ASX Announcement

# VivaGel® BV NDA advances to next stage of FDA review

- **VivaGel® BV NDA advances to next stage of the US FDA review, following completion of the filing review with no issues identified**
- **FDA confirms acceptance of the VivaGel® BV NDA and priority review for both indications**
- **VivaGel® BV is already licensed in the majority of territories; negotiations for a North American licence are well advanced**

**Melbourne, Australia; 9 July 2018:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that the US FDA has completed its filing review of the VivaGel® BV New Drug Application (NDA), with no issues identified, and confirmed its progress to the next stage.

Confirmation by the FDA that the NDA has been accepted for filing is a significant regulatory milestone for Starpharma. This achievement reflects the completeness of the VivaGel® BV data package and is expected to positively impact on licensing for the North American region, which is in the advanced stages of negotiation.

The FDA has confirmed that the VivaGel® BV NDA will be the subject of a priority review, which has a target review period of approximately 6 months from acceptance.

Dr Jackie Fairley, Starpharma CEO, commented: "We are extremely pleased to have achieved FDA's acceptance and confirmation that the substantive review is now in progress. This is an important achievement for Starpharma and creates significant commercial value. It's timely from a licensing perspective as this milestone will positively impact the advanced negotiations currently underway for the North American region – and we look forward to making an announcement shortly."

VivaGel® BV was granted QIDP and Fast Track status by the FDA – these priority 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.

Fast Track Status has accelerated the regulatory process for VivaGel® BV and is intended to provide early market access for products that address unmet medical needs. 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.

*About VivaGel® BV*

*VivaGel® BV is a patented, water-based vaginal gel for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV. VivaGel® BV is a breakthrough product which specifically targets the organisms that cause BV, rapidly relieves symptoms and has a novel mechanism of action affecting biofilm. VivaGel® BV is a non-antibiotic therapy and is not absorbed into the bloodstream.*

*VivaGel® BV is protected by patents in the US and elsewhere with coverage out to 2032. VivaGel® BV demonstrated compelling efficacy in phase 3 trials without the unpleasant side effects of current BV therapies and has been endorsed by clinicians and patients alike. VivaGel® BV is already approved in Europe and Australia and is expected to be first available in Australian pharmacies, under the brand name Fleurstat in 2018.*

## *About Bacterial Vaginosis (BV)*

*Bacterial vaginosis is the most common cause of vaginal infection for women of childbearing age and affects around 30% of women in the US. It is a highly recurrent condition with 50-60% of sufferers experiencing repeated episodes. BV is caused by an imbalance of naturally occurring bacterial flora (the usual bacteria found in a woman's vagina). Current therapies for BV are inadequate and have many unpleasant side-effects, there are also no approved products in the US for preventing recurrent BV, making VivaGel® BV a first-in-class therapy for this condition.*

### 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 several products internally and others via commercial partnerships.

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application is under Fast Track review by the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Australia and Canada under the Lifestyles® Dual Protect™ brand.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more.

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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.