

Richter receives FDA Submission Acceptance of New Drug Application for FYLREVV® in the U.S.

Budapest, Hungary, 14 October 2026 – Gedeon Richter Plc. ("Richter"), a company committed to advancing women's health, today announces that the U.S. Food and Drug Administration ("FDA") has accepted for review its New Drug Application (NDA) for FYLREVV®, its innovative, orally administered Estetrol ("E4")-based oestrogen therapy designed to treat moderate to severe vasomotor symptoms (VMS) due to menopause. The FDA is expected to complete its review by Q3 2027.

If approved, FYLREVV® would be the first Menopausal Hormone Therapy containing E4 on the U.S. market. In March 2026, FYLREVV® was already granted a marketing authorization by the European Commission for all member states of the European Economic Area as HRT for oestrogen deficiency symptoms in non-hysterectomised postmenopausal women with at least 12 months since last menses (FYLREVV® 14.2 mg and 18.9 mg) and as HRT for oestrogen deficiency symptoms in hysterectomized postmenopausal women (FYLREVV® 18.9 mg). To date, FYLREVV® is commercialized in Hungary, Czech Republic, Slovakia, Finland and Sweden.

Dr. Péter Turek, Head of Women's Healthcare Business Unit at Richter, commented: *"We are very pleased to have received filing acceptance in the U.S., the world's largest pharmaceutical market, for our latest innovation in menopause. Despite the significant burden that postmenopausal symptoms place on millions of women, therapeutic progress in this field has remained limited. This milestone reflects Richter's long-standing commitment to innovation and to address this significant unmet medical need. We continue to explore the best path to bring this therapy to patients in the U.S., as part of our broader ambition to advance women's health worldwide."*

About FYLREVV®

The orally administered Estetrol-based oestrogen therapy FYLREVV® is designed to treat the broad spectrum of oestrogen deficiency symptoms in postmenopausal women, including VMS. Estetrol ("E4") is a native and selective oestrogen produced by the foetal liver during pregnancy and is synthesized from plant sources for pharmaceutical purposes. Preclinical and clinical data for E4 points to a tissue-specific activity and a more selective pharmacological profile compared to other oestrogens, including a low impact on the liver, hemostasis balance and breast cell proliferation. The efficacy and safety of E4 in alleviating VMS was evaluated in two independent, confirmatory, pivotal phase 3 studies (E4COMFORT I and E4COMFORT II) having enrolled a total of 2576 postmenopausal women in Europe, Russia, United States of America (USA), Canada and Latin America. In addition to its authorization in over 50 countries worldwide as the oestrogen component of a combined oral contraceptive with drospirerone (marketed as DROVELIS® in EU and NEXTSTELLIS® in the U.S.), E4 is now further expanding its therapeutic reach in the menopause field.

About Menopause

Menopause is a natural biological process marking the end of a woman's reproductive years, typically occurring between 45 and 55 years old. It is characterized by the cessation of menstruation due to decreased production of oestrogens and progesterone by the ovaries.

The most frequently reported symptoms include vasomotor symptoms (VMS, which include hot flushes and night sweats), vulvo-vaginal atrophy (VVA), sleep disturbances, impaired bone health, physical changes (amongst which musculoskeletal symptoms, weight gain, thinning hair and dry skin), mood changes (including increased irritability, anxiety and depression), urinary incontinence, and cognitive changes.

VMS are among the most common and bothersome menopausal complaints, and one of the main reasons why women may seek medical care for the menopause. Hot flushes are characterized by sudden sensations of heat in the upper body, that last for 2 to 4 minutes and repeat multiple times each day. Up to 80% of menopausal women suffer from VMS, which have a mean duration of 7 to 9 years.

About Richter

Richter aspires to be a global innovator in some key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.8bn and sales of EUR 2.3bn in 2025, it operates Central Europe's largest R&D hub. Its research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen its affordable treatment portfolio. Committed to sustainable growth, Richter invests in R&D, manufacturing excellence, and digitalization to advance medical innovation. Learn more at www.gedeonrichter.com

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