



## ASX ANNOUNCEMENT

### EU Marketing Approval Granted for VivaGel® BV

**Melbourne, Australia; 24 September 2015:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced it has received, overnight, marketing approval in the European Union (EU) for VivaGel® BV for the treatment and rapid relief of bacterial vaginosis (BV) including symptoms.

The approval allows for the marketing of VivaGel® BV in the European Economic Area (EEA), which includes the 28 countries of the EU plus the European Free Trade Association (EFTA) countries, providing access to a population of more than 260 million women. In addition, the EU approval will be used as the basis for obtaining what is expected to be relatively rapid regulatory and marketing approvals for VivaGel® BV in a number of other countries that formally recognise the EU approval.

Bacterial vaginosis is the most common vaginal infection worldwide. It is the most common cause of abnormal vaginal discharge and unpleasant vaginal odour in women and is associated with an increased risk of pre-term births, miscarriage, and transmission and acquisition of STIs, including genital herpes and HIV/AIDS.

In clinical trials, VivaGel® BV, when used once daily for seven days, demonstrated significant benefits over a placebo in the treatment of BV in women. A key benefit of VivaGel® BV in clinical trials was the rapid relief of patients' symptoms associated with BV, including unpleasant vaginal odour and discharge. In addition, use of VivaGel® BV helped to normalise vaginal pH and suppress the bacteria that cause the vaginal microflora imbalance that characterises BV. In formal market research BV sufferers using VivaGel® BV reported very high levels of overall satisfaction, comfort and ease of use.

VivaGel® BV is a unique topical vaginal gel. The proprietary dendrimer active is not absorbed systemically following topical application, and acts locally to suppress the pathogens that cause BV and the associated signs and symptoms. VivaGel® BV is easy to use, and in clinical trials was associated with very low rates of candidiasis (2-3%), which is a significant secondary complication of other therapy options, for which rates of up to 30% have been reported.

Discussions regarding marketing rights for VivaGel® BV are already underway with a number of potential commercial partners and are expected to be facilitated by the EU approval. The current market for the management of BV and associated symptoms is estimated to be in excess of US\$750 million globally, with significant areas of unmet need for BV sufferers.

Starpharma Chief Executive, Dr Jackie Fairley, commented: "The marketing approval for VivaGel® BV in the EU is a very significant milestone both for Starpharma and the VivaGel® portfolio. It opens up a large and important market for the product and we expect this approval to expedite commercial discussions already underway. In addition, the EU approval will be used as

the basis of additional regulatory approvals for VivaGel® BV in regions that rely on the European approval. We will be actively pursuing these two priorities in parallel.”

The phase 3 clinical trial programme for the VivaGel® BV product for the prevention of recurrent BV is also progressing smoothly in North America, Europe and Asia, and is now well in excess of 50% recruited.

## 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, astodrimer 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 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®, 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](http://www.starpharma.com)

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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.