

US VivaGel® BV licensed for A\$142M milestones, plus royalties

- **Starpharma has licensed VivaGel® BV for the US to ITF Pharma**
- **Deal terms include up to US\$101M (A\$142M) in milestones, in addition to escalating double-digit royalties on sales**
- **Milestones comprise US\$20M (A\$28M) in FDA approval milestones for the two BV indications and up to US\$81M (A\$114M) in commercial milestones**
- **ITF Pharma is a specialty pharmaceutical company focused on Women's Health and will significantly expand its dedicated sales force for the launch of VivaGel® BV**
- **ITF Pharma is a subsidiary of multinational pharmaceutical company, Italfarmaco SpA**
- **VivaGel® BV's New Drug Application is currently undergoing FDA priority review with Fast Track status**

Melbourne, Australia; 20 December 2018: Starpharma (ASX: SPL, OTCQX: SPHRY) and ITF Pharma today announced they have signed a licence for the sales and marketing rights to VivaGel® BV in the United States. Starpharma will be eligible to receive up to US\$101M (A\$142M) in regulatory approval and commercialisation milestones in addition to attractive tiered royalties on sales.

VivaGel® BV is a novel, non-antibiotic therapy for bacterial vaginosis (BV) - the most common vaginal infection in the world and twice as common as thrush. There is a particularly high prevalence of BV amongst US women (1 in 3 women, with around two thirds experiencing recurrent episodes). The global market for BV treatment is estimated to be ~US\$750 million and ~US\$1 billion for prevention of recurrent BV.

ITF Pharma is a US-based specialty pharmaceutical company with a focus on prescription Women's Health products through its Womens Choice Pharmaceuticals Division (www.wcpharma.com). ITF Pharma is the US subsidiary of the leading private multinational pharmaceutical company, Italfarmaco SpA which employs around 3,100 people globally and has annual sales turnover of more than €720M.

Upon launch, VivaGel® BV will become ITF Pharma's top priority Women's Health product. Under the licence, ITF Pharma have committed to a substantial investment in sales, marketing and reimbursement activities ahead of the US launch of VivaGel® BV including significantly expanding its dedicated Women's Health salesforce to 60 specialised representatives. ITF Pharma's experienced salesforce will utilise specialised sales sector intelligence tools in optimising these efforts. ITF Pharma's sales and marketing capabilities include a team of dedicated telemarketing and digital marketing professionals who will complement its sales representatives in the field.

ITF Pharma's management team has extensive Women's Health experience in the pharmaceutical industry gained in companies including Ferring, Wyeth, Pfizer, Allergan, Actavis, Abbott, RPR and CSL. ITF Pharma's sales and marketing organisation has an impressive track record in selling Women's Health products in the US.



Under the licence, Starpharma is eligible to receive up to US\$101M (A\$142M) in regulatory approval and commercialisation milestones in addition to escalating double-digit royalties on sales. The milestones comprise US\$20M (A\$28M) in regulatory approval milestones for the two BV indications and up to US\$81M (A\$114M) in commercial milestones. Initially Starpharma will be responsible for supplying VivaGel® BV to ITF Pharma, however, in the future, Italfarmaco may apply for FDA approval of its own manufacturing facility.

Starpharma is responsible for regulatory activities for VivaGel® BV while ITF Pharma will be responsible for all commercialisation activities, including product launch, market pricing, reimbursement, marketing, promotion and sales.

The regulatory process for VivaGel® BV in the US is already well-advanced. Starpharma's New Drug Application (NDA) for VivaGel® BV is currently undergoing FDA priority review under Fast Track status, following acceptance of the NDA in July 2018.

Commenting on the licence, Dr Jackie Fairley, CEO of Starpharma said: "We are delighted to licence VivaGel® BV to ITF Pharma for the US. ITF Pharma is an organisation with a strong pedigree in Women's Health, a high calibre commercial team and a great deal of sales and marketing experience in the category. We look forward to working with them to bring this highly anticipated and innovative product to women throughout the US".

"There are currently no approved products in the US for prevention of recurrent BV, and feedback from clinicians and patients indicate a strong interest in new BV therapies. Following approval and launch of VivaGel® BV, these patients will finally have an effective, non-antibiotic BV treatment and an approved product for recurrent BV", added Dr Fairley.

Dennis Willson, ITF Pharma CEO, commented: "We're very pleased to be partnering with Starpharma in an area of such significant unmet need, with this innovative product. VivaGel® BV has been described as 'life-changing' by BV patients in the US. We think it's a breakthrough product in the management and prevention of BV".

The term of the US licence with ITF Pharma is the later of 10 years or patent expiry (at least 2030 with potential extensions out to 2033) and includes customary provisions to extend the agreement. There are binding performance obligations on ITF Pharma, including commitment to launch within a specified timeframe and minimum annual purchases for the duration of the agreement as well as termination provisions under certain circumstances. All other commercial terms of the agreement remain confidential.

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.

The VivaGel® BV treatment product targets an area of significant unmet medical need in a high-value market (est. US\$750M). Prevention of recurrent BV is another high value market (est. US\$1B) for VivaGel® BV which stands to be the first in class in the US as there are no other approved products to prevent recurrent BV in the US.

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 having it recurrently. 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 other approved products in the US for recurrent BV making VivaGel® BV a first-in-class therapy supported by large, randomised clinical studies.

About ITF Pharma, Inc.

ITF Pharma is a subsidiary of Italfarmaco S.p.A, a privately held European specialty pharmaceutical company. ITF Pharma's main emphasis is on sales and marketing of women's health, urology and neurology products. The ITF Pharma field sales representatives are strategically located in optimal locations throughout the US. They focus their promotional efforts exclusively on high-volume, office-based OB/GYN's and Urologists, as well as clinic-based neurologists. In addition to field sales representatives, ITF Pharma have a tele-detailing team that focuses on physicians in smaller markets and white spaces, while a national account team is focused on selected wholesalers, PBM's, MCO's and Medicaid programs.



Women's Choice Pharmaceuticals – a division of ITF Pharma – is focused on delivering the highest-quality products within the Women's Health Care and Urology Markets, Women's Choice has a commitment to quality and the well-being of patients across the globe.

For more information please visit: <https://itfpharma.com/> and <http://www.wcpharma.com/the-company/>

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 is under Fast Track review by 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. 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.