ASX ANNOUNCEMENT

VivaGel® phase 3 study results

Key points:

- *Phase 3 study results for treatment of BV – VivaGel® demonstrate statistically significant Clinical Cure and effectiveness in treating patient symptoms of BV at the end of treatment (EOT), but primary endpoint (Clinical Cure 2-3 weeks later) not met.*

- *Whilst for the USA, a new drug application (NDA) for BV treatment will not be filed as planned, given the efficacy shown for VivaGel® at EOT, other claim strategies (symptomatic relief) and other regulatory jurisdictions may well be available and will be explored.*

- *Demonstration of statistically significant Clinical Cure, resolution of patient symptoms of BV and excellent safety profile also support the prevention of BV recurrence indication for VivaGel®.*

- *Phase 2 trial of VivaGel® for the prevention of BV recurrence remains on track, with results anticipated in Q1 2013, and is not negatively impacted by these results.*

- *Patient acceptability research undertaken at the end of the trial was very positive with VivaGel® treated women reporting rapid and sustained relief from symptoms.*

- *No negative impact on other products based on SPL7013 (VivaGel®), while BV symptom resolution and safety data support other product lines (e.g. condom).*

Melbourne Australia; 28 November 2012: Starpharma Holdings Limited (ASX: SPL, OTCQX SPHRY) today announced the results of its two phase 3 studies of 1% SPL7013 Gel (VivaGel®) for the treatment of bacterial vaginosis (BV). Both studies showed that VivaGel® achieved statistically significant Clinical Cure and resolution of patient-reported symptoms of BV at the End of Treatment visit (EOT, 2-5 days post treatment). However, the primary endpoint of Clinical Cure 2-3 weeks after the cessation of treatment (Test of Cure, TOC visit) was not met.

A new drug application (NDA) for VivaGel® for the treatment of BV will not be filed with the FDA at this time due to the lack of statistical significance at TOC, although other claim strategies (e.g. symptomatic relief) and other regulatory jurisdictions may well be available and will be fully explored.

Importantly, although not sustained for the full 2-3 weeks after cessation of therapy, the highly statistically significant Clinical Cure achieved with VivaGel® compared with placebo gel at the EOT time point, 2-5 days after the end of treatment, confirms, in these large scale clinical studies, that VivaGel® can have a significant impact in the treatment and management of BV.

Each study (SPL7013-015 and SPL7013-016) enrolled approximately 250 women. In each study 50% and 57% women, respectively, achieved Clinical Cure with VivaGel® versus just 17% and 21% with placebo ($p<0.001$) at EOT. At TOC, the Clinical Cure rates for VivaGel® and placebo were 27% versus 21%, respectively, in SPL7013-015 and 28% versus 28% in SPL7013-016.

Vaginal discharge assessed by the clinician was resolved in 71% and 74% of women (statistically significant versus placebo, $p<0.001$), while 61% and 68% of participants reported absence of abnormal vaginal discharge ($p=0.033$ and $p<0.001$, respectively, versus placebo). Vaginal odour, as assessed by the clinician ('whiff' test) was resolved in 72% and 70% of women ($p<0.001$) at EOT, while 76% and 72% of participants reported resolution of unpleasant vaginal odour ($p<0.001$).

The results are entirely consistent with the strategy being pursued to address prevention of recurrence of BV, for which ongoing therapy every second day with VivaGel® is intended to achieve a reduced risk of recurrence of the condition.

Indeed, the demonstration of statistically significant Clinical Cure at EOT, which was the key secondary endpoint of these studies, is highly supportive of VivaGel® for prevention of recurrence of BV, and there is no negative impact of these phase 3 results on the investigation of the product for this indication. The phase 2 study of VivaGel® (SPL7013-014) for prevention of recurrence of BV is ongoing, and results are anticipated in Q1 2013.

These phase 3 results at TOC are in contrast to the results from the 2011 phase 2 BV treatment study in which highly statistically significant Clinical Cure was achieved for VivaGel® 1% at both EOT and TOC. There appear to be several potentially confounding factors in the phase 3 studies, including unusually high placebo Clinical Cure rates at some sites, and the fact that these placebo cure rates increased between the two time points (EOT to TOC), rather than decreased. Both of these factors may have contributed to the inability to achieve the required primary endpoint and reproduce the phase 2 results.

