

Press Release

September 18, 2026

**Tanabe Pharma announces FDA Acceptance of New Drug Application for
dersimelagon, a potential first-in-class oral therapy for EPP and XLP
and the Completion of the Transfer of dersimelagon business rights**

Tanabe Pharma Corporation (Head Office: Osaka, Japan; Representative Director, CEO: Akihisa Harada; hereinafter "Tanabe Pharma") announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for an investigational oral selective melanocortin 1 receptor (MC1R) agonist, MT-7117 (dersimelagon), for the treatment of erythropoietic protoporphyria (EPP) and X-Linked Protoporphyria (XLP). The NDA was submitted by Tanabe Pharma America, Inc. (TPA, President: Yasutoshi Kawakami), its U.S. subsidiary. The FDA has granted Priority Review, with a decision expected by the end of February 2027.

As announced on August 18, 2026 in "Tanabe Pharma Enters into Agreement with LEO Pharma for MT-7117 for EPP and XLP," Tanabe Pharma has completed the transfer of the global rights to dersimelagon to LEO Pharma.

Under the agreement, Tanabe Pharma will remain responsible for obtaining U.S. regulatory approval for dersimelagon. Ongoing clinical trials will also continue as planned and are expected to be transferred to LEO Pharma in accordance with the agreement.

The completion of the transfer strengthens Tanabe Pharma's financial foundation and supports strategic investment in its pipeline and future growth. The company will continue to invest in the Japanese market and strengthen its business foundation in Japan by expanding its pipeline through in-licensing and internal research and development.

Guided by our MISSION, "Creating hope for all facing illness," Tanabe Pharma will continue to address unmet medical needs, including rare diseases, through both in-house development and strategic partnerships, with the aim of delivering innovative medicines to patients.

About Tanabe Pharma

Tanabe Pharma Corporation is a Japan-focused, innovation-driven pharmaceutical company guided by its mission, "Creating hope for all facing illness." Founded in 1678, the company is one of Japan's oldest pharmaceutical companies and is committed to addressing unmet medical needs through R&D, business development, and strategic partnerships with the aim of improving the lives of patients.

For more information, visit <https://www.tanabe-pharma.com/en/>