



ASX ANNOUNCEMENT

Starpharma secures FDA agreement on BV treatment Phase 3

Melbourne, Australia; 10 October 2011: Starpharma (ASX: SPL; OCTQX: SPHRY) today announced that the Phase 3 clinical trial program for the VivaGel® bacterial vaginosis (BV) treatment program has been agreed with the US Food and Drug Administration (FDA) following recent positive trial results and subsequent End of Phase 2 (EOP2) Meeting.

With very positive Phase 2 results for VivaGel® in the treatment of BV (announced May 2011), Starpharma recently presented to the FDA the proposed design of Phase 3 studies and associated aspects of the development program to support a New Drug Application (NDA) for VivaGel® for the treatment of BV.

Following these EOP2 meeting discussions, Starpharma and the FDA are now in agreement on Phase 3 clinical trial design, including definition of primary and secondary endpoints, patient numbers and other design parameters. The company now plans to submit its Phase 3 protocols as soon as possible and it is anticipated that the trials will commence in early 2012 with completion expected before year end. Following the completion of Phase 3 trials the company plans to partner the product.

Consistent with Starpharma's original plans for the BV treatment program, these two Phase 3 studies will be conducted in parallel, each with approximately 220 participants enrolled. In these Phase 3 trials, as for the recently completed successful Phase 2 study, the primary endpoint will be Clinical Cure, as assessed by resolution of symptoms and other standard clinical criteria, and the comparator will be placebo gel.

"We are very pleased that the FDA agreed with our proposed clinical program in this important, final phase of the development of VivaGel® as a treatment for bacterial vaginosis and particularly that the design is so similar to our successful Phase 2 trial. We look forward to advancing the program as rapidly as possible, and to executing a commercial licence following its completion," said Starpharma Chief Executive Officer, Dr Jackie Fairley.

"BV is the most common vaginal infection in the world, and affects an estimated one-third of the adult female population in the US. The global market for topical BV treatments alone is estimated at approximately US\$350M and we and others believe VivaGel® has the potential to be a very important product in the management of this serious and unpleasant condition."

In May, Starpharma announced that VivaGel® had met the primary endpoint of its Phase 2 study, demonstrating significant efficacy for treatment of BV. The study showed that treatment with 1% VivaGel® once daily for seven days, resulted in 74% of patients achieving Clinical Cure of BV 2 to 5 days after completion of therapy compared with just 22% in the placebo group (P=0.0002). In addition, patient acceptability of the product was very high with 83% of patients using 1% VivaGel® being extremely satisfied, very satisfied or satisfied with the product when taking all aspects of the treatment into account.

Bacterial Vaginosis is the most common vaginal infection worldwide and is particularly prevalent in the US. Similar to imbalances between “good” and “bad” bacteria in the gut, an imbalance in the vaginal microbiota between good bacteria - which help maintain a normal healthy vagina - and harmful bacteria, leads to BV with symptoms including vaginal irritation, discharge and odour that are unpleasant and disrupt and interfere with a woman’s relationships and general quality of life. The condition also has more serious consequences, being implicated in pelvic inflammatory disease, infertility and an increased risk of pre-term birth. BV also significantly increases the risk of some sexually transmitted infections, including HIV.

ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimer technology for pharmaceutical, life-science and other applications. SPL has two operating companies, Starpharma Pty Ltd in Melbourne, Australia and DNT, Inc in the USA. Products based on SPL’s dendrimer technology are already on the market in the form of diagnostic elements and laboratory reagents through licence arrangements with partners including Siemens and Merck KGaA.

The Company’s lead pharmaceutical development product is VivaGel[®] (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV, genital herpes and bacterial vaginosis. Starpharma has a licence agreement with Ansell Limited to develop a VivaGel[®]-coated condom, and a licence agreement with Okamoto Industries Inc in relation to the VivaGel[®]-coated condom for the Japanese market. Okamoto is the market leader for condoms sold in Japan, the world’s second largest condom market.

Starpharma also has agreements in place with Lilly, Elanco, Stiefel Laboratories (a GSK Company), and Siemens Healthcare as well as many research collaborations with some of the world’s leading organisations in the fields of pharmaceuticals, drug delivery, cosmetics and agrochemicals.

A dendrimer is a type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

American Depositary Receipts (ADRs): Starpharma’s ADRs trade under the code **SPHRY** (CUSIP number 855563102). Each Starpharma ADR is equivalent to 10 ordinary shares of Starpharma as traded on the Australian Securities Exchange (ASX). Starpharma’s ADRs are listed on International OTCQX, a premium market tier in the U.S. for international exchange-listed companies.

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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 health authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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.