Other potentially confounding factors, all of which are known to impact BV, may include rate of condom use, decreased sexual activity in the placebo-treated groups due to ongoing symptoms, and the possibility of placebo participants with unresolved or ongoing symptoms changing their behavior or seeking other therapies to ameliorate their symptoms. These potentially confounding factors are currently being thoroughly investigated and will be discussed at planned meetings with the US FDA and other regulatory authorities as soon as practicable.

While the primary endpoint in these studies was not met, these results do demonstrate efficacy of 1% SPL7013 Gel in treating BV, and are supportive of the hypothesis that recurrence of BV could be prevented by ongoing therapy (every second day), as is being investigated in the current phase 2 prevention of recurrence study, SPL7013-014.

Patients treated with VivaGel® also reported rapid resolution of their symptoms (discharge and odour) within just 2-3 days of starting treatment, and this symptomatic relief was sustained in a significant proportion of women at the later (TOC) time point. This finding is another promising indicator for the performance of VivaGel® in the prevention of recurrence

indication as it shows that onset of the effect is rapid. This rapid onset of action in symptom control was matched by very encouraging patient feedback on acceptability (see below).

Dr Jackie Fairley, Starpharma Chief Executive Officer said: "We are surprised and disappointed in not meeting the phase 3 FDA endpoint for the treatment indication in these trials, given the phase 2 trial results; however, we are also greatly encouraged by the statistically significant efficacy and excellent symptomatic relief shown for VivaGel® at the end of treatment in these studies and we do plan to fully explore the potential for regulatory filings based on these data. In addition we, and our expert clinical advisors, see the efficacy demonstrated with VivaGel®, the excellent safety profile and patient feedback as very positive for the prevention indication,"

"With total global sales of ~$300-350M, the treatment market is significantly smaller and more competitive than the prevention of BV recurrence market. In that market – estimated to be at least 3 times larger – there are no approved products and VivaGel® would be first in class. Partner interest in the prevention of recurrence indication continues to be very strong," Dr Fairley added.

Due to its chronic nature and the high prevalence of recurrent BV (40-50% of BV sufferers), estimates by analysts, partners and Starpharma concur that the prevention of recurrence market is more than $1 billion (range 1-2 billion).

Expert clinical advisor to the program, Professor George Kinghorn, OBE, who is Clinical Director at NIHR Clinical Research Network, Department of Genitourinary Medicine, Royal Hallamshire and Sheffield Teaching Hospitals in the UK, commented: "Unfortunately the primary endpoint of these studies was not met, but the results showing statistically significant Clinical Cure of BV at the end of treatment are important, and combined with high patient acceptability and an excellent safety profile for the product, are highly encouraging in terms of the demonstration of a clinical effect of VivaGel®, and the potential utility of the product for prevention of recurrent BV, and as a potential adjunct in primary treatment using existing therapies."

The safety profile of VivaGel® in these phase 3 trials was excellent, with very low rates of both genitourinary and non-genitourinary adverse events, and was consistent with administration of a locally applied, non-systemically absorbed agent. Importantly, there were very few instances of candidiasis reported in women taking VivaGel®, with just 1.6% and 3.2% of women in 015 and 016, respectively, being diagnosed with the condition during the treatment and follow-up periods. This finding is in significant contrast to other BV treatments for which published candidiasis rates are around 10-20%. Following prolonged use of metronidazole, as many as 59% of women are reported to experience episodes of candidiasis, which result in further cost and inconvenience for women with BV. The safety profile of VivaGel® in these studies is, again, highly encouraging in terms of the prevention indication.

Given its good performance in symptom resolution in patients, not surprisingly, women rated VivaGel® significantly higher than placebo in terms of effectiveness and overall satisfaction ($p<0.001$) in a treatment satisfaction questionnaire for medications (TSQM) undertaken at EOT. Twice as many women were satisfied to extremely satisfied with VivaGel® compared with the placebo ($p<0.001$).

