

UPCOMING PRESENTATION OF IMVEXXY® CLINICAL DATA AT 2026 ISPE ANNUAL MEETING AND BIJUVA® SALES RECOGNITION

Key Points

- Upcoming poster presentation at the 2026 ISPE Annual Meeting on the risk of endometrial cancer in postmenopausal women prescribed very low dose vaginal estrogen (VLDVE) products, including IMVEXXY® in the United States
- Across the total study cohort (9.5 million women), comparative analyses and meta-analysis show no effect of VLDVE exposure on the risk of endometrial cancer
- IMVEXXY® (4 µg and 10 µg) is US Food and Drug Administration (FDA) approved in the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA) in postmenopausal women
- In addition, Mayne Pharma's other menopause product BIJUVA® has been named a finalist in three categories at the 2026 PM360 Trailblazer Awards

20 August 2026, Adelaide, Australia: Mayne Pharma Group Limited (Mayne Pharma or the Company)(ASX:MYX), today announces an upcoming poster presentation titled "*Risk of Endometrial Cancer in Postmenopausal Women Prescribed Very-Low-Dose Vaginal Estrogen Products in the US*¹" at the International Society for Pharmacoepidemiology (ISPE) 42nd Annual Meeting from 29 August to 2 September 2026 in Milan, Italy.

The observation- based clinical study was a post-marketing requirement by FDA. The safety study analysis was concluded in April 2026 and the primary objective was to determine if the use of VLDVE, including IMVEXXY® 4 µg and 10 µg, had an increased risk of endometrial cancer compared to patients who were not exposed. The study authors concluded "*Comparative analyses and meta-analysis show no effect of VLDVE exposure on the risk of endometrial cancer.*" This conclusion is consistent with the US FDA's recent request to remove the box warnings from the prescribing information for certain hormone replacement therapy drug products, including IMVEXXY® and BIJUVA®.

Dr Frank Casty, Global Head of R&D and Chief Medical Officer of Mayne Pharma said "*This is one of the largest real-world analyses of very low-dose vaginal estrogen undertaken to date, drawing on US data from more than nine million women. In this study, very low-dose vaginal estrogen use was not associated with an increased risk of endometrial cancer. Rigorous real-world evidence of this scale makes an important contribution to the scientific understanding of a class of therapies that many postmenopausal women rely on.*"

BIJUVA® has been named a finalist in three categories at the 2026 PM360 Trailblazer Awards, a long-established US life-sciences marketing program, with winners to be announced on 29 September 2026. The nominations, across Professional Campaign, Sales Aid, and

¹ <https://www.rtihs.org/publications/risk-endometrial-cancer-postmenopausal-women-who-have-been-prescribed-very-low-dose>



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Relaunch/Revitalisation of the Year reflects the commercial and marketing execution behind BIJUVA® as the Company continues to build momentum in its US Women's Health portfolio.

Mr Aaron Gray, CEO of Mayne Pharma said *"Menopause care is one of the largest and most under-served markets in women's health in the United States, and demand for therapies continues to grow. Mayne Pharma's Women's Health portfolio, which includes IMVEXXY® positions the Company to play a meaningful and growing role in that market, where the macro tailwinds are strong. In addition, being named a finalist for BIJUVA® across three categories is a credit to our commercial, marketing and medical teams and reflects the momentum we are building in Women's Health. It speaks to the growing role BIJUVA® plays in menopause care and the strength of the brand we are building in that market."*

Click [here](#) to view this announcement on Mayne Pharma's Investor Hub.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma is a leader in dermatology and women's health in the United States and also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.

IMVEXXY® (estradiol) is a vaginal insert indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. The most common adverse reaction with Imvexxy (≥3%) was headache. Serious adverse reactions associated with estrogen-alone therapy include endometrial cancer, cardiovascular disorders, and probable dementia among others. Please see full prescribing information [here](#).

BIJUVA® (estradiol and progesterone) is a combination of an estrogen and progesterone indicated in a woman with a uterus for the treatment of moderate to severe vasomotor symptoms due to menopause. The most common adverse reactions with Bijuva capsules (incidence ≥3% of women greater than placebo) are breast tenderness, headache, nausea, vaginal bleeding, vaginal



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discharge and pelvic pain. Serious adverse reactions associated with estrogen plus progestin therapy include cardiovascular disorders and malignant neoplasms among others. Please see full prescribing information [here](#).

BIJUVA® and IMVEXXY® are trademarks of a third party.