



ASX ANNOUNCEMENT

Starpharma's clinical trial programs accelerating

Melbourne, Australia; 5 June 2014: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today provided an update on the progress of its clinical trial programs, which include the Phase 1 DEP™ docetaxel trial and the Phase 3 pivotal trials of VivaGel® for prevention of recurrent bacterial vaginosis (BV).

Highlights:

- Phase 1 DEP™ docetaxel trial:
 - Ethics approval at 3 sites in Australia
 - Enrolling patients; a number having received multiple cycles of therapy
 - No evidence of neutropenia
- Phase 3 VivaGel® for prevention of recurrent BV:
 - Agreement with EMA and FDA on study design
 - First ethics approval obtained
 - Quintiles CRO engaged
 - Nearing commencement

Phase 1 DEP™ docetaxel trial

The first group of patients has been enrolled at Nucleus Network in Melbourne and have received one or more cycles of DEP™ docetaxel treatment. The Phase 1 trial is currently in the dose escalation phase and a number of patients have now received multiple cycles of therapy with this novel form of improved docetaxel. Results so far show very good tolerability for DEP™ docetaxel with no evidence of neutropenia (low white blood cell count).

Two additional sites, Austin Health/Olivia Newton-John Cancer & Wellness Centre and Royal Brisbane & Women's Hospital, have recently received ethics approval and are due to commence enrolment shortly.

Dr Jackie Fairley, Starpharma Chief Executive Officer said: "It is very pleasing to see such good tolerability with DEP™ docetaxel, Starpharma's dendrimer-enhanced version of the major chemotherapeutic agent, Taxotere®. Whilst in the early stages of this trial, it is very encouraging to see that the patients treated so far have shown no signs of neutropenia, one of the most important, dose-limiting side effects of docetaxel and other forms of chemotherapy."

Approximately 25-30 patients with solid tumours will be enrolled in the trial, which has the primary objective of establishing the maximum tolerated dose, as determined by the occurrence of dose limiting toxicities, of DEP™ docetaxel given intravenously, once every three weeks.

The secondary objectives of the study are to characterise the safety, pharmacokinetic and tolerability profiles of DEP™ docetaxel in patients with advanced cancer.

In characterising the safety profile of DEP™ docetaxel, the study will investigate the impact of the improved dendrimer formulation on problematic side effects seen with Taxotere®, such as neutropenia, which was markedly reduced with the dendrimer formulation in pre-clinical studies, as well as anaphylaxis and hair loss.

The study will also employ a variety of imaging techniques and specific investigations aimed at exploring anti-tumour efficacy. These include CT scans and bone scans, as well as tumour markers.

DEP™ docetaxel is Starpharma's dendrimer enhanced version of the major chemotherapeutic agent, docetaxel, which is marketed worldwide by Sanofi Aventis under the trade name Taxotere®. Used to treat a wide range of solid tumours including breast, lung and prostate, Taxotere® generated sales in excess of US\$3 billion in 2010.

Interestingly docetaxel was recently featured at the international oncology meeting ASCO where impressive survival improvements were shown in first-line treatment of prostate cancer. [Reference http://abstracts.asco.org/144/AbstView_144_127755.html / <http://www.medicalnewstoday.com/articles/277621.php>]

Phase 3 Recurrent BV trial

Final preparations are also underway for the imminent commencement of two pivotal Phase 3 clinical trials of VivaGel® for the prevention of recurrent BV at sites in North America, Europe and Asia.

Through meetings with the US Food and Drug Administration (FDA) and Scientific Advice from the European Medicines Agency (EMA), Starpharma has reached agreement with the regulators on the design of the Phase 3 trial program and initial ethics committee approval has been obtained.

Quintiles, a leading global clinical research organisation, has been appointed by Starpharma and many study preparations, including site identification and engagement are now either complete or significantly advanced with a view to rapid trial start-up.

Around 600 women will be recruited to each trial with the primary efficacy endpoint of recurrence of BV over a 16 week treatment period.

There are no approved products for the prevention of recurrent BV, a market estimated to be worth in excess of US\$1 billion. The previous Phase 2 trial for

prevention of recurrent BV – a double-blind exploratory study in 205 US women (VivaGel[®] vs. placebo) – showed 1% VivaGel[®] reduced recurrent BV and delayed time to first recurrence.

“Starpharma has an opportunity to be first in class with a therapeutic to prevent the recurrence of BV, which occurs in a large number of women, and we are looking forward to the commencement of enrolment,” said Dr Fairley.

In the Phase 2 clinical trial, more than 80% of 1% VivaGel[®] users remained BV free at 16 weeks and the product also provided protection against the occurrence of BV symptoms, which include unpleasant vaginal odour and discharge.

In addition to the prevention of recurrence indication for VivaGel[®], Starpharma is pursuing regulatory approval in multiple geographies for VivaGel[®] with a claim of symptomatic relief. Following regulatory input, the first submissions for the symptomatic relief product are expected in the second half of calendar year 2014. Past VivaGel[®] trials have yielded strong clinical data which support a symptomatic relief claim and market research shows high patient acceptance and demand for a product to treat the symptoms of BV.

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 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 products are based on VivaGel[®] (SPL7013, astodimer sodium), a proprietary dendrimer which is a potent microbicidal agent. VivaGel[®] formulated as a water based gel and delivered vaginally is under clinical development for the management and prevention of bacterial vaginosis (BV). Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries, Inc., (TSE: JP3192800005) to market a value-added, VivaGel[®]-coated condom. A VivaGel[®]-coated condom has received marketing approval in Japan. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles[®], ZERO[®] and SKYN[®].

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. 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 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).

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 FURTHER INFORMATION

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Forward Looking Statements

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