In addition, formal market research undertaken with trial participants and key opinion leaders elicited substantial positive feedback on VivaGel® both in terms of effectiveness, rapid onset of effect and desirability of the formulation compared to current products. In this research, women with BV reported "constantly worrying" about "embarrassing" and "absolutely horrible" odour and discharge. Women also report the existing therapies as tasting "horrible", causing unpleasant side effects such as an "upset stomach", candidiasis (thrush)

and interfering with sexual intercourse. The clear gel and localised nature of VivaGel® use was preferred by women. Women who used VivaGel® reported very quickly noticing a "huge difference" in their BV.

Ultimately, the inability to meet the primary endpoint in either SPL7013-015 or -016 means that an NDA for VivaGel® for treatment of BV will not be submitted to the FDA as originally planned based on these data in Q1 2013. However, because of the positive results at EOT, the beneficial impact of the product on patient-reported symptoms, and the potentially confounding factors, discussions with the FDA and other regulators are certainly warranted to investigate the product options which may be open based on these data. These interactions will be scheduled as soon as practicable.

Partnering discussions are already underway for VivaGel® with a significant number of parties and will continue. Given that the majority of potential licensing partners have emphasized the importance and value of prevention of recurrence of BV indication for VivaGel®, it is expected that the achievement of statistically significant Clinical Cure at EOT in two large phase 3 studies, along with symptomatic relief and the excellent side effect profile, will assist in advancing these discussions.

In addition, these phase 3 study results have no negative implications for the condom coating products, as the marketing claims being pursued for condoms relate to the potent antiviral activity of SPL7013, the active dendrimer ingredient in VivaGel®. Many of the phase 3 study findings, including the demonstration of significant control of unpleasant vaginal odour, may have potential commercial applications in some geographic markets, while the excellent safety data add to the increasingly large database on the safety of SPL7013.

"In conclusion, despite this disappointing result the fundamentals of Starpharma's strategy have not changed. We have a platform technology that has broad applicability with the potential to generate multiple revenue streams. We have already demonstrated through our three development programs our ability to secure multiple partnerships with large, leading international companies. Starpharma remains in a strong cash position, with a cash balance of $37.6M at 30 September 2012. This balance excludes the newly announced $5.3M in estimated cash from R&D tax incentives and together these will allow Starpharma to continue to progress the multiple VivaGel® programs, as well as drug delivery and agrochemical programs as planned." Dr Fairley concluded.

Further details on the results of both trials are presented in the Appendix to this announcement.

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 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 product is VivaGel® (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel® 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 (Tokyo Stock Exchange) to market a value-added, VivaGel®-coated condom. Ansell manufactures

and sells leading condom brands worldwide, including Lifestyles®, ZERO® and SKYN®. 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. Partners include GSK, Lilly and AstraZeneca. In its internal program Starpharma recently announced significant tumour-targeting results in its docetaxel (Taxotere®) program, with animal studies resulting in levels of the cancer drug in tumour tissue more than 40 times greater than seen with the convention formulation. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships with leading industry players including Nufarm (ASX:NUF) as well as with 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 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.

