ASX ANNOUNCEMENT

# FDA Grants Special Protocol Assessment (SPA) Agreement for Starpharma Phase 3 Recurrent BV Trial

**Melbourne, Australia; 14 July 2014:** Starpharma Holdings Ltd (ASX:SPL, OTCQX:SPHRY) today announced that the US Food and Drug Administration (FDA) has granted Special Protocol Assessment (SPA) agreement on the design and planned analyses of the phase 3 clinical studies of the VivaGel® bacterial vaginosis (BV) product for the prevention of recurrent BV.

The favourable SPA outcome provides a binding agreement from the FDA that the phase 3 clinical study design, endpoints, statistical analyses and other aspects of the planned studies adequately address objectives in support of a US regulatory submission for approval of the product.

The granting of SPA agreement by the FDA follows the earlier agreement of the European Medicines Agency (EMA) on the design of the phase 3 studies.

Starpharma will now commence its two pivotal phase 3 clinical trials of VivaGel® for the prevention of recurrent BV at sites in North America, Europe and Asia.

The two phase 3, double-blind, randomised, placebo-controlled trials will be identical in design and will compare the rate of BV recurrence in women using VivaGel® to the rate of recurrence in women using a placebo gel during a 16 week treatment period. Approximately 600 women will be recruited into each study.

Starpharma Chief Executive Officer, Dr Jackie Fairley, said: “Receiving agreement on the SPA is an important and very positive development as it effectively eliminates the US regulatory risk associated with clinical development, by specifying upfront the FDA’s agreed trial design. This significantly reduces overall development risk for VivaGel®. SPA agreement from the FDA is protected by US law and gives Starpharma certainty and confidence that the studies will support a regulatory submission for the approval of VivaGel® for the prevention of recurrent BV in the US.”

VivaGel® (SPL7013, astodrimer sodium) is a non-antibiotic agent formulated as a vaginally applied gel for prevention of BV recurrence. It is also being developed for the management of BV symptoms, which include unpleasant vaginal odour and discharge, and regulatory submissions to support the symptomatic relief indication are also planned for 2HCY14.

There are no approved products for the prevention of recurrent BV and so VivaGel® will be a world-first therapy for this troublesome condition. Bacterial vaginosis affects around 1 in 3 women and recurs in approximately 50 per cent of women within 12 months.

In the previous exploratory phase 2 clinical trial, more than 80 per cent of women receiving 1% VivaGel® remained BV-free at 16 weeks and the product also provided protection against the occurrence of BV symptoms. Formal market research with both patients and clinicians and from Key Opinion Leaders strongly supports the demand for a product such as VivaGel® in the management of BV.

***About BV***

Bacterial vaginosis is the most common cause of vaginal infection for women of childbearing age affecting around 30% of women in the US. It is a highly recurrent condition with 50-60% of sufferers having it recurrently. Bacterial vaginosis is caused by an imbalance of naturally occurring bacterial flora (the usual bacteria found in a woman's vagina). Smoking and the use of some hygiene products are linked to a higher risk of developing BV.

BV results in unpleasant and embarrassing symptoms such as odour and vaginal discharge. It has been linked to still birth, pregnancy complications, pelvic inflammatory disease, and lower rates of fertility. It also is associated with increased susceptibility of women to HIV and other STIs, and an increased risk of transmission of HIV from women to men.

## 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, 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, astodrimer 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

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.