



## ASX ANNOUNCEMENT

### **VivaGel<sup>®</sup> condom receives TGA device certification - Launch preparations to follow**

**Melbourne, Australia; 21 July 2014:** Starpharma (ASX:SPL, OTCQX:SPHRY) today announced achievement of a major milestone with the receipt of Conformity Assessment Certification for the VivaGel<sup>®</sup> condom by the Australian Therapeutic Goods Administration (TGA). This TGA certification is similar to CE certification of devices (CE Mark) in Europe.

Starpharma's marketing partner, Ansell (ASX:ANN) plans to launch the VivaGel<sup>®</sup> condom under their brand, LifeStyles Dual Protect<sup>™</sup>, in the coming months, following listing on the Australian Register of Therapeutic Goods (ARTG). TGA certification will also support certain regulatory processes in other markets.

The VivaGel<sup>®</sup> condom is a world-first product based on innovative Australian technology. It is the only condom of its type, providing barrier protection and incorporating a proprietary antiviral compound (VivaGel<sup>®</sup>) in the lubricant.

LifeStyles Dual Protect<sup>™</sup> condoms to be marketed by Ansell will carry the VivaGel<sup>®</sup> brand and Starpharma will receive royalties based on sales.

Ansell President & General Manager, Sexual Wellness Global Business Unit, Peter Carroll, said:

*"Ansell looks forward to rolling out its marketing and sales campaign to support the launch of LifeStyles Dual Protect<sup>™</sup> over the coming months with the first product expected to be available on shelves soon."*

*"Our partnership with Starpharma is a great example of two highly innovative Australian businesses working together to bring to market a ground-breaking new sexual health product. New product development is central to Ansell's business strategy and this highly innovative product is exciting for both companies."*

Ansell is a global leader in protection solutions, manufacturing and marketing condoms across the world and ranked number two globally. In Australia, Ansell's share of the condom market is around 70%. The global branded condom market is estimated to be worth approximately \$1.1 billion.

*"With the launch of LifeStyles Dual Protect<sup>™</sup> expected in the near future, certification by TGA marks another major milestone for the VivaGel<sup>®</sup> condom and our partnership with Ansell, one of the world's leading condom companies and healthcare innovators,"* said Starpharma Chief Executive Officer, Dr Jackie Fairley.

*"The LifeStyles Dual Protect<sup>™</sup> condom is a great example of a globally significant innovation pioneered, developed and commercialised by two Australian companies."*

LifeStyles Dual Protect™ condoms are lubricated with VivaGel® lubricant, which contains 0.5% astodimer sodium (previously SPL7013, also referred to as VivaGel®). Condoms can help reduce the risk of pregnancy and condom use may help reduce the risk of transmission of HIV/AIDS and other STIs. VivaGel® is intended to help reduce the risk of exposure to viruses that cause STIs, having been shown in laboratory studies to inactivate up to 99.9% of HIV (human immunodeficiency virus), HSV (herpes simplex virus) and HPV (human papillomavirus).

Extensive international consumer research conducted in condom users confirms a high level of consumer interest in the VivaGel® condom concept with more than 80% of participants surveyed rating the product as very interesting and more than 90% indicating they would buy it.

In Australia, the prevalence of STIs continues to rise. Genital herpes, caused by HSV, is estimated to affect one in eight Australians aged 25 years and over, although many people are unaware of their status and can pass on the infection without knowing.<sup>1</sup> Alarming, the rate of newly diagnosed HIV infections rose 10% in the 12 months to the end of 2012 – the largest increase in 20 years.<sup>2</sup> The number of infections diagnosed in 2013 remains at a 20-year high and represents a 70% increase over the number detected in 1999, when diagnoses were at their lowest.<sup>3</sup>

The TGA Conformity Assessment Certification was achieved after examination by TGA of the evidence of conformity of the VivaGel® condom to the Essential Principles for medical devices, which set out the requirements relating to the safety and performance of products.

Starpharma has a licensing agreement that provides marketing rights to Ansell for the VivaGel® condom in countries outside of Japan. In Japan Starpharma has licensed the product to Okamoto Industries, Inc. Okamoto is Japan's leading marketer of condoms with approximately 60% of the Japanese condom market, the second largest global market next to the US.

Achievement of this regulatory milestone for the VivaGel® condom follows Starpharma's announcement in March 2014 of regulatory certification of the VivaGel® condom in Japan. Regulatory processes are ongoing in a number of other markets and this TGA approval will support some of these.

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*LifeStyles Dual Protect™ is a trademark of Ansell  
VivaGel® is a registered trademark of Starpharma*

## 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

<sup>1</sup> [http://www.sexualhealthaustralia.com.au/page/genital\\_herpes.html](http://www.sexualhealthaustralia.com.au/page/genital_herpes.html)

<sup>2</sup> The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia – Annual Surveillance Report 2013. The Kirby Institute, The University of New South Wales.

<sup>3</sup> The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia – Annual Surveillance Report 2014. The Kirby Institute, The University of New South Wales.

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, astodimer 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®-coated condom. A VivaGel®-coated condom has received marketing approval in Japan. 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

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.