed using the Mantel Cox log rank test. The data represent the mean ± standard error of the mean (SEM). The experiment was ended on day 150.

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 three core development programs: VivaGel® portfolio, DEP™ drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead products are based on VivaGel® (SPL7013, astodimer sodium), a proprietary dendrimer which has antimicrobial properties. VivaGel® formulated as a water based gel and delivered vaginally now has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and is under clinical development for the prevention of recurrent BV. Starpharma has signed a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel® BV in Australia and New Zealand. Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries. Inc., (TSE: JP3192800005) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia under Ansell's Lifestyles® Dual Protect™ brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

In the wider pharmaceutical field, Starpharma has both partnered and internal programs in Drug Delivery. A number of dendrimer-enhanced or DEP™ versions of existing drugs are under development. The most advanced of these is DEP™ docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®), which is in clinical development in patients with solid tumours. In preclinical studies DEP™ docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP™ drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound, with potential for follow on compounds directed at a defined family of targets.

In agrochemicals Starpharma has a series of partnerships with leading industry players including global leader Adama (formerly Makhteshim Agan) as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®). For more information please visit: www.starpharma.com

FOR FURTHER INFORMATION

Media:

Buchan Consulting

Rebecca Wilson

Mob: +61 417 382 391

rwilson@buchanwe.com.au

Starpharma:

Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary

+61 3 8532 2704

investor.relations@starpharma.com

www.starpharma.com

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 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.

ⁱ Statistical analysis of tumour growth inhibition was performed using ANOVA and Dunnett's post hoc test.

ⁱⁱ Statistical analysis was performed the Mantel-Cox log-rank test