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Update

VIVAGEL® BV NEWS – MARCH 2019

AUSTRALIAN LAUNCH

>> Fleurstat BVgel

The first shipment of Fleurstat BVgel was delivered to Aspen's warehouse in February 2019 in preparation for launch of the product by Aspen into wholesalers and Australian pharmacies, expected during April/May 2019.

Following salesforce training during January, Aspen representatives are now calling on key customer groups, which include wholesalers, pharmacies and GPs.

Aspen has already created a comprehensive suite of marketing materials tailored to multiple audiences including patients, pharmacists, GPs and Ob/Gyns.

Aspen's marketing plans are targeted at these audiences and involve extensive healthcare professional and consumer outreach, including advertising via various platforms, a dedicated website and digital marketing activities.

Photo, below: Fleurstat BVgel display at a recent Women's Health conference.

Feedback from the Australian market on Fleurstat BVgel has been universally positive, indicating a high-level of enthusiasm for the product and illustrating the significant unmet medical need. The novel non-antibiotic mode of action, patient benefits, strong clinical data package and availability of the product from pharmacies have been viewed as particularly favourable characteristics of Fleurstat BVgel.

Photo, above: Fleurstat BVgel product.

Aspen's medical and pharmacy salesforces have all now undertaken comprehensive training programs for Fleurstat BVgel and are extremely excited to be involved in the first launch in the world of such an innovative product with clear advantages. The product's Australian origins have also been well-received by the market.

Fleurstat BVgel will be available over-the-counter in pharmacies without the need for a prescription, and therefore without having to visit a GP. Instead, for the first time, BV sufferers will be able to go directly to the pharmacy to access the product. Fleurstat BVgel will be the only OTC product available in Australia for the treatment of BV. This is an important benefit for women who suffer from BV, as well as for pharmacists who currently have nothing to offer their customers for this condition.

Examples of Aspen's marketing materials will be featured on Starpharma's website following launch.

EUROPEAN LAUNCH & ROW ROLL-OUT

>> Mundipharma's European launch of VivaGel® BV

Mundipharma's preparations are also well-advanced for the launch of VivaGel® BV in Europe, which is expected to occur in Q2CY2019. Product for launch in Europe is expected to be delivered to Mundipharma shortly.

Starpharma is working closely with Mundipharma's cross-functional launch team, which includes representatives from multiple business units dedicated to the marketing and launch of VivaGel® BV.

Final pre-launch marketing activities are now underway following the completion of detailed market research involving BV patients, pharmacists and Ob/Gyn specialists across multiple countries.

Photo, left:

Mundipharma VivaGel® BV product

>> Mundipharma's international roll-out of VivaGel® BV

Starpharma's and Mundipharma's marketing and regulatory teams also continue to work actively together in preparation for the roll-out of VivaGel® BV in other regions, such as Asia, Latin America, the Middle East and Africa. Regulatory activities are underway for multiple countries across these regions.

As part of the marketing effort in preparation for the launch of VivaGel® BV in these regions, Mundipharma has formed Key Opinion Leader (KOL) advisory boards.

Photo, below: Starpharma participates in Mundipharma's regional advisory board meeting in Singapore.

US FDA

>> FDA meeting to discuss VivaGel® BV approval in the US

In preparation for the upcoming meeting with the FDA, Starpharma has completed and submitted a comprehensive package of information, including further analyses of existing clinical data for VivaGel® BV. A meeting with the FDA is expected to occur in the second week of April 2019, subject to final confirmation of availability of all parties. The meeting will be attended by senior representatives of Starpharma as well as internationally recognised KOLs in the area of BV, and the Company's expert FDA regulatory consultants.

Since receiving the FDA's request for confirmatory clinical data, Starpharma has undertaken a comprehensive program with a view to expediting approval, which has included extensive regulatory advice from FDA experts and specialist US legal counsel. The information submitted for the meeting, which includes additional statistical analyses of existing data, was prepared in consultation with, and following input from Starpharma's team of expert FDA consultants, including former senior FDA personnel, KOLs and statisticians. These analyses provide further support for the approval of VivaGel® BV.

The meeting is expected to clarify what confirmatory data will be required for approval and whether the requirement can be satisfied by additional analyses of existing clinical data, or whether this will require the generation of new confirmatory clinical data. Starpharma will be in a position to provide additional information following the FDA meeting, once the outcomes of the discussion at the meeting have been confirmed in writing.

Feedback on VivaGel® BV from US clinicians and patients has been extremely positive. We are looking forward to a productive and informative meeting with the FDA. Starpharma is committed to working with the FDA to secure approval with minimal delay to make VivaGel® BV available to US patients as soon as possible.

Dr Jackie Fairley, CEO of Starpharma

Requests for additional data from the FDA are not unusual among New Drug Applications. In 2016, almost 40% of NDAs submitted were not approved in the first instance and additional data were requested. A longer-term review between 2001 and 2015 showed that 44% of NDAs were not approved upon first round review.

VivaGel® BV is a wonderful product which specifically targets BV bacteria. My patients have called it a 'life changing and miraculous treatment'.

Dr Belvia Carter, VivaGel® BV Clinical Trial Principal Investigator and Ob-Gyn, US