PRESSRELEASE

SHIONOGI

Shionogi Receives Approval in Japan to Manufacture and Market ZURZUVAE® Capsules 30 mg for the Treatment of Major Depressive Disorder

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OSAKA, Japan, December 22, 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") is pleased to announce that it has obtained manufacturing and marketing approval in Japan for "ZURZUVAE® Capsules 30 mg" (non-proprietary name: zuranolone; hereafter "ZURZUVAE") as of [December 22, 2025], for the indication of depression and depressive state.

The approval of ZURZUVAE is based on positive results from a Phase 3 randomized placebo-controlled clinical trial of Japanese adults with major depressive disorder conducted in Japan[1]. In this study, Oral administration of ZURZUVAE at 30 mg once daily for 14 consecutive days demonstrated efficacy and safety, showing rapid onset of symptom improvement from the early stages of treatment. Furthermore, efficacy and safety were confirmed even upon re-administration after a drug-free interval of six weeks or longer. The primary endpoint was the change from baseline in the HAM-D17 total score at the end of the 14-day treatment period. The treatment group showed a mean change of -7.43, which was statistically significantly greater than the placebo group (-6.23), with a least-squares mean difference of -1.20 (95% CI, -2.32 to -0.08; $p < 0.0365$). Based on these favorable results, ZURZUVAE has now been approved in Japan.

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[2]. Conventional antidepressants often require several weeks to achieve therapeutic effect[3], creating an unmet need for treatments with rapid onset[4]. ZURZUVAE is expected to address significant unmet needs in the field of depression by providing timely symptom relief for patients in need of therapeutic intervention.

Shionogi has identified "Contributing to a healthy and prosperous life" as a key materiality and is committed to building a society where everyone can live longer, healthier, and more fulfilling lives in their own way. We will continue striving to deliver this medicine—potentially capable of transforming the paradigm of depression treatment—to patients as quickly as possible.

About zuranolone (ZURZUVAE®**)**
Zuranolone is a novel oral antidepressant with a mechanism of action different from conventional therapies. It acts as a GABA-A receptor positive allosteric modulator (PAM) at both synaptic and extrasynaptic sites. Based on clinical trial results conducted by Shionogi, Oral administration of 30 mg once a day for 14 days has been shown to rapidly improve symptoms of major depressive disorder (MDD) without the need for dose adjustment.

About Shionogi
Shionogi & Co., Ltd. is a leading global research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and well-being of the patients we serve." Shionogi has discovered and developed novel antibiotics, medicines for HIV and influenza and currently markets medicines for infectious diseases and central nervous system

disorders. Shionogi's global pipeline includes research programs in infectious disease, pain/CNS, metabolic disorders, rare disease, oncology and stroke.

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.

For Further Information, Contact:

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

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.