



## ASX ANNOUNCEMENT

### **VivaGel® BV phase 3 results timing and commercialisation**

**Melbourne, Australia; 4 July 2017:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced revised timing for results of its two pivotal VivaGel® BV phase 3 trials for the prevention of recurrent bacterial vaginosis – now expected to be available in late July/early August 2017.

This timing has allowed for additional confirmation from the US FDA on the statistical analysis plan to ensure consistency of the trial data analyses with Starpharma's Special Protocol Agreement (SPA), prior to un-blinding and analysis of the data. The SPA granted by the FDA provides binding FDA agreement on the phase 3 trial design including the primary endpoint.

Following completion of the trials, data collation and routine blinded quality control review were undertaken and are now complete. The statistical analysis plan and bio-statistical programming are now being finalised, prior to the unblinding of the data.

Starpharma is also leveraging the FDA's recently granted QIDP designation and Fast Track status for these trial results. These designations carry significant benefits for regulatory approval and commercialisation, including increased dialogue with the FDA, priority regulatory review and an additional five years of market exclusivity.

In parallel, Starpharma is well-advanced in its preparation of the New Drug Application (NDA) submission for VivaGel® for the treatment and symptomatic relief of BV. This NDA is planned for as early as possible in the second half of 2017, with final pre-submission discussions with the FDA to be held in July 2017.

#### ***Appointment of global healthcare investment bank***

Starpharma is also actively engaged in both global and regional negotiations for commercial rights to VivaGel® BV, with a number of term sheets under discussion. Negotiations have been positively impacted by the FDA recently granting Starpharma QIDP and Fast Track designations for both indications which has attracted further significant commercial interest in VivaGel® BV. As part of this process, the Company has appointed a leading global healthcare investment bank to support the competitive process for negotiating commercial terms with potential partners for VivaGel® BV.

#### 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.

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 is also 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 license agreements with Ansell Limited (ASX:ANN), Okamoto Industries, Inc., (TSE: JP3192800005), Sky and Land (China) and Koushan Pharmed (Iran) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia and in Canada 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.

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.

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.