ASX Announcement

VivaGel® BV secures TGA approval for prevention of BV

- **VivaGel® BV approved claims in Australia have been expanded to also include prevention of recurrent bacterial vaginosis (BV)**
- **VivaGel® BV is the only OTC pharmacy product in Australia to be approved for the treatment of BV and prevention of recurrent BV**
- **Approximately one in three women experience BV and 40-50% will have a recurrence within 3-6 months**

Melbourne, Australia; 25 September 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that the Australia Therapeutic Goods Administration (TGA) has approved an expansion of the marketing authorisation for VivaGel® BV (Fleurstat BVgel) to now include the indication of *prevention of recurrent bacterial vaginosis*. These expanded claims bring the approved indications for VivaGel® BV (Fleurstat BVgel) in line with those in Europe and Asia.

BV is the most common vaginal condition worldwide and twice as common as thrush. One in three women experience BV and it is a highly recurrent condition with 40-50% of sufferers having a recurrence of BV within 3-6 months. BV is a serious condition that is characterised by unpleasant vaginal odour and discharge, and caused by an overgrowth of pathogenic bacteria. BV is associated with a range of serious reproductive health-related medical problems and results in significant social impacts for women. Recurrent BV has particularly significant psychosocial impacts on women, including severely affecting self-esteem and sex life, and avoidance of public settings including their workplace.

The new indication approved by TGA for VivaGel® BV includes prevention of unpleasant vaginal odour and discharge, and helping to maintain normal vaginal pH and vaginal flora balance.

VivaGel® BV is an Australian innovation – invented, fully developed and taken through to commercialisation by Starpharma. VivaGel® BV (Fleurstat BVgel) is the #1 ranked topical BV treatment[1] in Australia, is the only non-antibiotic treatment approved for BV and is available over-the-counter (OTC) at pharmacies in Australia, without the need for a prescription. VivaGel® BV is now approved in 40 countries around the world and has also been launched in Europe, Asia and New Zealand.

Dr Jackie Fairley, Starpharma CEO, commented: “It is great to see the Australian approved indications for VivaGel® BV now aligned with Europe and Asia. We are also pleased that Australian women can use the product to prevent, as well as treat, this troublesome and highly recurrent condition. VivaGel® BV is the only product approved to prevent BV in Australia.”

Alison Holland, Head of Consumer OTC Business at Aspen Pharmacare Australia, commented: “Fleurstat BVgel represents a true innovation in the management of bacterial vaginosis (BV) and empowers women to access BV treatment through their pharmacy. BV and recurrent BV are both areas of significant unmet need. We are excited to now also be able to provide an option for the many Australian women that suffer recurrent BV.”

[1] #1 ranking by A$ ex IMS

About VivaGel® BV

VivaGel® BV is a novel, non-antibiotic therapy for the treatment of bacterial vaginosis (BV) and relief of symptoms and prevention of recurrent BV. BV is the most common vaginal condition worldwide and twice as common as thrush. One in three women will experience BV and half of these women will have recurrent BV.

BV is a troublesome and often recurrent condition that causes unpleasant vaginal odour and discharge symptoms that have significant social impact for women. BV has also been associated with a range of other serious reproductive health-related medical problems.

VivaGel® BV is available for sale under the brand names Fleurstat BVgel (Australia), Betafem® BV Gel (UK), BETADINE BV™ Gel (Europe) and BETADINE™ BV Gel (Asia).

FLEURSTAT BVGEL (VivaGel® BV) for the treatment of BV and relief of symptoms

Ask your pharmacist – they must decide if this product is right for you. Always read the label. Follow the directions for use. Do not use for more than 7 days unless a doctor has told you to. See your doctor if symptoms persist after 7 days or recur within 2 weeks, and if you consider you may be at risk of an STI. See a doctor if you are diabetic or pregnant/breastfeeding (or plan to be).

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 for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) 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 Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

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 three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. 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. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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Disclosure
This ASX Announcement was authorised for release by the Chairman, Mr Rob Thomas.

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.