



# VivaGel<sup>®</sup> BV launched in Europe

- VivaGel<sup>®</sup> BV has been launched in Europe by Mundipharma, under the brand name Betadine BV<sup>™</sup>
- Betadine BV<sup>™</sup> will be available Over-The-Counter, without prescription
- Mundipharma is rolling out Betadine BV<sup>™</sup> throughout Europe during the year
- European launch triggers a milestone payment of US\$0.5M (A\$0.72M)
- Starpharma is eligible to earn total milestones up to US\$24.7M, plus revenue share, for all territories under Mundipharma's licence
- Regulatory activities are underway for multiple countries across other Mundipharma regions

**Melbourne, Australia; 27 June 2019:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that VivaGel<sup>®</sup> BV has been launched in Europe under the brand name Betadine BV<sup>TM</sup>. The product has been launched in several countries in Europe, including Germany, with further roll-out in additional European countries during the year.

Betadine BV<sup>TM</sup> will be available over-the-counter (OTC), without the need to see a doctor or obtain a prescription. Europe is the second region to launch VivaGel<sup>®</sup> BV and represents a large commercial opportunity with access to more than 260 million women.

VivaGel<sup>®</sup> BV (Betadine BV<sup>TM</sup>) is a novel, non-antibiotic therapy for treatment and prevention of bacterial vaginosis (BV). BV is the most common vaginal condition worldwide and twice as common as thrush. VivaGel<sup>®</sup> BV (Betadine BV<sup>TM</sup>) is an Australian innovation –invented, fully developed and taken through to commercialisation by Starpharma.

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

Betadine BV<sup>™</sup> is being marketed by Mundipharma, a leading global pharmaceutical company which owns the successful international brand BETADINE<sup>®</sup>. Mundipharma is one of the largest privately-owned pharmaceutical companies in the world employing over 8,600 people.

The launch of Betadine BV<sup>™</sup> in Europe triggers a milestone payment of US\$0.5M (A\$0.72M) to Starpharma. Starpharma is eligible to earn total milestones up to US\$24.7M, plus revenue share, for all territories under Mundipharma's licence.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to achieve another territory launch of VivaGel<sup>®</sup> BV this year, and our first with Mundipharma. Europe represents a very important market for VivaGel<sup>®</sup> BV and we're delighted that our breakthrough product will be available to millions of European women who suffer from BV. Mundipharma have a excellent track record in the OTC space and a leading position in feminine care with their successful international brand BETADINE<sup>®</sup>. We look forward to working with Mundipharma on further registrations and launches across the globe".



Raman Singh, Mundipharma CEO, commented: "We are delighted to launch Betadine BV<sup>™</sup> in Europe. This product represents a true innovation in the management of bacterial vaginosis (BV). It sits well under the BETADINE<sup>®</sup> brand, which has emerged as a powerful brand platform for consumer healthcare products, trusted by women globally."

Starpharma's and Mundipharma's marketing and regulatory teams continue to work actively together on further launches of VivaGel<sup>®</sup> BV in Europe and also in other regions, such as Asia. Regulatory activities are underway for multiple countries across Mundipharma's regions.

### About VivaGel® BV

VivaGel<sup>®</sup> BV is a patented, water-based vaginal gel containing the dendrimer, astodrimer sodium (SPL7013). VivaGel<sup>®</sup> BV has a novel mechanism of action targeting biofilms. It works to treat BV by disrupting the attachment of BV-causing bacteria to the vaginal lining. The original dendrimer technology on which VivaGel<sup>®</sup> BV is based was discovered by CSIRO.

VivaGel® BV is marketed in Europe by Mundipharma under the brand name Betadine BV<sup>TM</sup> and in Australia by Aspen Pharmacare. VivaGel® BV is a breakthrough product that works rapidly. It 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). VivaGel® BV is approved in Europe for treatment and prevention of recurrent BV, and has been submitted to regulatory authorities in a number of international markets, including the US. Prevention of recurrent BV is another high value market (est. US\$1B) for VivaGel® BV.

#### About Bacterial Vaginosis (BV)

Bacterial vaginosis is the most common vaginal infection worldwide, and twice as common as thrush. It 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). Smoking, the use of some hygiene products and several other risk factors are linked to a higher risk of developing BV. BV has been associated with a range of serious medical problems.

#### 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<sup>®</sup> portfolio and DEP<sup>®</sup> drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel<sup>®</sup>: Starpharma's women's health product - VivaGel<sup>®</sup> BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel<sup>®</sup> BV for bacterial vaginosis (BV), is available for sale under the brand name Betadine BV<sup>™</sup> (Europe) and Fleurstat BVgel (Australia) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel<sup>®</sup> 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<sup>®</sup> condom (an antiviral condom which includes VivaGel<sup>®</sup> in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel<sup>®</sup> condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the Lifestyles<sup>®</sup> Dual Protect<sup>™</sup> brand.

**DEP®** - **Dendrimer Enhanced Product**<sup>®</sup>: Starpharma's DEP<sup>®</sup> drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP<sup>®</sup> programs, including improved efficacy, safety and survival. Starpharma has two internal DEP<sup>®</sup> products – DEP<sup>®</sup> docetaxel and DEP<sup>®</sup> cabazitaxel - in clinical development in patients with solid tumours, with DEP<sup>®</sup> irinotecan due to commence clinical trials shortly. Starpharma's partnered DEP<sup>®</sup> programs include a multiproduct DEP<sup>®</sup> 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<sup>®</sup> version of one of AstraZeneca's major marketed oncology medicines.

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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, est