

# Starpharma Completes Enrolment for Phase 2 Study of VivaGel<sup>®</sup> for Treatment of BV

**Melbourne, Australia; Tuesday 23<sup>rd</sup> March 2011** – Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced it had completed enrolment and all patient follow-up visits in its phase 2 study of VivaGel<sup>®</sup> for the treatment of bacterial vaginosis (BV).

This study investigated the effectiveness of VivaGel<sup>®</sup> administered once daily for seven days in the treatment of BV and enrolled 132 participants in the US. Data is now being processed and results will be available in the second quarter of this year.

BV is the most common vaginal infection worldwide, and the most common cause of vaginal irritation, discharge and malodor. It is particularly prevalent in the US, where it affects an estimated one-third of the adult female population. The condition is implicated in pelvic inflammatory disease and may also be associated with an increased risk of sexually transmitted infections, including HIV, and pre-term birth.

BV is characterised by frequent recurrence, with some women experiencing it as many as three or more times a year. Current therapies are generally considered by clinicians to be inadequate, and lasting cure is rare and difficult to achieve. There are also few real options for women to address frequent recurrence of the condition. Existing antibiotic treatments are not considered suitable for frequent or long-term use.

Dr Jackie Fairley, Chief Executive Officer of Starpharma, said: "The completion of this study represents an important milestone in the development of VivaGel<sup>®</sup>. The global market for topical BV treatments alone is estimated to be approximately US\$300-350M per year, while the market for a product to prevent BV recurrence is estimated to be significantly larger than the acute treatment market. Therefore, we look forward to the results of this trial, as well as progressing studies for prevention of BV. The low risk of side effects and other features, such as condom compatibility, make VivaGel<sup>®</sup> particularly well suited for both treatment and prevention of BV."

Therefore, as well as the current study for investigation of VivaGel<sup>®</sup> as an alternate to antibiotics for short term treatment of BV, Starpharma also plans within the next two to three months to initiate a second phase 2 study to assess the ability of VivaGel<sup>®</sup> to prevent recurrence of BV. Planning for this study is already well advanced with CRO and site selection processes well underway.

The following table summarises the Phase 2 trial program and commercial opportunities for the use of VivaGel<sup>®</sup> in BV:

Indication	Current Market/est	Existing therapies	Stage of Development	Commercial Strategy
BV Treatment	US \$300-350M (topical agents alone)	Metronidazole Clindamycin (antibiotics)	Enrolment completed for Phase 2 trial; results Q2 2011	Late stage licence
Prevention of BV recurrence	Likely to be significantly larger than treatment	None approved	Phase 2 trial commencing 2H 2011	Late stage licence

#### 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 KgA.

The Company's lead pharmaceutical development product is VivaGel<sup>®</sup> (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes. Starpharma has a licence agreement with Reckitt Benckiser (LSE:RB) to develop a VivaGel<sup>®</sup> coated condom. Reckitt Benckiser manufactures and sells Durex<sup>®</sup> condoms, the market-leading condom brand worldwide.

Starpharma also has agreements in place with Lilly, Elanco, Stiefel Laboratories (a GSK Company), and Unilever as well as many research collaborations with some of the world's leading organisations.

**Dendrimer:** 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). The Bank of New York Mellon is the depositary bank. Starpharma's ADRs are listed on International OTCQX, a premium market tier in the U.S. for international exchange-listed companies, operated by OTC Markets Group Inc. (www.otcmarkets.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'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.

# FOR FURTHER INFORMATION

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