

Starpharma meets with US FDA to discuss VivaGel® BV

Melbourne, Australia; 11 April 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that a meeting was held with the US FDA overnight as part of the process to clarify and address FDA's request for confirmatory data prior to the approval of VivaGel® BV in the US. This meeting was attended by senior representatives of Starpharma as well as internationally recognised Key Opinion Leaders in BV, statisticians and the Company's expert FDA regulatory consultants, which include former senior FDA clinical personnel.

Prior to the meeting, Starpharma submitted a comprehensive package of information to the FDA, including additional statistical analyses of existing data on VivaGel® BV, which was prepared in response to the FDA's request, and to provide further support for the approval of VivaGel® BV. The submission was prepared with input from Starpharma's team of expert FDA consultants and statisticians.

Commenting on the meeting, Starpharma CEO Dr Jackie Fairley said: "This was an important step to better understand and address the FDA's feedback – it was a constructive and interactive meeting and we were very pleased with the level of engagement by the FDA in the discussions".

Starpharma appreciates that the outcome of this FDA process is of particular interest to shareholders and expects to be able to provide further information once formal outcomes of the FDA meeting and the subsequent follow up has been confirmed in writing by the FDA.

"VivaGel® BV is already approved and will soon be launched in Europe and Australia with regulatory submissions underway for other regions. We look forward to working with the FDA to enable this important product to also be available to BV sufferers in the US", concluded Dr Fairley.

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, astodimer sodium, a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; 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

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