



## ASX ANNOUNCEMENT

### Starpharma's VivaGel® Phase 3 trials 60% enrolled

#### Key points

- Enrolment passes 60% for VivaGel® Phase 3 BV treatment trials
- Trials well on track for completion in 2012
- One of the trials has already enrolled more than 80% of subjects

**Melbourne Australia; 4 June 2012:** Starpharma Holdings Ltd (ASX:SPL, OTCQX: SPHRY) is pleased to report excellent progress in the recruitment for its pivotal Phase 3 trials for VivaGel® as a treatment for bacterial vaginosis (BV).

Two concurrent Phase 3 trials are underway and recruitment for these trials, which commenced in late March 2012, has recently passed the halfway mark with 60% of patients already enrolled. One of the trials has already exceeded 80% enrolment.

The Phase 3 treatment trials are taking place across more than 30 international sites, primarily in the United States. Following the completion of the Phase 3 trials Starpharma expects to prepare and submit a New Drug Application (NDA) to the US Food and Drug Administration (FDA) in parallel with engaging in licensing negotiations. The FDA has already provided formal agreement as part of a Special Protocol Assessment (SPA) declaring that the phase 3 trials' design, clinical endpoints and statistical analyses are acceptable for FDA approval once completed.

"We are extremely pleased with the rate of enrolment for the pivotal Phase 3 trials underway. We are already approaching two thirds enrolment in less than three months, which means we are well on track to complete and report the trials in 2012 as indicated," said Dr Jackie Fairley, Chief Executive Officer of Starpharma.

BV is the most common vaginal infection worldwide, and the most common cause of vaginal irritation, discharge and malodour. It is particularly prevalent in the US, where it affects an estimated one-third of the adult female population. BV is often implicated in pelvic inflammatory disease and may also be associated with pre-term birth and an increased risk of sexually transmitted infections, including HIV.

"Completion of these Phase 3 trials is a very important milestone for Starpharma as it is the precursor to seeking regulatory approval for VivaGel® as a treatment for BV," Dr Fairley said.

The market for topical treatments of BV is estimated at US\$300-\$350 million. However, existing conventional antibiotic treatments are considered suboptimal with relatively low cure rates and high rates of recurrence, unpleasant side-effects, and high levels of bacterial resistance. VivaGel® is a non-antibiotic gel that is applied to the vagina with an applicator. VivaGel® is not absorbed into the bloodstream (as antibiotics are), and as such it is not

associated with the side effects of antibiotics. Clinical trials of VivaGel<sup>®</sup> have shown a high level of patient acceptability.

Details of the Phase 3 trial design are contained in the announcement of the trial commencement made on 22 March 2012 available at

[http://www.starpharma.com/asx\\_announcements](http://www.starpharma.com/asx_announcements).

## ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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 uses. Starpharma has three core development programs: VivaGel<sup>®</sup> portfolio, drug delivery and agrochemicals with the Company developing a number of products internally and others via commercial partnerships. In addition, products for diagnostics and laboratory reagents are already on market through licence arrangements with partners including Siemens Healthcare and Merck KGaA.

Starpharma's lead product is VivaGel<sup>®</sup> (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel<sup>®</sup> is under clinical development for the treatment and prevention of bacterial vaginosis (BV) and also as a vaginal microbicide to prevent the transmission of sexually transmitted infections including HIV and genital herpes.

Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries Inc (TSE) to market a value-added, VivaGel<sup>®</sup>-coated condom. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles<sup>®</sup>, ZERO<sup>®</sup> and SKYN<sup>®</sup>. Okamoto is the market leader for condoms sold in Japan, the world's second largest condom market.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Most recently Starpharma announced pre-clinical results in its Docetaxel (Taxotere<sup>®</sup>) program demonstrating significant improvements in that agent's anticancer efficacy and the enhancement of solubility offering potential safety benefits as well. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup<sup>®</sup>).

Starpharma's headquarters and research facilities are located in Melbourne, Australia.

## FOR FURTHER INFORMATION

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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 health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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.