





ASX ANNOUNCEMENT

Japan VivaGel® condom launch timing impacted by classification review

Melbourne, Australia; 5 December 2014: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced that the planned launch timing of the VivaGel® condom in Japan would be delayed following a review of the specific category of medical device classification by the Japanese regulatory authorities.

The regulatory status of the VivaGel® condom in other regions where the product is approved for sale (Australia and New Zealand) or is undergoing regulatory review is not affected and does not rely upon the Japanese classification or approval process.

Since receiving regulatory certification for the VivaGel® condom in Japan earlier this year, Starpharma's commercial partner, Okamoto Industries (Okamoto), has been actively undertaking launch preparations for the product with a view to launching the product shortly. In the context of pre-launch labelling discussions and against a background of recent changes to medical device regulations in Japan, the parties have been informed by the Japanese regulatory authorities that they are reviewing the specific device classification of the VivaGel® condom. The product cannot be sold in Japan until the review process is complete.

Starpharma and Okamoto are working closely with Japan's Ministry of Health, Labour and Welfare (MHLW) to confirm the classification as soon as possible. At this time, Starpharma cannot be certain about the precise extent of the delay in the Japanese market launch but estimate it to be at least 3-6 months.

Starpharma CEO, Dr Jackie Fairley, said, "Whilst we are disappointed and surprised with the need to review the classification of our VivaGel condom in the Japanese market, we are working closely with Okamoto and the authorities to expedite this process. This is a matter of regulatory classification in one market and there is no indication of concern with the product itself.

"Last week the MHLW introduced significant changes to medical device regulations in Japan. These include changes to the regulatory bodies that approve certain categories of medical devices and the associated regulatory processes in Japan, and it appears that these changes may have influenced this situation."

VivaGel® condoms are already on sale in Australia and approved for sale in New Zealand. Regulatory processes are underway in a number of other markets and will continue in parallel with, and are not impacted in any way by, the review of the classification status in Japan.

The VivaGel® condom is one of three products in Starpharma's VivaGel® portfolio, with the other two in late stage development for the management of bacterial vaginosis (BV). Regulatory files for the BV Symptomatic Relief product will be submitted in the near future

and this re-classification is not relevant to that product or the Phase 3 trials for prevention of recurrent BV, which are progressing well.

About VivaGel®

Starpharma's VivaGel® has both antibacterial and antiviral properties and has been shown in laboratory studies to inactivate up to 99.9% of HIV, Herpes and HPV, which are common viruses that cause STIs. The VivaGel® condom incorporates VivaGel® in the condom lubricant. VivaGel® is also in late stage development as a vaginal gel formulation for the management of bacterial vaginosis.

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 three core development programs: VivaGel® portfolio, drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead products are based on VivaGel® (SPL7013, astodrimer sodium), a proprietary dendrimer which is a potent microbicidal agent. VivaGel® formulated as a water based gel and delivered vaginally is under clinical development for the management and prevention of bacterial vaginosis (BV). Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries. Inc., (TSE: JP3192800005) to market a value-added, VivaGel® condom. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, ZERO® and SKYN®.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Drug Delivery partners include GSK, Lilly and AstraZeneca. A number of dendrimer-enhanced, or DEP™ versions of existing drugs are under development. The most advanced of these is DEP™ docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®), which is in clinical development. In preclinical studies DEP™ docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel).

In agrochemicals Starpharma has a series of partnerships with leading industry players including global leader Adama (formerly Makhteshim Agan) as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

FOR FURTHER INFORMATION

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Forward Looking Statements

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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.