ASX ANNOUNCEMENT

# SPL receives FDA Special Protocol Assessment for BV Phase 3

**Melbourne, Australia; 11 January, 2012:** Starpharma (ASX: SPL; OCTQX: SPHRY) today announced that it has received final written agreement from the FDA on the design of its Phase 3 clinical studies of VivaGel® for the treatment of bacterial vaginosis (BV) under the FDA's Special Protocol Assessment (SPA) scheme.

The SPA is a binding declaration from the FDA that the Phase 3 clinical study design, endpoints, statistical analyses, and other aspects of the planned studies are acceptable to support regulatory approval of the product.

"Receiving this SPA agreement gives Starpharma great confidence in our Phase 3 program, and allows us to proceed through this final development stage with a high level of clarity about the approval pathway for VivaGel® for treatment of BV," said Dr Jackie Fairley, Chief Executive Officer of Starpharma.

"It was pleasing to have received binding agreement so rapidly and without the need for further discussion with the Agency," she said.

As previously announced, the company plans to commence its Phase 3 BV treatment program early in 2012 with completion expected before year end. Following the completion of Phase 3 trials, the company plans to partner the product.

"Following our recent financing, we are also implementing various initiatives in collaboration with our CRO to expedite the trial timelines as much as possible," added Dr Fairley.

These two Phase 3 studies will be conducted in parallel and the design – now agreed with both the FDA and EMA – is extremely similar to Starpharma's successful Phase 2 trial of VivaGel® for the treatment of BV.

## ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimers for pharmaceutical, drug delivery and other applications. Products based on SPL's proprietary 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 microbicide designed to prevent the transmission of STIs, including genital herpes, HIV and treat bacterial vaginosis. Starpharma also 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 commercial agreements in place with Lilly, Elanco, GSK, 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, highly branched nanoscale polymer.

**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.

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 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.