

## VivaGel® BV granted marketing approval in Australia

**Melbourne, Australia; 25 October 2017:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced it has received Australian marketing approval from the Therapeutic Goods Administration (TGA) for VivaGel® BV, which is intended for treatment of bacterial vaginosis (BV). Launch plans for VivaGel® BV are well advanced and the product is expected to be available in pharmacies in the New Year.

VivaGel® BV, an Australian innovation, was developed by Starpharma and will be marketed in Australia by Aspen Pharmacare as Fleurstat™ BV gel, and will carry the VivaGel® brand. Aspen is responsible for all marketing, promotion and local distribution of the product to clinicians and pharmacies. Starpharma will supply Aspen with the VivaGel® BV product and will also receive royalties on net sales.

The TGA approval is significant not only for the Australian market but also internationally as there are many countries in Asia, the Middle East and South America where marketing approval is largely based on Starpharma's home-country registration.

VivaGel® BV is a patented vaginal gel developed by Starpharma that works rapidly to resolve BV and the associated signs and symptoms. Patient and clinician experience with BV indicates that current treatment options, such as antibiotics, are lacking in terms of their efficacy and the magnitude of unwanted side-effects. VivaGel® BV is a novel product which provides a new approach to the management of BV. Its proprietary dendrimer active is not absorbed systemically, and acts locally to help restore the normal vaginal flora balance, working quickly to resolve the associated signs and symptoms. VivaGel® BV is easy to use, and in clinical trials was associated with high levels of patient satisfaction and very low rates of candidiasis (thrush), which is a significant secondary complication of other current antibiotic therapy options.

Starpharma Chief Executive, Dr Jackie Fairley, commented: "We are delighted that VivaGel® BV has been approved for sale in Australia. There's a significant need for new, clinically proven therapeutic options for this very common and persistent condition, which is associated with serious medical consequences and problematic symptoms if left untreated. Given the prevalence of antibiotic resistance worldwide, the fact that VivaGel® BV is not a conventional antibiotic makes it a particularly appealing solution for patients and doctors alike."

"With the upcoming launch of VivaGel® BV, Australian clinicians and pharmacists will soon be able to recommend this novel non-antibiotic treatment for this common and problematic condition. For Starpharma, it is particularly exciting to launch this Australian innovation into the local market. Aspen is an ideal partner for VivaGel® BV in Australia with a proven track record in women's health."

Aspen Australia, Head of Nutritionals & Consumer OTC, Robert Barnes added "Aspen is looking forward to marketing this innovative product in the Australian marketplace."

VivaGel® BV is also approved in the EU. Starpharma is pursuing regulatory approval in the US, with Starpharma's marketing application (NDA) to the US Food and Drug Administration



(FDA) already well-advanced and expected to be submitted shortly. Regulatory approval is also being pursued in other regions.

Starpharma has licensed the marketing and distribution rights for VivaGel® BV to Aspen for the Australian and New Zealand markets. In the US, Europe and the rest of the world the marketing rights for VivaGel® BV currently rest with Starpharma. The Company is working with a leading global healthcare investment bank to support the competitive process and finalisation of commercial arrangements for these territories.



### About Bacterial Vaginosis (BV)

BV is the most common vaginal infection worldwide. BV is the result of a major imbalance in the types and numbers of bacteria in the vagina resulting in a characteristic odour and discharge.

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### 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 two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing a number of products internally and others via commercial partnerships.

**VivaGel®:** Starpharma's portfolio includes late stage women's health products based on VivaGel® (SPL7013, astodimer sodium), a proprietary dendrimer. VivaGel® formulated as a water based gel and delivered vaginally - VivaGel® BV - has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and has recently completed 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 developed an antiviral condom which uses VivaGel® in the lubricant. The VivaGel® condom is available in Australia and Canada under the Lifestyles® Dual Protect™ brand and Starpharma also has a number of license agreements to market the VivaGel® condom in other regions, including China and Japan.

**DEP®:** The other major part of Starpharma's pharmaceuticals business is its proprietary DEP® drug delivery platform. Starpharma has both partnered and internal DEP® programs in Drug Delivery. A number of dendrimer-enhanced, or DEP® versions of existing drugs are under development by the Company. 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). In the partnered area, AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of a number of AstraZeneca oncology compounds.

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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.