

Mundipharma licenses Starpharma's VivaGel BV

Mundipharma; PR Newswire

1,599 words

3 May 2018

10:27

PR Newswire Asia

PRNASI

English

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- Mundipharma licenses Starpharma's VivaGel® BV for Asia, Middle East, Africa and the majority of Latin America, to be marketed as part of the popular BETADINE® Feminine Care portfolio

- Mundipharma is a leading global pharmaceutical company and owns the successful international brand - BETADINE®

- BETADINE® has a market leading position in Feminine Care, trusted by women globally

- Mundipharma will commence regulatory activities in their licensed territory immediately to secure expedited launch of VivaGel® BV

- Deal terms include milestones of ~A\$12.2 million and a revenue share

SYDNEY, May 3, 2018 /PRNewswire/ -- Starpharma (ASX: SPL, OTCQX: SPHRY) and Mundipharma today announced they have signed a multi-region licence for the sales and marketing rights to VivaGel® BV in Asia (including China, Japan and Korea), the Middle East, Africa and the majority of Latin America.

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Mundipharma is one of the largest privately-owned pharmaceutical companies in the world and has a presence in over 120 countries, employing over 8,600 people.

Mundipharma will register and launch VivaGel® BV as part of the popular BETADINE® range, which is sold in more than 120 countries. BETADINE® has a market leading position in Feminine Care and this licence enables Mundipharma to develop the consumer market for VivaGel® BV in rapidly developing markets across Asia, the Middle East, Africa and Latin America, where demand for trusted intimate health and hygiene products is growing.

Under the licence, Starpharma will receive returns via a revenue share on VivaGel® BV sales. In addition, Starpharma is eligible to receive signing, regulatory and commercial milestones totaling up to A\$12.2 million (US\$9.2 million) including a A\$1.3 million (US\$1 million) upfront payment. The term of the agreement is 15 years and incorporates commercial performance obligations, including minimum annual purchases by Mundipharma. Other commercial terms of the agreement remain confidential.

Mundipharma is responsible for regulatory activities, market pricing and marketing and promotion of the product. Mundipharma will commence regulatory activities immediately with initial approvals anticipated towards the end of 2018. Under the agreement, Starpharma retains ownership of the VivaGel® BV trademark and will supply Mundipharma with product.

VivaGel® BV already has regulatory approval in both Europe and Australia. In addition, Starpharma has lodged its New Drug Application (NDA) with the US FDA under a Fast Track designation. The NDA submission provide a comprehensive clinical and regulatory package to support rapid approval in many of Mundipharma's licensed countries.

Starpharma is also in advanced commercial negotiations for marketing rights to VivaGel® BV in the rest of world, including North America and Europe, and expects to announce further licensing arrangements in the coming months.

Commenting on the licence, Dr Jackie Fairley, CEO of Starpharma said: "We are delighted to have licensed VivaGel® BV to Mundipharma, a global leader in healthcare. Mundipharma's market leading position and

extensive sales, marketing and regulatory network make them the ideal partner for VivaGel® BV in this expansive territory. The licence represents a financially attractive deal for Starpharma. Over the coming months, we'll be working closely with Mundipharma to secure market access for VivaGel® BV as quickly as possible throughout their territory."

Raman Singh, Mundipharma CEO, commented: "The VivaGel® BV product represents a true innovation in the management of bacterial vaginosis (BV). It sits well under the BETADINE® brand, which has emerged as a powerful brand platform for consumer healthcare products, trusted by women globally."

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.

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). Smoking, the use of some hygiene products and several other risk factors are linked to a higher risk of developing BV. Current therapies for BV are inadequate and have many unpleasant side-effects, there are also no approved products in the US for rBV making VivaGel® BV a first-in-class therapy supported by large, randomised clinical studies.

About Mundipharma

Mundipharma and its network of privately owned Independent Associated Companies (IACs) is dedicated to alleviating human suffering and improving quality of life for the human race. The Mundipharma story, spanning over six decades brings together a visionary approach and a pioneering spirit -- what is best told through its patients, employees and the communities across six continents in which they serve. Mundipharma is focused on business transformation by leveraging global leadership in pain and, through a shared spirit of innovation, building a growing presence in antisepsis, respiratory, oncology, ophthalmology, consumer healthcare and other specialty areas.

For more information please visit: www.mundipharma.com

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, a dendrimer 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 120+ countries in Asia, the Middle East, Africa and majority of Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma 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.

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