APPENDIX 1 – CLINICAL TRIAL SUMMARY

Official Title:	A phase 3, double-blind, multicenter, randomized, placebo controlled study to assess the efficacy and safety of SPL7013 Gel (VivaGel®) for the treatment of bacterial vaginosis
Identifying Codes:	Starpharma Protocol Numbers: SPL7013-015 and SPL7013-016
Primary Objective:	To assess the efficacy of 1% SPL7013 Gel compared with placebo gel for the treatment of bacterial vaginosis (BV)
Primary Endpoint:	Clinical Cure at the Test of Cure (TOC) (Day 21-30) visit defined as resolution of clinical findings (i.e. Amsel criteria) from the Baseline visit (Day 1).
Secondary Objectives:	To determine the safety and tolerability of 1% SPL7013 Gel
Secondary Endpoints:	Clinical Cure at the End of Treatment (EOT) (Day 9-12) visit Nugent Cure, defined as a Nugent score of 0-3, at the TOC visit Nugent Cure at EOT visit Incidence of adverse events
Study Design:	Double-blind, multicentre, randomised, placebo-controlled, phase 3 studies. After screening eligible participants were randomised in a 1:1 ratio to receive either 1% SPL7013 Gel or hydroxyethyl cellulose (HEC) placebo gel at a dose of 5g administered vaginally at bedtime for 7 consecutive days. Participants were assessed for BV (both by Amsel criteria and Nugent score) at screening/Baseline, after last application (End-of-Treatment, EOT, Day 9-12) and at the final study visit approximately 2-3 weeks after last dose (Test-of-Cure, TOC, Day 21-30).
Sites:	SPL7013-015 was conducted at 18 sites in the US. SPL7013-016 was conducted at 11 sites in the US and 9 sites in Europe.
Key Inclusion Criteria:	• Post-menarchal females, aged 12 years or more • diagnosis of BV by Amsel criteria (*i.e.* all four of the following symptoms: presence of white to grey homogeneous discharge; positive whiff test indicating an amine (fishy) odor with addition of potassium hydroxide; vaginal pH greater than 4.5; and presence of clue cells ≥ 20% of total epithelial cells) • Nugent score of ≥ 4 • otherwise healthy, as determined by medical history, physical examination • normal Pap smear at or documented within 24 months of screening
RESULTS	All results presented in this release refer to the modified Intent to Treat (mITT) population.
Demographics	• SPL7013-015: A total of 247 participants, aged 17 to 57 years, were randomised to receive 1% SPL7013 Gel (N=126) or placebo gel (N=121) and received at least one dose of study gel. In the mITT population, a total of 92% of patients in the 1% group complied with the treatment regimen compared with 94% in the placebo group. • SPL7013-016: A total of 249 participants, aged 17 to 88 years, were randomised to receive 1% SPL7013 Gel (N=126) or placebo gel (N=121) and received at least one dose of study gel. In the mITT population, a total of 96% of patients in the 1% group complied with the treatment regimen compared with 86% in the placebo group.

Clinical Cure:	SPL7013-015		SPL7013-016	
	1% SPL7013 Gel	Placebo Gel	1% SPL7013 Gel	Placebo Gel
EOT *(2-5 days post R_x)*	50.4%**	16.5%	56.7%**	21.4%
TOC *(2-3 weeks post R_x)*	26.5%	20.9%	28.3%	28.2%

*** Statistically significant result compared with placebo, p < 0.001*

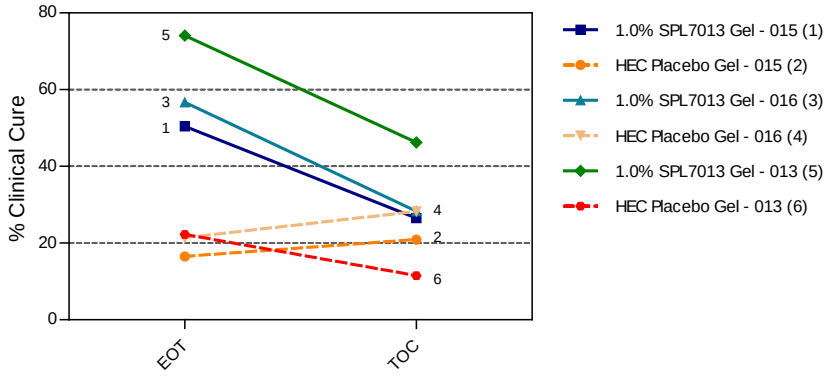
Highly statistically significant Clinical Cure was achieved in both phase 3 studies at EOT, but not at TOC. While the primary endpoint in these studies was not met, these results demonstrate efficacy of 1% SPL7013 Gel in treating BV, and predict that recurrence of BV could be prevented by ongoing therapy, as is being investigated in the current phase 2 prevention of recurrence study, SPL7013-014.

The results of the phase 3 studies were in contrast to the phase 2 study, in that statistically significant Clinical Cure at TOC in the 1% SPL7013 Gel groups compared with placebo was not achieved.

Figure 1 shows the BV Clinical Cure rates achieved with 1% SPL7013 Gel and placebo gel in phase 2 (013) and phase 3 (015 and 016) studies. The figure shows the increases in placebo cure rate between EOT and TOC in 015 and 016 that were in contrast to the decrease in placebo cure rate that occurred in the phase 2 study (013). Several potentially confounding factors may explain these surprising findings and these are currently being investigated.

Figure 1.

