ASX Announcement

VivaGel® condom receives final regulatory approval in Japan

Melbourne, Australia; 2 January 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that the VivaGel® condom has received final regulatory approval and is now able to be marketed in Japan, following the completion of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) review of the product's medical device classification and associated data. This final approval follows on from the previously granted regulatory certification, which was attained for the VivaGel® condom.

Starpharma has worked closely with its commercial partner for Japan, Okamoto Industries (Okamoto), throughout the regulatory process. Okamoto has already commenced key launch preparations, including labelling and manufacturing activities, and plans to launch the VivaGel® condom in the first half of 2019. Starpharma will be eligible to receive royalty payments under its licence with Okamoto.

Okamoto is Japan's leading marketer of condoms with a majority share of the Japanese condom market, which is one of the world's largest condom markets and estimated to be in the order of US$500 million per annum[1]. Okamoto has sales revenue of more than US$1.1 billion and around 2,600 employees. In addition to its dominant position in the Japanese condom market, Okamoto also holds strong market positions in several other Asian markets, including Korea, Taiwan, Malaysia, Singapore and China.

Starpharma Chief Executive Officer, Dr Jackie Fairley, said, "This regulatory achievement marks a key commercial milestone for the VivaGel® condom, particularly given the significant value of the Japanese condom market and our partner's leading market position. Okamoto has an outstanding product portfolio and heritage in the successful commercialisation of new products and we're very excited to soon see VivaGel® condoms for sale in Japan."

Okamoto's senior managing director, Mr. Keiji Ikeda, has noted that condoms with functional coatings and gels represent the next wave of innovation in the Japanese condom market following on from a previous focus on condom thinness. Mr. Ikeda said, "We are very pleased to be in a partnership with Starpharma for this innovative product and excited about its upcoming launch."

The VivaGel® condom is also approved for sale in Australia and Canada, and further regulatory reviews continue in a number of other geographic regions.

About the VivaGel® condom

The VivaGel® condom is a world-first product based on innovative Australian technology. It is the only condom of its type, providing barrier protection and incorporating the proprietary compound, astodrimer sodium (SPL7013, VivaGel®) in the condom lubricant. VivaGel® has been proven in laboratory studies to inactivate up to 99.9% of HIV, HSV and HPV.

[1] Market Data Bank (MDB) Report issued February 2009, Condoms: A Global Strategic Business Report and Industry Data

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer 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 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 Japan (Okamoto), Australia, Europe, Canada and China. 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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