

## First treatment for endometriosis\* in 13 years in Australia approved by TGA<sup>1,2</sup>

- Ryeqo<sup>®</sup> 40/1/0.5 (relugolix, estradiol, norethisterone acetate) is the first endometriosis treatment approved in 13 years.<sup>2</sup>
- 1 in 7 Australian women<sup>†</sup> live with endometriosis,<sup>3</sup> they can experience debilitating pain and other symptoms which hold them back in many aspects of life, including career and family.<sup>4</sup>
- There is no cure for endometriosis,<sup>5</sup> and women suffer in silence for too long with a preventable 8-year delay to diagnosis.<sup>4</sup>

**Sydney, Australia, 23 February 2024** – Gedeon Richter Australia announced today the Therapeutic Goods Administration (TGA) approval of Ryeqo<sup>®</sup> 40/1/0.5 (relugolix, estradiol, norethisterone acetate) for the treatment of endometriosis symptoms, including endometriosis pain, for adult women of reproductive age who have previously tried medical or surgical treatment for their endometriosis.<sup>1</sup>

Ryeqo is a once daily oral tablet containing a unique combination of relugolix, a GnRH (gonadotropin-releasing hormone) receptor antagonist, and hormone add-back therapy estradiol and norethisterone acetate.<sup>1</sup> Eligible Australian women can access Ryeqo via private prescription for up to 2-years initially, and possibly longer following medical assessment by a gynaecologist.<sup>1</sup>

Endometriosis symptoms are different for everyone and can be under-recognised, which contributes to women with endometriosis waiting up-to 8-years to be diagnosed.<sup>4</sup> It is a progressive chronic disease, often with debilitating symptoms that can include severe endometriosis pain that is distinct from period pain (invisible to others and can occur at any time of the month), as well as abdominal bloating, nausea, fatigue, depression, anxiety, and infertility.<sup>5,6</sup>

“The first new treatment for endometriosis in 13 years is welcomed as an important step forward for the Australian endometriosis community,” said Maree Davenport, CEO of Endometriosis Australia.

“While focus and progress in endometriosis management has never been greater, we continue to see an unacceptable and significant negative impact on daily lives of Australian women<sup>†</sup> living with the condition – including physical, social and mental wellbeing – especially for those in rural or less advantaged communities. Furthermore, our recent workplace survey showed one in six people with endometriosis will lose their employment due to managing the disease, and one in three will be overlooked for a promotion,” added Maree Davenport.

Those living with endometriosis have been turning to a toolbox of decades-old treatments<sup>2</sup> to help manage their symptoms, such as short-term hormonal therapies, repeated invasive surgeries, non-steroidal anti-inflammatory drugs (NSAIDs) and pain medications, including opioids.<sup>5,7,8,9</sup>

“The approval of Ryeqo for endometriosis provides another option for treating the life-impacting symptoms experienced by women living with this condition. I often see patients who have been

suffering unnecessarily for too long, they are fed up and looking for answers to manage their endometriosis pain so they can get back to doing the things they love,” said Professor Gino Pecoraro, Gynaecologist and Endometriosis Specialist, The Wesley Hospital.

Recent surveys amongst Australians with endometriosis found they were unsatisfied with their current treatment,<sup>10</sup> and their biggest priority was to find effective treatments.<sup>11</sup>

“Many women with endometriosis live in pain every day and find themselves trapped in a cycle of struggling through their pain to go to work so they can afford the various treatments and surgeries they need to keep going, or unfortunately sat on long waiting lists for surgery. It’s important for these women to speak to their gynaecologist about all the options available to them,” said Professor Thierry Vancaillie, Gynaecologist and Pain Specialist, Women’s Health & Research Institute of Australia (WHRIA).

Those living with endometriosis often face high out-of-pocket costs for medicines, hospital stays or allied and complementary treatments which are not funded by Government.<sup>12</sup> This often has an impact on long-lasting financial burden, smaller salary growth, and higher risk of leaving the workforce altogether.<sup>13</sup>

Ryeqo is not currently listed on the Pharmaceutical Benefits Scheme (PBS). Gedeon Richter Australia has made a submission to the Pharmaceutical Benefits Advisory Committee (PBAC), to be considered for reimbursement at its March 2024 meeting.