Clinical Cure in Phase 2 (013) and Phase 3 (015 and 016)

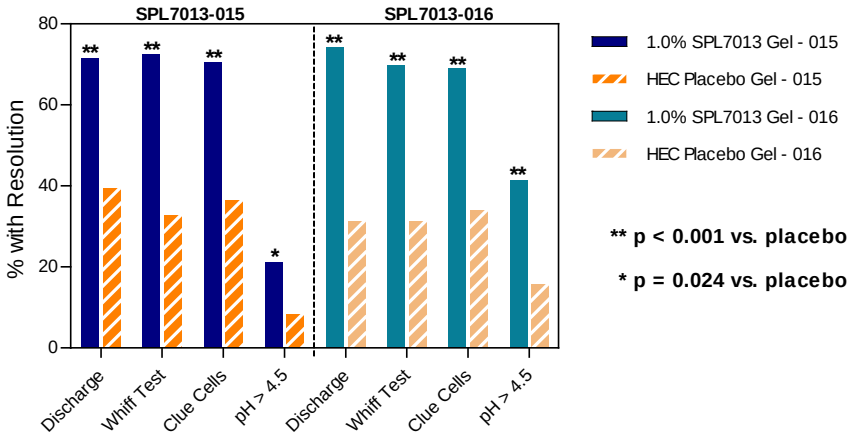


Symptom Resolution:

There was clear, consistent and statistically significant resolution of all 4 Amsel criteria at EOT in 1% SPL7013 Gel groups in both studies compared with placebo (see Figure 2). In study 015, the rate of resolution of the Amsel criterion related to odour, the whiff test, was statistically significantly higher than placebo at TOC.

Figure 2.

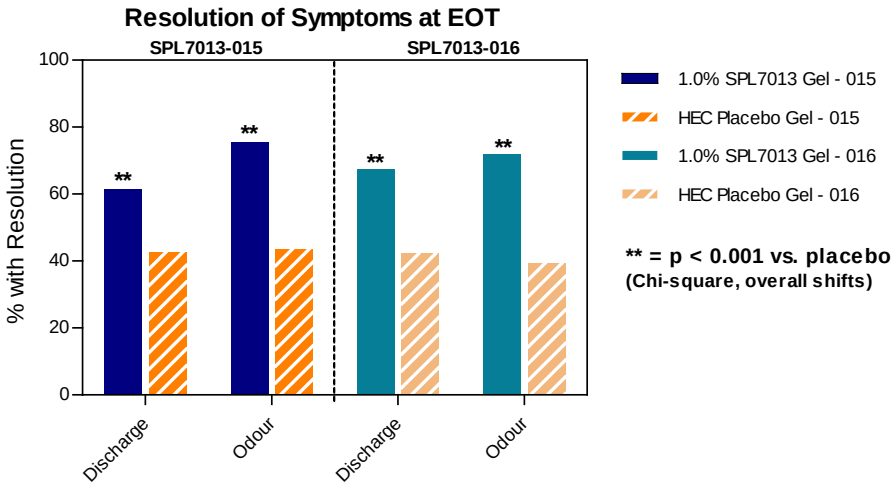
Resolution of Amsel Criteria at EOT



Treatment with 1% SPL7013 Gel led to significant improvement in patient-reported clinical symptoms of BV, being unpleasant vaginal discharge and odour.

