



Vanda Pharmaceuticals Announces EMA Positive Opinion for Orphan Drug Designation of Imsidolimab for Generalized Pustular Psoriasis - A Milestone Recognition of GPP as a Distinct Rare Disease in Europe

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WASHINGTON, July 16, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the Committee for Orphan Medicinal Products at the European Medicines Agency (EMA) has adopted a positive opinion recommending orphan drug designation for imsidolimab, the company's investigational medicinal product, a high-affinity humanized immunoglobulin G4 (IgG4) monoclonal antibody, for the treatment of generalized pustular psoriasis (GPP).

This marks the first time the EMA has granted orphan drug designation recognition for a drug to treat GPP in the European Union (EU). GPP is a severe, chronic, and potentially life-threatening inflammatory skin disease, genetically and clinically distinct from plaque psoriasis, driven by dysregulation in the interleukin-36 (IL-36) signaling pathway.¹ It is characterized by widespread pustular eruptions, systemic inflammation, and serious complications that can lead to increased mortality.^{2,3,4}

Imsidolimab inhibits IL-36 receptor signaling, addressing the deficiency in the endogenous IL-36 receptor antagonist commonly observed in patients with GPP.

The EMA's orphan drug designation is granted to medicines intended for the treatment of life-threatening or chronically debilitating rare conditions affecting fewer than 5 in 10,000 people in the EU. Benefits include protocol assistance, reduced regulatory fees, and market exclusivity provisions in the EU following approval.

"The EMA's positive opinion is a significant milestone that reinforces the highly encouraging clinical data supporting the imsidolimab program and formally recognizes GPP as an orphan disease in the EU for the first time," said Dr. Mihael H. Polymeropoulos, "This designation highlights the urgent unmet medical need in GPP and brings us one step closer to delivering a meaningful new therapy to patients in the EU."

This designation follows similar regulatory recognitions in the United States and Japan. Additionally, the imsidolimab Biologics License Application (BLA) for GPP is currently under review by the FDA with a target action date of December 12, 2026.

References

1. Smieszek, S. et al. Efficacy and Safety of Imsidolimab for Generalized Pustular Psoriasis. NEJM Evidence 5, (2026).
2. Ministry of Health Labour and Welfare (MHLW), "Pustular psoriasis (generalized type) (Designated Intractable Disease 37)," Japan Intractable Diseases Information Center. Accessed: Mar. 10, 2026. [Online]. Available: <https://www.nanbyou.or.jp/entry/168>
3. H. Fujita, R. Iwasaki, S. Tsuboi, Y. Murashiuma, and M. Akiyama, "Regional differences in the prevalence of generalized pustular psoriasis in Japan," J. Dermatol., vol. 51, no. 3, pp. 380–390, Mar. 2024, doi: 10.1111/1346-8138.17089.
4. H. Miyachi et al., "Treatments and outcomes of generalized pustular psoriasis: A cohort of 1516 patients in a nationwide inpatient database in Japan," J. Am. Acad. Dermatol., vol. 86, no. 6, pp. 1266–1274, Jun. 2022, doi: 10.1016/j.jaad.2021.06.008.

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including but not limited to statements regarding the potential benefits associated with EMA approval of an orphan drug, the therapeutic potential of imsidolimab for patients with GPP in the EU, and the anticipated timing of the completion of the FDA's review of the imsidolimab BLA are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's ability to obtain approval of, and to successfully commercialize, imsidolimab in the EU for the treatment of patients with GPP, Vanda's ability to satisfy the conditions necessary to receive the benefits associated with EMA approval of an orphan drug, and the FDA's ability to complete its review of, and reach a decision with respect to, the imsidolimab BLA by December 12, 2026. Therefore, no assurance can be given that the results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent Annual Report on Form 10-K, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this press release is provided only as of the date of this press release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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