“Gedeon Richter is committed to providing long-term, real solutions for women’s health, including for those living with and affected by endometriosis. We are now able to support eligible Australian women living with the substantial burden of endometriosis. We look forward to working with the Government to provide broader access to Ryeqo,” said Glen Pearce, General Manager, Gedeon Richter Australia.

Ryeqo was initially approved by the TGA in September 2022 for the treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age.<sup>1</sup>

The TGA approval of Ryeqo for endometriosis is supported by two, 24-week, multi-national clinical studies (SPIRIT 1 and SPIRIT 2) in more than 1,200 women with moderate-to-severe pain associated with endometriosis, as well as the 80-week, open-label extension study to assess longer-term use of Ryeqo.<sup>1</sup> Together, these data represent up to two years of efficacy and safety information for the treatment of endometriosis with Ryeqo.<sup>1</sup>

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#### **Footnotes**

\*RYEQO® 40/1/0.5 (relugolix, estradiol, norethisterone acetate) is approved by the Therapeutic Goods Administration (TGA) for adult women of reproductive age for the symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis (from January 2024), and for the treatment of moderate to severe symptoms of uterine fibroids (from September 2022).

†Endometriosis can also occur in men, transgender men and non-binary persons who were assigned female at birth/presumed female at birth (AFAB/PFAB).

## About Ryeqo

RYEQO® 40/1/0.5 is not PBS listed.

If you have been prescribed Ryeqo, please refer to the Consumer Medicine Information (CMI) found online here: <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2023-CMI-01327-1&d=20240208172310101>.

Ryeqo, like all medicines, may cause side effects. Very common side effects include headache and hot flush, and common side effects decreased libido, hyperhidrosis, night sweats, back pain, arthralgia, uterine bleeding and vulvovaginal dryness. Because this product is new, it is subject to additional monitoring. Please report side effects to your doctor, or via [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

For further information on Ryeqo, please contact the Gedeon Richter Australia Medical Information team by email: [medinfo@gedeonrichter.com.au](mailto:medinfo@gedeonrichter.com.au) or phone: 1300 433 366.

### About endometriosis pain

Endometriosis pain (endo pain) is different from period pain because it occurs due to the inflammation caused when tissue similar to the lining of the uterus (endometrial tissue) grows outside of the uterus.<sup>7</sup>

While it is unique for everyone, there are some typical features including chronic pelvic pain (CPP), period pain (dysmenorrhea) back pain and lower abdominal pain.<sup>14</sup>

At worst, endo pain is extreme and can occur at any time of the month and anywhere in the body; importantly, it's not always associated with menstruation or ovulation and can be unpredictable in its severity, timing and duration.<sup>5</sup>

Endo pain is invisible and is often dismissed or 'played down' by healthcare professionals, employers, family members and others. As with any type of pain, 'endo pain' is a subjective experience, making it harder for patients to talk about and for healthcare professionals to assess.<sup>5,6</sup>

Endo pain isn't always logical: the level experienced doesn't match neatly with the stage of the disease, and the experience can also change throughout a lifetime.<sup>5,14</sup>

Endo pain to a greater or lesser extent affects every facet of a person's life, including their ability to work, undertake education, maintain friendships, have children, have intimate relationships and participate in leisure activities and exercise.<sup>15</sup>

### About Gedeon Richter Australia

Recognised for its contribution to women's health, original research and biotechnology, Gedeon Richter is headquartered in Hungary and has over 120 years global experience in healthcare.

Gedeon Richter Australia was established in 2017 and offers solutions with a focus on providing real health support for women and those assigned female at birth.

Gedeon Richter offer a comprehensive portfolio of treatments for fertility and gynaecological conditions, including endometriosis. Research efforts are focused on developing non-invasive medical treatments for common gynaecological conditions which are currently under-treated and can have a severe impact on the patient's quality of life.

### Media contact

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## Disclosures

In relation to this Gedeon Richter Australia media announcement, no honoraria were provided to Maree Davenport (Endometriosis Australia), Professor Gina Pecoraro or Professor Thierry Vancaillie.

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