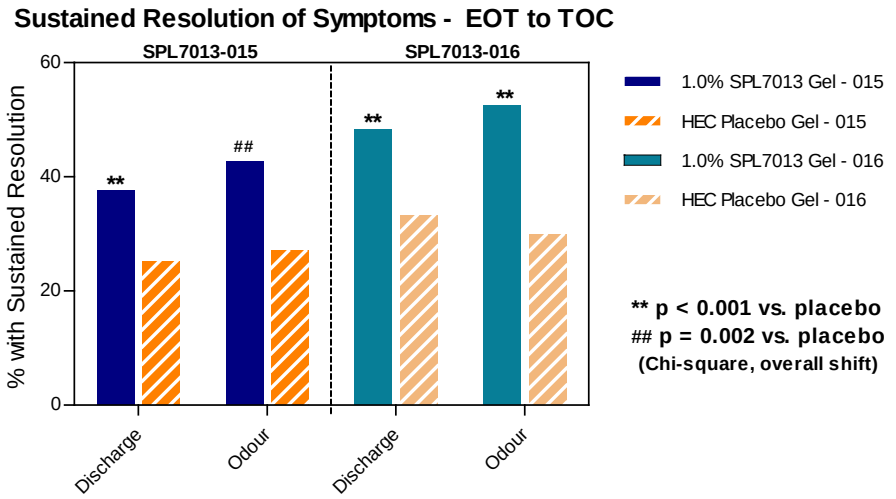
A significant number of patients in the 1% SPL7013 Gel groups (approx. 60-75%) reported resolution of the symptoms of BV at EOT (see Figure 3). The rates of symptom resolution were statistically significantly higher compared with placebo rates in both studies. In 50-55% of women in the 1% SPL7013 Gel groups, vaginal odour present at baseline was absent at TOC.

Figure 3.



A significant proportion of patients in the 1% SPL7013 Gel groups compared with placebo also had sustained relief of symptoms between EOT and TOC (see Figure 4).

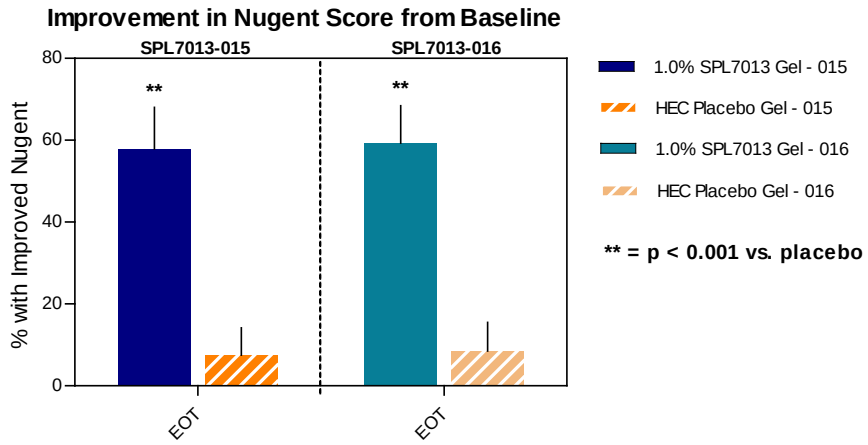
Figure 4.



Nugent Cure: The rates of normalisation of vaginal microbiology from baseline, as determined by a Nugent score of 0-3, were relatively low but statistically significantly higher in the 1% SPL7013 Gel groups (12.8% and 13.3% in 015 and 016, respectively), compared with the placebo groups at EOT (2.6% and 5.1%, respectively. The differences in Nugent Cure at TOC were not statistically significant.

There was also a highly statistically significant improvement in patients' Nugent scores, from 7-10 to 0-6 or from 4-6 to 0-3, in 57.9% and 59.3% of participants in the 1% SPL7013 Gel groups (015 and 016, respectively), compared with just 7.5% and 8.5% of participants in the placebo groups at EOT ($p<0.001$) (Figure 5).

Figure 5.



Treatment Satisfaction: SPL7013 was rated statistically significantly higher than placebo gel in a survey taken at EOT with respect to effectiveness and satisfaction. 59-68% of patients taking 1% SPL7013 Gel were satisfied to extremely satisfied compared with only 35-39% of those taking placebo gel.

Patients rated the gels equally, and highly positively, in terms of convenience and side effects.

Safety: The safety profile of VivaGel® was comparable with placebo gel across both studies. The rates of treatment-related genitourinary (GU) adverse events (AEs) and non-GU AEs were low and typical of a topically applied, non-systemically absorbed agent. In particular, rates of candidiasis (fungal infection or 'thrush') were very low with VivaGel® in comparison with other marketed products.

	SPL7013-015		SPL7013-016	
	1% SPL7013 Gel	**Placebo Gel**	**1% SPL7013 Gel**	**Placebo Gel**
All treatment related non-GU AEs	3.2%	5.0%	6.3%	2.4%
All treatment related GU AEs	13.5%	9.1%	9.5%	5.7%
Candidiasis	1.6%	0%	3.2%	0%