



Vanda Pharmaceuticals Announces Orphan Drug Designation in Japan for Imsidolimab in Generalized Pustular Psoriasis

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WASHINGTON, May 27, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: Vnda) today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has granted orphan drug designation to imsidolimab, a high-affinity humanized immunoglobulin G4 (IgG4) monoclonal antibody, for the treatment of generalized pustular psoriasis (GPP).

Imsidolimab inhibits interleukin-36 (IL-36) receptor signaling, addressing the deficiency in the endogenous IL-36 receptor antagonist regulator that is commonly observed in patients with GPP.¹

The MHLW grants orphan drug designation to medicines intended to treat rare diseases with significant unmet medical need. In Japan, approximately 2,200 people have been diagnosed with GPP.² *IL36RN* genetic variants—which are associated with dysregulation of the IL36 pathway—are enriched in the Japanese population, including well-characterized founder families in Hokkaido.³

In Japan, orphan drug designation provides development incentives, including subsidies for research and development costs, as well as the potential for up to 10 years of market exclusivity following approval.

This designation follows similar regulatory recognition in the United States and underscores the global interest in the potential of imsidolimab to address the significant unmet medical needs of patients with GPP, a rare and severe inflammatory skin disease associated with systemic complications and increased mortality.⁴

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 therapeutic potential of imsidolimab for patients with GPP and the potential to extend regulatory and patent exclusivity for imsidolimab into the late 2030s, are "forward-looking statements" within the meaning of 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 on 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 regulatory approval of, and to successfully commercialize, imsidolimab for the treatment of GPP and Vanda's ability to satisfy the conditions necessary to extend regulatory and patent exclusivity for imsidolimab into the late 2030s. 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 risks and uncertainties described in the sections titled "Cautionary Note Regarding Forward-Looking Statements," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in 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 forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements set forth herein. Vanda cautions investors not to place undue reliance on forward-looking statements. The information contained in this press release is provided as of the date hereof, and Vanda undertakes no obligation, and expressly disclaims any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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