

December 24, 2025

JCR Pharmaceuticals Co., Ltd.

**Italfarmaco and JCR Pharmaceuticals Announce Commercialisation Agreement
for Givinostat in Japan and Strategic Collaboration in Rare Disease**

Hyogo, Japan – December 24, 2025 – [JCR Pharmaceuticals Co., Ltd.](#) and [Italfarmaco S.p.A.](#) today announced that the companies have entered into a licensing agreement for JCR to develop and commercialise givinostat in Japan, and a strategic collaboration in rare disease therapies.

Please refer to the attached press release for further details.

The impact on JCR's consolidated results for the fiscal year ending March 2026 is currently under review.

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Italfarmaco and JCR Pharmaceuticals Announce Commercialisation Agreement for Givinostat in Japan and Strategic Collaboration in Rare Disease

- Italfarmaco grants JCR Pharmaceuticals exclusive rights to develop and commercialise givinostat in Japan -*
- Additional strategic collaboration in rare diseases aimed at enhancing both companies' portfolios including exploring joint opportunities across JCR's R&D pipeline and platform technologies -*

Milan (Italy) / Hyogo (Japan) – December 24, 2025 – [Italfarmaco S.p.A.](#) and [JCR Pharmaceuticals Co., Ltd.](#) (TSE 4552; “JCR”), today announced an exclusive licensing agreement for the development and commercialisation of givinostat in Japan.

Under the terms of the agreement, JCR receives exclusive rights to commercialise givinostat for the treatment of Duchenne muscular dystrophy (DMD) in Japan and will be responsible for the local execution of clinical development activities, as well as regulatory submissions.

Givinostat (marketed as Duvyzat® in the US, UK and EU) is an orally administered histone deacetylase inhibitor developed by Italfarmaco to treat DMD, regardless of the underlying dystrophin gene mutation. It has obtained regulatory authorisation across several major markets, including the US, EU and the UK; it is currently not approved in Japan.

The agreement also establishes a broader strategic collaboration between the two companies to explore joint opportunities for the treatment of rare diseases.

“This partnership is a key milestone in our global strategy to expand access to givinostat and deepen our impact in rare diseases,” said Antonio Nardi, Vice President and Head of Business & Portfolio Development of Italfarmaco. “JCR’s commitment to innovation, strong local expertise, and focus on patient-centred science make them an ideal partner for the expansion of our rare disease portfolios, not only in Japan, but also globally.”

“Partnering with Italfarmaco is an important step for JCR as we enter the next phase of our growth and may be the first step in a long-lasting relationship between both companies that may extend into future research and development partnerships and cross-licensing opportunities,” said Shin Ashida, Chairman, President and CEO of JCR Pharmaceuticals. “We remain dedicated to developing therapies for the rare disease community, and givinostat extends this commitment to an even broader group of patients with rare diseases in Japan.”

Francesco De Santis, Chairman of Italfarmaco Group, added: “By joining forces with JCR, we are expanding access to an important DMD therapy for the Japanese Duchenne community and also laying the groundwork for future innovations in rare diseases. Together, we are committed to delivering meaningful solutions where they are needed most.”

About Duchenne Muscular Dystrophy (DMD)

Duchenne muscular dystrophy (DMD) is a rare, progressive neuromuscular disorder caused by mutations in the dystrophin gene. These mutations prevent the production of functional dystrophin, causing the dystrophin-associated protein complex (DAPC) to break down. This makes muscle fibres more vulnerable to damage and increases histone deacetylase (HDAC) levels in the muscle cells, blocking the activation of important genes needed for muscle maintenance and repair. As a result, muscle fibres experience ongoing damage, leading to chronic inflammation and poor

regeneration. Over time, muscle cells die and are replaced by scar tissue and fat.¹⁻⁴ DMD primarily affects males, with symptoms typically appearing between the ages of two and five years. As the condition progresses, muscle weakness worsens, leading to difficulty walking and eventually loss of ambulation. Over time, the heart and respiratory muscles are also affected, which are the leading causes of premature death.⁵ DMD is one of the most severe and common forms of childhood muscular dystrophy, with a global birth incidence of approximately 1 in 5,050 boys.⁶ DMD affects an estimated 3,500 patients in Japan.⁷

About Givinostat

Givinostat (Duvyza®) was discovered through Italfarmaco's research and development efforts in collaboration with Telethon and Duchenne Parent Project (Italy). Givinostat is the first nonsteroidal drug approved to treat patients with all genetic variants of DMD. It is a histone deacetylase (HDAC) inhibitor that works by targeting pathogenic processes to reduce inflammation and loss of muscle. Givinostat's mechanism of action inhibits HDAC pathological overactivity in an effort to address the cascade of events leading to muscle damage, thereby counteracting the disease pathology and slowing down muscle degeneration.

About Italfarmaco S.p.A.

Founded in 1938 in Milan, Italy, Italfarmaco is a private global pharmaceutical company that has led the successful development and approval of many pharmaceutical products around the world. The Italfarmaco group has operations in more than 90 countries through directly controlled or affiliated companies. The company is a leader in pharmaceutical research, product development, production and commercialisation with proven success in many therapeutic areas including immuno-oncology, gynaecology, neurology, cardiovascular disease and rare diseases. Italfarmaco's rare disease unit includes programmes in Duchenne muscular dystrophy, Becker muscular dystrophy, amyotrophic lateral sclerosis and polycythaemia vera.

About JCR Pharmaceuticals Co., Ltd.

JCR Pharmaceuticals Co., Ltd. (TSE 4552) is a global specialty pharmaceutical company that develops treatments that go beyond rare diseases to solve the world's most complex healthcare challenges. We continue to build upon our 50-year legacy in Japan while expanding our global footprint into the U.S., Europe, and Latin America. We improve patients' lives by applying our scientific expertise and unique technologies to research, develop, and deliver next-generation therapies. Our approved products in Japan include therapies for the treatment of growth disorder, MPS II (Hunter syndrome), Fabry disease, acute graft-versus host disease, and renal anemia. Our investigational products in development worldwide are aimed at treating rare diseases including MPS I (Hurler, Hurler-Scheie and Scheie syndrome), MPS II, MPS IIIA and B (Sanfilippo syndrome type A and B), and more. Our core values – Putting people first, Forging our own path, Always advancing, and Committed to excellence – mean that the work we do benefits all our stakeholders, including partners, patients and employees. We strive to expand the possibilities for patients while accelerating medical advancement at a global level. For more information, please visit JCR's global website: <https://jcrpharm.com/>.

Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements that are subject to known and unknown risks and uncertainties, many of which are outside our control. Forward-looking statements often contain words such as "believe," "estimate," "anticipate," "intend," "plan," "will," "would," "target" and similar references to future periods. All forward-looking statements regarding our plans, outlook, strategy and future business, financial performance and financial condition are based on judgments derived from the information available to us at this time. Factors or events that could cause our actual results to be materially different from those expressed in our forward-looking statements include, but are not limited to, a deterioration of economic conditions, a change in the legal or governmental system, a delay in launching a new product, impact on competitors' pricing and product strategies, a decline in marketing capabilities relating to our products, manufacturing difficulties or delays, an infringement of our intellectual property rights, an adverse court decision

in a significant lawsuit and regulatory actions.

This document involves information on pharmaceutical products (including those under development). However, it is not intended for advertising or providing medical advice. Furthermore, it is intended to provide information on our company and businesses and not to solicit investment in securities we issue.

Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

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