News Release

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# Merck KGaA, Darmstadt, Germany, Announces FDA Breakthrough Therapy Designation for Enpatoran in Lupus Patients with Active Skin Manifestations

- **Enpatoran could address a significant unmet need in lupus, specifically targeting cutaneous manifestations of the disease, which currently have no approved therapies**
- **FDA's decision was supported by Phase 2 WILLOW study results, which demonstrated meaningful symptoms improvement, particularly among patients with active cutaneous manifestations**
- **Enpatoran's potential to go beyond current treatment standards in lupus prompted FDA´s breakthrough designation, which is designed to expedite drug development and review**

DARMSTADT, Germany, July 8, 2026 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to enpatoran for the treatment of lupus with active cutaneous manifestations. Enpatoran is an oral selective toll-like receptor (TLR) 7/8 inhibitor, designed to modulate pathways central to lupus-related inflammation.

"For the 85% of lupus patients whose disease includes skin manifestations, often associated with substantial physical and psychosocial burden, the lack of targeted treatment makes the disease hard to control," said David Weinreich M.D., Global Head of R&D and Chief Medical Officer, Merck KGaA, Darmstadt, Germany. "This

Breakthrough Therapy designation demonstrates that enpatoran has the potential to redefine how we approach lupus, by addressing the visible burden of rash, while potentially driving benefit beyond the skin. We look forward to working with the FDA to potentially bring this much-needed option to patients as quickly as possible."

The FDA Breakthrough Therapy designation is supported by results from the Phase 2 WILLOW study, a multicenter, randomized, double-blind, placebo-controlled, dose-finding study to evaluate the safety and efficacy of orally administered enpatoran. The trial used an innovative basket and adaptive study design including patients with both CLE (Cutaneous Lupus Erythematosus) and SLE (Systemic Lupus Erythematosus). The results demonstrated that enpatoran delivered clinically meaningful improvements of lupus symptoms, particularly in patients with active cutaneous manifestations.

Additionally, the company recently initiated the ELOWEN 1 and ELOWEN 2 studies, a global Phase 3 program evaluating the therapy's impact on both cutaneous and systemic symptoms in patients with lupus and potential links between skin and systemic disease activity.

Lupus is a chronic autoimmune disease that can affect multiple organ systems, including the skin, joints, kidneys, and central nervous system. Skin manifestations, which can present as inflamed, photosensitive lesions on the face, scalp and other areas, may be life-altering and are sometimes irreversible on their own. But, despite skin manifestations being the first sign of disease in nearly one-third (29%) of lupus cases,[1] many patients still do not achieve adequate disease control.[2]

FDA Breakthrough Therapy designation is a process aimed at expediting the development and review of drugs for serious conditions, where the preliminary clinical evidence indicates that the drug may offer a substantial improvement over available therapy.

**About enpatoran**
Enpatoran is an investigational, oral, selective inhibitor of toll-like receptors 7 and 8 (TLR7/8), which play a key role in immune pathways involved in lupus. Enpatoran has the potential to be the first targeted therapy for lupus patients with active cutaneous manifestations, with the goal of broadening the treatment paradigm beyond the current standards of care for patients with CLE and SLE. Enpatoran is

currently under clinical investigation and has not been approved for any use anywhere in the world.

**About the Phase 3 ELOWEN Program**
ELOWEN-1 (NCT07332481) and ELOWEN-2 (NCT07355218) are two global randomized, double-blind, placebo-controlled Phase 3 studies evaluating enpatoran taken twice daily versus placebo, on top of standard of care, in patients with lupus who have active cutaneous manifestations. The ELOWEN studies will be conducted in 266 sites in 26 countries. Each study will recruit approximately 200 lupus participants, and the primary endpoint will be a change in CLASI-A from baseline.

**About Lupus Erythematosus**
Lupus erythematosus is a chronic autoimmune disease characterized by inflammation that can affect multiple organs and systems in the body. The disease is heterogeneous, with symptoms ranging from mild to life-threatening, and often follows a relapsing-remitting course.

Cutaneous manifestations are common (72-85%) in patients and can occur alongside or independently of systemic involvement. Beyond their physical presentation, they are associated with increased disease burden, including scarring, psychological impact and reduced quality of life.

Lupus disproportionately affects women and people of color, and many patients continue to experience unmet medical needs due to insufficient disease control or treatment-related side effects.

**Merck KGaA, Darmstadt, Germany in Neurology and Immunology**
Merck KGaA, Darmstadt, Germany has a long-standing legacy in neurology and immunology. The company's current neurology portfolio includes two products for the treatment of relapsing MS. Merck KGaA, Darmstadt, Germany aims to improve the lives of patients by addressing areas of unmet medical needs. In addition to Merck KGaA, Darmstadt, Germany's commitment to MS, the company also has a pipeline focusing on discovering new therapies that have potential in other neuroinflammatory and immune-mediated diseases, including lupus and generalized myasthenia gravis (gMG).

**About Merck KGaA, Darmstadt, Germany**
Merck KGaA, Darmstadt, Germany, a leading science and technology company, operates across life science, healthcare and electronics. More than 62,000 employees work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. From providing products and services that accelerate drug development and manufacturing as well as discovering unique ways to treat the most challenging diseases to enabling the intelligence of devices – the company is everywhere. In 2025, Merck KGaA, Darmstadt, Germany, generated sales of € 21.1 billion in 65 countries.

The company holds the global rights to the name and trademark "Merck" internationally. The only exceptions are the United States and Canada, where the business sectors of Merck KGaA, Darmstadt, Germany, operate as MilliporeSigma in life science, EMD Serono in healthcare and EMD Electronics in electronics. Since its founding in 1668, scientific exploration and responsible entrepreneurship have been key to the company's technological and scientific advances. To this day, the founding family remains the majority owner of the publicly listed company.

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[1] Childs B and Merola JF. From the Masterclasses in Dermatology 2025 Meeting: Practical Approaches to Cutaneous and Systemic Lupus for Dermatologists. J Clin Aesthet Dermatol. 2025;18(10):40–47.
[2] Kandane-Rathnayake R, Louthrenoo W, Hoi A, et al. 'Not at target': prevalence and consequences of inadequate disease control in systemic lupus erythematosus—a multinational observational cohort study. Arthritis Res Ther. 2022;24(1):70.