



## ASX ANNOUNCEMENT

# VivaGel® BV granted QIDP and Fast Track designation by US FDA

**Melbourne, Australia; 12 January 2017:** Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced it has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designation for VivaGel® BV by the US Food and Drug Administration (FDA).

QIDP and Fast Track designations were granted independently for both the VivaGel® BV treatment and prevention indications for bacterial vaginosis (BV). This positive development recognises the high unmet medical need in the management of BV and the potential of VivaGel® BV to address that need for both treatment and prevention of recurrent BV, markets estimated to be worth in excess of US\$1 billion globally.

These two important designations are designed to make new therapeutics available to patients as rapidly as possible, carrying significant benefits for regulatory approval and commercialisation of VivaGel® BV.

QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act, and provides incentives for the development of new antimicrobial products. These incentives include priority regulatory review and an additional five years' of market exclusivity. The Fast Track designation enables more frequent interactions with the FDA and expedited review, leading to faster approval, and facilitates earlier market access for patients.

Starpharma CEO, Dr Jackie Fairley, said, "We are delighted that the FDA has granted VivaGel® QIDP and Fast Track designation. This is a very positive commercial development which expedites the path to US market entry for VivaGel® BV. VivaGel® BV is understood to be the only product to receive such designations for both the BV treatment and prevention indications. The granting of QIDP and Fast Track status is important to accelerate access to VivaGel® BV for patients in the US that suffer from BV."

### **Current status of VivaGel® BV programs**

#### *VivaGel® BV – to prevent recurrent BV (chronic use)*

VivaGel® BV for the prevention of recurrent BV is currently being evaluated via two phase 3 clinical studies. Patient enrolment in the program was completed in October 2016, and the trials are expected to conclude in Q1 of CY2017, with top line results expected in Q2.

#### *VivaGel® BV – BV treatment and symptomatic relief (acute use)*

VivaGel® BV for treatment of BV, which has already been evaluated in phase 3 clinical trials, has been approved for marketing in the EU and is under review in a number of other jurisdictions.

In July 2016, the FDA published a revised draft regulatory guidance for the development of products for BV treatment. The FDA guidance now recommends that the assessment of the primary endpoint for efficacy in BV treatment studies occur 7-14 days after commencing

treatment (rather than 21-30 days after commencing treatment). This timing aligns favourably with Starpharma's phase 3 clinical trial results, which showed a highly statistically significant benefit of VivaGel<sup>®</sup> BV at this time point. This revised guidance, coupled with the designations above, significantly enhances the commercial opportunity for VivaGel<sup>®</sup> BV.

Starpharma is already preparing and plans to submit a marketing application for VivaGel<sup>®</sup> BV to the FDA in the near future. As noted above, a key benefit of the QIDP and Fast Track status is the priority and expedited review aimed at giving potential patients earlier access to approved products.

## 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<sup>®</sup> portfolio, DEP<sup>®</sup> 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<sup>®</sup> (SPL7013, astodimer sodium), a proprietary dendrimer which has antimicrobial properties. VivaGel<sup>®</sup> 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 signed a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel<sup>®</sup> 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<sup>®</sup> condom. The VivaGel<sup>®</sup> condom is available for purchase in Australia under Ansell's Lifestyles<sup>®</sup> Dual Protect™ brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles<sup>®</sup>, Manix<sup>®</sup>, ZERO<sup>®</sup> and SKYN<sup>®</sup>. 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<sup>®</sup> versions of existing drugs are under development. The most advanced of these is DEP<sup>®</sup> docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere<sup>®</sup>), which is in clinical development in patients with solid tumours. In preclinical studies DEP<sup>®</sup> 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<sup>®</sup> (docetaxel). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP<sup>®</sup> 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<sup>®</sup>).

For more information please visit: [www.starpharma.com](http://www.starpharma.com)

## 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.