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Starpharma completes US New Drug Application for VivaGel BV

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VivaGel BV stands to be the first and only product approved for the prevention of recurrent BV

Australian pharma giant Starpharma today announced that its rolling new drug application (NDA)i for VivaGel BV including two indications, for the treatment of bacterial vaginosis (BV) and prevention of BV, has been completed, and the final module of the NDA will be submitted to the US Food and Drug Administration (FDA) on Monday 30 April 2018 (US time).

The review of the VivaGel BV NDA by the FDA has already commenced and will be conducted as a priority review based on the Fast Track status of the product. The NDA review is expected to take approximately 6-8 months from the completed submission.

Fast Track status is intended to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs. VivaGel BV was also granted Qualified Infectious Disease Product (QIDP) designation, which applies to certain important new antibacterial products. As well as making the product eligible for Fast Track status, QIDP designation provides other significant commercial advantages such as an additional 5 years' market exclusivity. Starpharma also has a Special Protocol Agreement in place from the FDA for VivaGel BV which provides binding FDA agreement on the phase 3 trial design.

VivaGel BV offers the potential to fill a currently unmet medical need with respect to both the treatment and prevention of BV. Compared with existing therapies, none of which are approved for prevention of BV,. VivaGel BV acts via a novel mechanism of action, whereby it affects BV-related biofilms, which have been linked to persistence and recurrence of the condition. The product is well suited to longer-term use, given the lack of absorption of the product into the bloodstream and resulting lack of systemic side effects attributable to the product.

Dr Jackie Fairley, Starpharma CEO, commented: "Completion of our NDA filing is an exciting milestone for Starpharma, and a great story for Australian innovation. We look forward to VivaGel® BV being available for patients in the US, where the rate of BV is particularly high, with one in three women suffering from this troubling and recurring condition. The combined value of the BV treatment and prevention markets globally is estimated to be more than US$1.75 billion annually"

VivaGel BV is already approved for sale in Europe and Australia. In Australia, VivaGel® BV is licensed to Aspen Pharmacare, who will launch the product under the Fleurstat brand in the near future.