



Shionogi Completes Acquisition of All Rights to RADICAVA (edaravone)

**Integration Fully Operational on Day One to Ensure Continuity of Care for the ALS Community
With More than 100 Team Members Joining Shionogi from Tanabe Pharma America**

Acquisition Establishes a Strong Commercial Platform in Rare Disease to Support Future Launches

OSAKA, Japan, April 2, 2026 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) announced that we have completed the transfer of all rights for RADICAVA (edaravone), including intellectual property rights and sales rights, in major countries and regions to our company from Tanabe Pharma Corporation. Transfer of rights in additional countries and regions is forthcoming. The acquisition and integration of RADICAVA team members, programs and platforms adds to ongoing strategic investments in rare disease and establishes Shionogi as a commercially viable rare disease company ready to introduce new treatments to patients with unmet medical needs.

RADICAVA is approved by the U.S. Food and Drug Administration (FDA) and other regulatory authorities around the world for the treatment of amyotrophic lateral sclerosis (ALS), a progressive neurodegenerative disease for which there is no cure and limited treatment options. RADICAVA ORS, along with a previously available intravenous formulation, have been used to treat more than 22,000 people with ALS in the U.S. to date.

“By completing the acquisition of RADICAVA we are demonstrating progress toward our 2030 Vision and fulfilling our commitment to supply the best possible medicines to protect the health and wellbeing of the patients we serve,” said Isao Teshirogi, Ph.D., CEO of Shionogi. “With RADICAVA we are not only acquiring a medication, we are also acquiring an established rare disease capability and assuming responsibility for a relationship with the ALS community. We take this responsibility seriously and commit to providing continuity of care and continued innovation in ALS and rare disease.”

Under the terms of the agreement [originally announced on December 22, 2025](#), Shionogi paid a lump sum of USD 2.5 billion through Shionogi Inc. to acquire the global rights to RADICAVA, and may pay additional royalties on future sales subject to certain conditions. The transaction is expected to be immediately accretive in fiscal year 2026, adding approximately USD \$700 million in annual global sales.

“RADICAVA is an important option for people with ALS and we are committed to serving the community’s needs today and working toward future innovations in care,” said Nathan McCutcheon, President and CEO of Shionogi Inc. “We are excited to continue growing our rare disease capabilities with the addition of the talented cross-functional team from Tanabe. The RADICAVA team will complement our efforts to establish a best-in-class rare disease franchise in the U.S. and ensure readiness to deliver future innovations to patients.”

About RADICAVA ORS[®] (edaravone)

The U.S. Food and Drug Administration (FDA) approved RADICAVA ORS[®] (edaravone) on May 12, 2022, for the treatment of amyotrophic lateral sclerosis (ALS). In 2024, the FDA granted RADICAVA ORS Orphan Drug Exclusivity based on its major contribution to patient care by providing an oral suspension route of administration that avoids the burdens of IV administration. RADICAVA ORS is taken daily for 14 consecutive days followed by a 14-day drug-free period for the initial treatment cycle. For subsequent treatment cycles, RADICAVA ORS is taken for 10 days within a 14-day period followed by a 14-day drug-free period. Each 105 mg (5mL) dose of RADICAVA ORS should be taken in the morning after overnight fasting. Patients should not eat or drink (except water) within one hour after taking RADICAVA ORS.¹

Edaravone was discovered and developed for ALS by Tanabe Pharma and commercialized in the U.S. by Tanabe Pharma America, Inc. The Tanabe Pharma group companies began researching ALS in 2001 through an iterative clinical platform over a 13-year period. In 2015, edaravone was approved as RADICUT[®] for the treatment of ALS in Japan and South Korea. Marketing authorizations were subsequently granted in Canada (October 2018), Switzerland (January 2019), Indonesia (July 2020), Thailand (April 2021), Malaysia (December 2021), Australia (February 2023) and Brazil (February 2024). Marketing authorization for RADICAVA[®] Oral Suspension was granted in Canada (November 2022) and Switzerland (May 2023), and RADICUT[®] Oral Suspension 2.1% was granted regulatory approval in Japan in December 2022. To date, in the U.S., RADICAVA ORS, along with the previously available IV RADICAVA[®] (edaravone), have been used to treat over 22,000 people with ALS, with over 2.8-million days of therapy, and have been prescribed by over 2,800 HCPs.^{2,3}

Following the completion of Shionogi's acquisition of the global RADICAVA business, Shionogi now holds global rights to RADICAVA ORS and RADICAVA IV.

