



ASX ANNOUNCEMENT

Reduced neurotoxicity with SPL's dendrimer enhanced oxaliplatin

Melbourne, Australia; Monday 14 October 2013: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced further positive results for its Dendrimer-Enhanced Oxaliplatin (DEO), specifically that its dendrimer version of oxaliplatin results in a significant reduction in the serious neurotoxicity commonly seen with oxaliplatin.

Oxaliplatin is widely used primarily to treat colon and colorectal cancer and it achieved sales of approximately US\$2B in 2012. The leading brand is ELOXATIN[®] marketed by Sanofi.

Neurological adverse effects are the dose-limiting toxicity for ELOXATIN[®] (oxaliplatin) with peripheral neuropathy occurring in around 85-95% of patients¹. The neuropathy caused by the drug takes two main forms, one which is often triggered by cold and is usually transient, and another more serious form that results in chronic neuropathic pain and disturbances of nerve function which can lead to difficulties in fine motor tasks such as writing or using a computer keyboard.

In this blinded study, conducted at the University of Maryland in Baltimore², Starpharma's novel, proprietary Dendrimer-Enhanced Oxaliplatin showed significantly reduced neurotoxicity in validated animal models for both forms of these neuropathies. In fact, both neuropathies were reduced with Dendrimer-Enhanced Oxaliplatin compared to oxaliplatin alone, even when DEO was used at twice the dose of oxaliplatin.

The finding of significantly reduced neurotoxicity with DEO follows results released in September which demonstrated Starpharma's Dendrimer-Enhanced Oxaliplatin also both improved anti-cancer efficacy and resulted in reduced bone marrow toxicity, when compared to ELOXATIN[®] in a mouse model of colon cancer.

"The neuropathy which occurs commonly with oxaliplatin is a serious and debilitating condition for patients and often lasts for years. In the clinic typically the intensity and duration of symptoms of neuropathy increase as the cumulative dose of oxaliplatin increases and may lead to the need for dose reduction or even treatment cessation. For this reason clinicians and patients agree that it would be of tremendous benefit if it were possible to reduce or prevent this most unpleasant side effect," said Starpharma chief executive Dr Jackie Fairley.

¹ ELOXATIN[®] Product Information; Sanofi-Aventis.co.uk

² Professor Susan G. Dorsey, Director, University of Maryland Center for Pain Studies, School of Medicine, University of Maryland Baltimore and Professor Cynthia L. Renn, University of Maryland Center for Pain Studies.

The dose limiting toxicity of this widely used drug, marketed by Sanofi, is known to cause short-term disordered nerve function (cold sensitivity) coinciding with cycles of treatment and also longer-term nerve damage in the hands and feet (peripheral neuropathy) which, for many patients, will be life-long.

“What we’ve now shown here with our dendrimer version of oxaliplatin, is that, in addition to earlier reported advantages in efficacy and reduced blood toxicity, we are also able to reduce the primary dose-limiting neurotoxic side-effect of ELOXATIN® - even at double the dose. This is very exciting news indeed,” added Dr Fairley.

“Just the reduction in neurotoxicity alone would represent a significant advantage for oxaliplatin but when considered alongside the earlier improvements in efficacy and reduced bone marrow toxicity, this finding demonstrates that our dendrimer technology can deliver a considerable overall enhancement to this blockbuster drug. The beneficial characteristics of Starpharma’s dendrimer technology have also been shown in other drugs including the chemotherapeutics docetaxel and doxorubicin,” she said.

Starpharma has already announced it is advancing Dendrimer-Enhanced Oxaliplatin derivatives into development, based on the positive results of the earlier pre-clinical trials.

These results showing a reduction in the neurotoxic effect with the dendrimer version (DEO) compared to ELOXATIN® were conducted by leading researchers in the field of drug induced neuropathy at the University of Maryland in Baltimore³. In commenting on the significance of these results lead researcher, Professor Susan G. Dorsey, Director, University of Maryland, Baltimore, Center for Pain Studies, said:

“We see these findings are very significant because this condition is a serious clinical problem and the dendrimer version of oxaliplatin clearly shows a reduced level of neurotoxicity. We are unaware of any other examples of this effect reported for other oxaliplatin formulations in the literature.”

Study Description and Findings

The chronic neurotoxicity of ELOXATIN® and Dendrimer-Enhanced Oxaliplatin (DEO) was assessed as follows in a mouse model:

All mice (8 per group) underwent neurologic assessments prior to drug treatment. They were treated twice weekly for 4 weeks (a total of 8 doses) with either oxaliplatin (1.75mg/kg platinum equivalents) or DEO (3.5 mg/kg platinum equivalents). Neurologic assessments were then conducted weekly for 4 weeks. All assessments were conducted in a blinded manner using a standardised protocol.

Two neurologic assessments previously validated for oxaliplatin were used - assessing responses to mechanical and thermal stimuli (Von Frey and cold sensitivity). Mechanical allodynia⁴ is sensitivity to a stimulus that would not normally cause a reaction. The reduced response to stimuli for oxaliplatin and DEO was measured using the Von Frey assessment method and plotted as % reduction from baseline (Figure 1). Thermal sensitivity was assessed by recording response to cold stimuli (Figure 2).

³ Professor Susan G. Dorsey, Director, University of Maryland Center for Pain Studies, School of Medicine, University of Maryland Baltimore and Professor Cynthia L. Renn, University of Maryland Center for Pain Studies.

⁴ Allodynia is a condition in which pain arises from a stimulus that would not normally be experienced as painful.

