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Creating hope for all facing illness.

Press Release

January 15, 2026

MT-7117 Demonstrates Positive Topline Results in Development for the Ultra-Rare Disease, Erythropoietic Protoporphyria (EPP) and X-Linked Protoporphyria (XLP)

Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter,; "Tanabe Pharma") obtained positive topline results demonstrating favorable efficacy in which the primary endpoint was met, and safety from the global phase 3 clinical trial (INSPIRE study) of MT-7117 (generic name: dersimelagon), a selective melanocortin 1 receptor agonist, being developed for the oral treatment of adult and adolescent patients with erythropoietic protoporphyria (EPP) * and X-Linked Protoporphyria (XLP)* in December, 2025.

EPP and XLP are rare hereditary disorders of the heme biosynthesis pathway, characterized by severe pain in the skin upon exposure to sunlight or certain artificial light sources. EPP is estimated to occur in approximately 1 in 75,000 to 1 in 200,000 individuals.
There are limited treatment options for adults with EPP or XLP, and there are no approved therapies for adolescent patients; as a result, these patients must take sun protection and avoidance measures, which significantly impact their daily lives.

The INSPIRE study is a global, randomized, double-blind, placebo-controlled phase 3 clinical trial targeting adult and adolescent patients with EPP or XLP. The study consists of a 16-week double-blind treatment period, in which participants are randomly assigned to either the placebo group or active treatment group (dersimelagon 200 mg once daily), followed by a 36-week open-label extension period of active treatment. The primary endpoint is the time to first prodromal symptoms (such as burning, tingling, itching, or stinging) associated with sunlight exposure. The trial is primarily conducted by our U.S. subsidiary, Tanabe Pharma America, Inc. (Head Office: New Jersey, US), and the open-label extension period is ongoing.

Tanabe Pharma will continue to advance the development of the oral agent MT-7117 as a new therapeutic option for patients with EPP and XLP, striving to offer more choices to patients and healthcare professionals.

*Japan Intractable Diseases Information Center website: https://www.nanbyou.or.jp/entry/5546

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■ About Dersimelagon (MT-7117):
Dersimelagon is a novel synthetic, orally-administered, non-peptide small molecule, which acts as a selective agonist of melanocortin-1 receptor (MC1R) with a potential for being

effective to increase pain free light exposure in patients with a history of phototoxicity from erythropoietic protoporphyria (EPP) and X-Linked Protoporphyria (XLP). Tanabe Pharma is developing dersimelagon for the treatment of EPP or XLP. Dersimelagon is an investigational medication and not approved by FDA or any other regulatory authority. Tanabe Pharma received Fast Track Designation for dersimelagon by the U.S. Food and Drug Administration in June 2018.

■About Erythropoietic Protoporphyria and X-Linked Protoporphyria

Erythropoietic Protoporphyria (EPP) is an inherited disorder of the heme biosynthetic pathway that results from mutations of the ferrochelatase (FECH) gene or, less commonly X-Linked Protoporphyria (XLP) that results from mutations in the aminolevulinic acid synthase-2 (ALAS2) gene. Both EPP and XLP are characterized by accumulation of protoporphyrin in blood, erythrocytes and tissues and cutaneous photosensitivity. EPP and XLP usually present early in childhood with extremely painful phototoxic reactions which are preceded by a “prodrome” of tingling, stinging, and/or burning of sun-exposed skin. The onset of prodromal symptoms after direct sun exposure varies but may occur in less than 10 minutes. Importantly, continued exposure to sunlight following the onset of prodromal symptoms will lead to phototoxicity-induced pain.

■About Tanabe Pharma America, Inc.

The U.S. headquarters of Tanabe Pharma America (TPA), Inc. is located in Jersey City, New Jersey. TPA has obtained the approval of Radicava® the new treatment option for ALS in more than 20 years in the ALS therapeutic area in the United States. TPA is dedicated to research and develop innovative pharmaceutical products that address the unmet medical needs of patients.