INDICATION

RADICAVA ORS[®] (edaravone) is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

IMPORTANT SAFETY INFORMATION

Hypersensitivity Reactions

RADICAVA ORS[®] (edaravone) is contraindicated in patients with a history of hypersensitivity to edaravone or any of the inactive ingredients of this product. Hypersensitivity reactions (redness, wheals, and erythema multiforme) and cases of anaphylaxis (urticaria, decreased blood pressure, and dyspnea) have occurred.

Patients should be monitored carefully for hypersensitivity reactions. If hypersensitivity reactions occur, discontinue RADICAVA ORS, treat per standard of care, and monitor until the condition resolves.

Sulfite Allergic Reactions

RADICAVA ORS contain sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown but occurs more frequently in asthmatic people.

Adverse Reactions

The most common adverse reactions ($\geq 10\%$) reported in RADICAVA[®] (edaravone)-treated patients and

at least 2% more frequently than placebo were contusion (15% vs 9%), gait disturbance (13% vs 9%), and headache (10% vs 6%), respectively. In an open label study, fatigue was also observed in 7.6% of patients receiving RADICAVA ORS.

Pregnancy

Based on animal data, RADICAVA ORS may cause fetal harm.

To report suspected adverse reactions or product complaints, contact 888-292-0058. You may also report suspected adverse reactions to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full [Prescribing Information](#), also available at www.RADICAVAORS.com.

About ALS

ALS (Amyotrophic Lateral Sclerosis) is a progressive neurodegenerative disease characterized by the selective degeneration and loss of motor neurons, leading to muscle weakness and respiratory impairment. After onset, muscle atrophy gradually progresses, and ultimately respiratory muscle paralysis severely impacts life expectancy. Globally, the annual incidence is estimated at approximately 1–2 cases per 100,000 population, making it a rare disease for which no fundamental cure currently exists.³ Multiple factors, including oxidative stress and glutamate-induced excitotoxicity, are involved in its pathophysiology, and treatment options to slow disease progression remain extremely limited. For this reason, ALS is recognized as a disease with a high level of unmet medical need, and the development and delivery of innovative therapies are strongly required.

About Shionogi in Rare Disease

Shionogi is committed to the research and development of innovative medicines that address unmet medical needs for people worldwide. Rare diseases often have limited treatment options and affect the lives of individuals and families around the world. In the U.S., Shionogi is advancing a rare disease franchise that includes an approved therapy for amyotrophic lateral sclerosis (ALS) as well as clinical programs in Fragile X syndrome, Jordan's Syndrome and Pompe disease. For more information, view our pipeline here: <https://www.shionogi.com/us/en/innovation/pipeline.html>.

About Shionogi & Co., Ltd.

Shionogi & Co., Ltd. is a 148-year-old global, research-driven pharmaceutical company headquartered in Osaka, Japan, that is dedicated to bringing benefits to patients based on its corporate philosophy of "supplying the best possible medicine to protect the health and wellbeing of the patients we serve." The company currently markets products in several therapeutic areas including anti-infectives, pain, CNS disorders and cardiovascular diseases. Shionogi's research and development currently targets two therapeutic areas: infectious diseases and diseases with unmet medical needs in pain/CNS, including Alzheimer's disease, oncology, rare diseases, and sleep apnea. For more information on Shionogi & Co., Ltd., please visit <https://www.shionogi.com/global/en>.

References

1. [Press Release: December 1, 2025](#): Notice regarding Completion of Succession of Japan Tobacco Inc.'s Pharmaceutical Business through Simplified Absorption-Type Company Split
2. Data on file. Shionogi Inc.

3. Xu, et al. Global variation in prevalence and incidence of amyotrophic lateral sclerosis: a systematic review and meta-analysis. J Neurol. 2020 Apr;267(4):944-953. DOI: 10.1007/s00415-019-09652-y

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:

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