



## ZURZUVAE® Capsules 30 mg for the Treatment of Major Depressive Disorder launched in Japan

**OSAKA, Japan, March 19, 2026** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced today that Shionogi launched ZURZUVAE® Capsules 30 mg (generic name: zuranolone; hereafter "ZURZUVAE"), for the treatment of major depressive disorder (MDD).

ZURZUVAE is a novel oral antidepressant with a mechanism of action different from conventional therapies. It acts as a positive allosteric modulator of GABA<sub>A</sub> receptors at both synaptic and extrasynaptic sites.

In a Phase 3 randomized, placebo-controlled clinical trial<sup>1</sup> conducted in Japan involving adults with major depressive disorder, oral administration of ZURZUVAE at 30 mg once daily for 14 consecutive days demonstrated rapid improvement in depressive symptoms. Furthermore, no safety-related concerns were identified upon re-administration.

Depression affects an estimated 5 million people in Japan, representing one of the most burdensome non-fatal diseases in terms of social and health impact<sup>2</sup>. Conventional antidepressants often require several weeks to achieve therapeutic effect<sup>3</sup>, creating an unmet need for treatments with rapid onset<sup>4</sup>. ZURZUVAE is expected to address significant unmet needs in the treatment of depression by providing timely symptom relief for patients requiring therapeutic intervention.

Shionogi has identified "Contributing to a healthy and prosperous life" as a key materiality and is committed to the research and development, manufacturing, and commercialization of healthcare solutions addressing QOL diseases with high social impact\*, building a society where everyone can live longer, healthier, and more fulfilling lives in their own way. Through the delivery of ZURZUVAE, which has the potential to transform the paradigm of depression treatment, we aim to address the unmet needs of patients with depression.

\*QOL diseases with high social impact: sleep disorders, hearing loss, rare pediatric diseases, Immunology/Allergy, etc.

### Product Information

Product name	ZURZUVAE® Capsules 30 mg
Generic Name	Zuranolone
Indication	major depressive disorder (MDD) • depressive symptoms
Dosage regimen	The recommended dosage for adults is 30 mg capsules (30mg as zuranolone) to be administered once daily orally for 14 consecutive days after the evening meal in adults. If treatment with this product is to be repeated, an interval of at least six weeks should be observed after completion of the prior dosing regimen.
Date of marketing approval	December 22, 2025

Date of NHI price listing	March 18, 2026
Date of launch	March 19, 2026
Marketing Authorization Holder	Shionogi & Co., Ltd.

**Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

**For Further Information, Contact:**

SHIONOGI Website Inquiry Form : <https://www.shionogi.com/global/en/contact.html>

**References**

1. Psychiatry Clin Neurosci.2025 Nov 18.doi: 10.1111/pcn.13917.
2. WHO, Depression and Other Common Mental Disorders Global Health Estimates
3. Japanese Society of Mood Disorders Treatment Guidelines
4. Watanabe, Koichiro et al. Clinical Psychopharmacology. 2008; 11(12): 2295-2304.