Results:

1. DEO results in reduced peripheral neuropathy compared to oxaliplatin

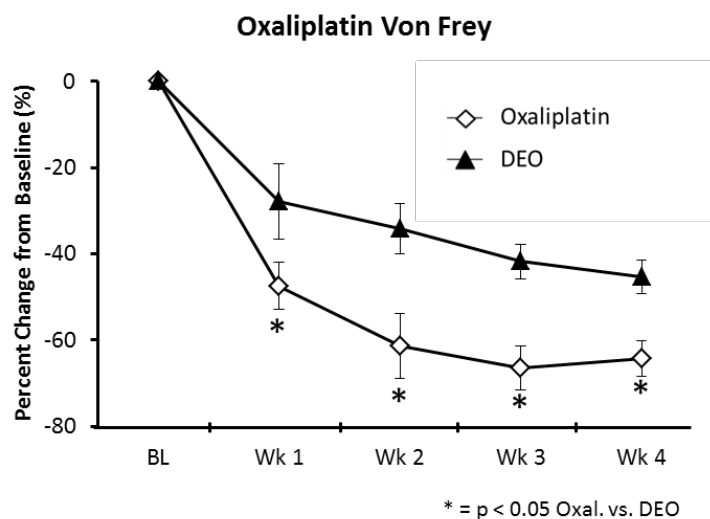


Figure 1 – Mechanical allodynia (increased sensitivity) measured using Von Frey

As can be seen from Figure 1, the DEO treated animals exhibited a significantly reduced mechanical allodynia throughout the 4 week experiment despite the fact that DEO treated mice were dosed at 3.5mg/kg platinum equivalents which was twice the platinum dose that given to the ELOXATIN® treated animals (1.75mg/kg platinum equivalents). This suggests a marked reduction in the neurotoxic effect for DEO compared to ELOXATIN®.

2. DEO results in reduced cold sensitivity compared to oxaliplatin

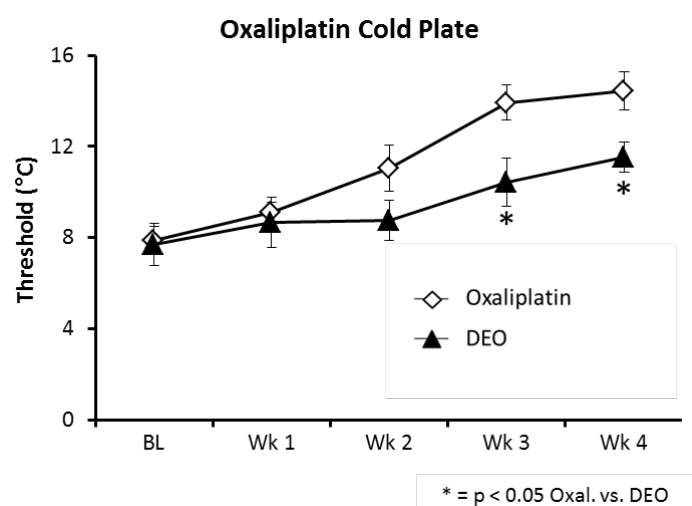


Figure 2 – Cold allodynia (increased sensitivity to cold) measured using Cold Plate

As can be seen from Figure 2, the DEO treated animals exhibited a significantly reduced cold allodynia at weeks 3 and 4. This also suggests a marked reduction in the neurotoxic effect for DEO compared to ELOXATIN®.

Conclusion

In September Starpharma reported advancing its Dendrimer-Enhanced Oxaliplatin derivatives into development following impressive improved tumour-inhibiting effectiveness and reduced bone marrow toxicity. This latest data, demonstrating the reduced neurotoxicity of Dendrimer-Enhanced Oxaliplatin, indicates a further commercial enhancement of this product candidate.

This further demonstration of the advantages the Company's dendrimer technology adds to a growing body of data on the platform's ability to provide clinically valuable benefits over existing products. These provide us with much confidence as we progress our most advanced product candidate - dendrimer-docetaxel into the clinic later this year.

The commercially attractive findings reported here for oxaliplatin add to the growing list of advantages offered by the company's proprietary dendrimer nanoparticle technology across a range of therapeutic agents. These include:

- enhanced tumour efficacy
- reduction in several important toxicities
- improved solubility
- tumour targeting
- half-life extension and
- Manufacturing advantages such as improved product stability, high particle loading, and scalability.

Starpharma's Dendrimer-Enhanced Oxaliplatins are protected by a portfolio of filed and granted patents, both for the molecules themselves, and on Starpharma's underlying drug delivery technology.

ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY), 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 uses. Starpharma has three core development programs: VivaGel® portfolio, drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead product is VivaGel® (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel® is under clinical development for the treatment and prevention of bacterial vaginosis (BV) and also as a vaginal microbicide to prevent the transmission of sexually transmitted infections including HIV and genital herpes. Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries Inc (Tokyo Stock Exchange) to market a value-added, VivaGel®-coated condom. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, the world's second largest condom market.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Drug Delivery partners include GSK, Lilly and AstraZeneca. In its internal program Starpharma has announced significant tumour-targeting results in its docetaxel (Taxotere®) program, with animal studies showing its dendrimer-enhanced version of docetaxel to have significantly superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel).

In agrochemicals Starpharma has a series of partnerships with leading industry players including Nufarm (ASX:NUF) and Makhteshim Agan as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

FOR FURTHER INFORMATION

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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.