



ASX ANNOUNCEMENT

Enrolment complete for Phase 3 VivaGel[®] BV-R program

- **100% enrolment for phase 3 trials of VivaGel[®] BV for prevention of recurrence**
- **Trial completion expected Q1 CY2017**
- **Favourable revision to FDA guidance for BV treatment product opportunity**

Melbourne, Australia; 13 October 2016: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced completion of patient enrolment for its pivotal phase 3 trials evaluating the efficacy and safety of VivaGel[®] BV for prevention of recurrent bacterial vaginosis (BV). Trial completion is expected in the first quarter of calendar 2017, with topline results available early-to-mid second quarter of calendar 2017.

The two phase 3 trials are being conducted according to the requirements of the US Food and Drug Administration (FDA) and the European authorities to support global marketing applications for VivaGel[®] BV for the prevention of recurrent BV. Starpharma also secured the binding agreement of FDA on the trial design including the primary endpoint, by way of a Special Protocol Assessment (SPA). The SPA minimises regulatory risk associated with acceptance of the trial data to support marketing approval. The studies are being conducted across multiple sites in the US, Canada, Mexico, Europe and Asia.

The two double-blind, randomised, placebo-controlled trials are identical in design. The primary endpoint of the studies is recurrence of BV during the 16-week treatment period. The primary objective of the study is to demonstrate that the rate of BV recurrence in women using VivaGel[®] BV is lower than the rate of BV recurrence in women using a placebo gel during the 16-week treatment period. After the treatment period, there is a 12-week follow-up period off treatment which will assess secondary endpoints including safety.

Starpharma Chief Executive Officer, Dr Jackie Fairley, said: "We are delighted to have achieved full enrolment of our pivotal phase 3 trials for this indication and look forward to trial completion early next year.

"There are no approved products for this indication, so we have an opportunity to be first in class with VivaGel[®] BV for the prevention of BV recurrence. This important differentiating factor is a significant commercial advantage recognised by potential partners. There is significant unmet medical need for this chronic condition, where the global market is estimated to be worth around \$1 billion annually."

Starpharma has already developed VivaGel[®] BV for bacterial vaginosis treatment separate to the prevention of recurrence indication. VivaGel[®] BV is approved in Europe for the treatment of BV, including relief of symptoms, and is well advanced in regulatory review in other markets, with launch planned in coming months.

Significantly, in a related development, the FDA recently issued a new draft clinical guidance for the development of products for BV treatment. This new guidance recommends the assessment of the primary endpoint for efficacy in treatment studies be soon after cessation of treatment (End of Treatment: day 7-14 post randomisation), and not 2-3 weeks after treatment is ceased, which was the required timing previously. This development is particularly important as the new FDA revised End of Treatment time point is consistent with Starpharma's 2012 phase 3 results for VivaGel[®] BV for treatment of BV, which showed, in both studies, highly statistically significant Clinical Cure of BV at the End of Treatment time point.

Starpharma has licensed VivaGel[®] BV to Aspen Pharmacare for Australia and New Zealand and has advanced negotiations underway with a number of parties for other regions, including Europe. Naturally, the shift in FDA requirements has positive implications in terms of partnering for VivaGel[®] BV - for both the treatment and the prevention of recurrent BV product opportunities.

The FDA draft guidance is available:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510948.pdf>.

About VivaGel[®] BV

VivaGel[®] (SPL7013, astodimer sodium) is a non-antibiotic agent formulated as a vaginally applied gel (VivaGel[®] BV) for treatment of BV and prevention of BV recurrence. VivaGel[®] BV has been approved in Europe as a topical treatment for the rapid relief of BV, including symptoms of unpleasant vaginal odour and discharge.

About Bacterial Vaginosis (BV)

Bacterial vaginosis is the most common cause of vaginal infection for women of childbearing age, and affects around 30% of women in the US. It is a highly recurrent condition with 50-60% of sufferers having it recurrently. BV is caused by an imbalance of naturally occurring bacterial flora (the usual bacteria found in a woman's vagina). Smoking, the use of some hygiene products and several other risk factors are linked to a higher risk of developing BV. The global market value for the prevention of recurrent BV is estimated to be more than US\$1 billion.

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[®], Manix[®], 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

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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.