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Starpharma vagina infection gel shows good result

08 April 2013 | News | By BioSpectrum Bureau

Singapore: Starpharma Holdings announced the positive results of its exploratory phase II study of VivaGel for the prevention of recurrent bacterial vaginosis (R-BV). The results showed a reduced overall risk of R-BV during the study in patients using one percent VivaGel and time to first recurrence was delayed compared with placebo. The results demonstrated the ability of VivaGel to inhibit BV recurrence, as was suggested by results of earlier clinical trials, and they provide strong support for the advancement to phase III clinical trials of VivaGel for the prevention of R-BV.

To put these results into context, if the risk reduction results seen with one percent VivaGel were applied more generally to all women with BV using published incidence data it is estimated that this would translate to the prevention of more than 10 million cases of R-BV annually in the US alone. The phase II study also showed high levels of user satisfaction, in line with earlier clinical trials of VivaGel. In this study 79 percent of users of one percent VivaGel were either satisfied, very satisfied or extremely satisfied with the product's effectiveness and overall satisfaction.

In the study, 205 women were randomized to VivaGel containing either one percent or three percent SPL7013, or placebo following a course of conventional BV treatment (metronidazole). Women used the product every second day for 16 weeks. The primary objective of the study was to assess the efficacy of VivaGel in reducing the risk of R-BV compared with placebo.

As an exploratory, dose ranging phase II study for a new indication with no approved treatments, a number of different efficacy measurements were undertaken at various time points with a view to identifying the most appropriate endpoints and trial design for Phase 3 studies. The primary clinical endpoint of recurrence of BV was assessed during the 16 week treatment period.

Dr Jackie Fairley, CEO, Starpharma, "We are very pleased with these phase II results. We have seen consistently lower recurrence rates with VivaGel by every measure and these clinically relevant findings, if replicated in an appropriately designed larger phase III study, would yield a positive pivotal result. The commercial opportunity for recurrent BV is very attractive with an estimated market of more than $1 billion and following these results we have a high degree of confidence to move this product forward into phase III clinical trials."