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NDA submission for Starpharma's VivaGel BV

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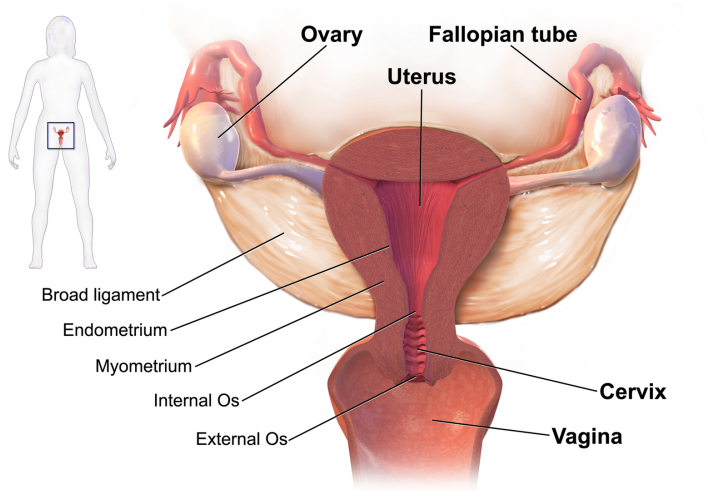

Singapore - Australian biotech company Starpharma submitted its New Drug Application (NDA) with the US FDA through a rolling submission process for its VivaGel BV product which targets treatment and prevention of recurrent bacterial vaginosis (BV).

This news means Starpharma joins an exclusive group of Australian companies to have submitted an NDA; only five Australian companies have successfully developed a drug to this critical stage.

VivaGel BV has been granted Fast Track status and Qualified Infectious Disease Product (QIDP) designation, which ensures priority regulatory review by the FDA. These designations illustrate the need for a product like VivaGel BV. BV affects 30% of US women and is highly recurrent, with up to 60% of sufferers having it recurrently. The market for prevention of recurrent BV alone is worth US$1B annually.Ã¢â?¬Â¯

FDA Fast Track status is designed to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs. The QIDP designation applies to certain new antibacterial products and provides other significant commercial advantages such as an additional five years' market exclusivity.

Importantly, Starpharma has taken VivaGel BV from discovery to the end of successful phase 3 trials while retain commercial rights along the way.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to be submitting our NDA for VivaGel® BV. Starpharma is one of very few Australian companies to have achieved an NDA submission. It is very satisfying strategically that we have retained the commercial rights to VivaGel® BV, while developing the product from discovery through to the successful phase 3 trials and NDA submission – in doing so we've maximised its commercial value."