Vanda Pharmaceuticals Announces FDA Acceptance of Biologics License Application Filing for Imsidolimab for the Treatment of Generalized Pustular Psoriasis

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WASHINGTON, Feb. 25, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of its Biologics License Application (BLA) for imsidolimab for the treatment of Generalized Pustular Psoriasis (GPP), with a target action date of December 12, 2026.

GPP is a rare, chronic, life-threatening autoinflammatory skin disorder characterized by sudden flares of widespread pustules, erythema, and systemic symptoms such as fever and fatigue. The pathogenesis of GPP is increasingly understood through its genetic characterization (OMIM #614204), and its molecular etiology is mainly attributed to excessive activity of the interleukin-36 (IL-36) pathway.[1] The majority of GPP cases for which a causal single gene defect has been identified are caused by various consequential genetic variants in the IL36RN gene, encoding the IL-36 receptor antagonist (IL-36Ra).[2,3,4]

Imsidolimab is a fully humanized IgG4 monoclonal antibody that inhibits IL-36 receptor signaling and is believed to achieve its therapeutic effects in GPP where IL-36 signaling is unbalanced. If approved, imsidolimab could address a significant unmet medical need in this rare and life-threatening disorder with potential benefits over currently existing treatments.

Imsidolimab was studied in global clinical studies conducted in the United States, France, Spain, Poland, Turkey, Malaysia, Thailand, Georgia, Tunisia, Taiwan, and Morocco. In the pivotal efficacy studies GEMINI-1 and GEMINI-2, a single intravenous dose of imsidolimab led to rapid disease clearance, with 53% of patients achieving clear or almost clear skin (GPPPGA 0/1) at Week 4 compared to 13% on placebo. Efficacy was maintained throughout an approximately 2-year maintenance period with monthly doses, and no flares occurred in the active treatment arm. Imsidolimab exhibited a favorable safety profile and demonstrated a low incidence of anti-drug antibodies, which can be a significant advantage over existing treatments. GPP is a rare disorder with prevalence estimates varying widely by region, ranging from approximately 2 to 124 cases per million worldwide (lower in Europe and higher in parts of Asia).[5,6]

"The acceptance of the BLA filing for imsidolimab marks a critical milestone in our efforts to bring this innovative therapy to patients suffering from GPP," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of the Board of Vanda Pharmaceuticals. "Imsidolimab builds on our growing expertise in rare orphan disorders and our anti-inflammatory portfolio. Imsidolimab represents a precision medicine approach targeting a disorder with a known genetic cause using a fully humanized monoclonal antibody against the IL-36 receptor. We look forward to potential FDA approval and leveraging our commercial infrastructure to address this debilitating condition."

Vanda celebrates this significant milestone for imsidolimab's acceptance for review by the FDA during Rare Disease Week on Capitol Hill (February 24–26, 2026), as advocates unite to promote innovation and access to treatments for rare orphan diseases like generalized pustular psoriasis.

If imsidolimab is approved, it will be the third new drug product approved for Vanda in the past 12 months, following NEREUS™ (tradipitant) and BYSANTI™ (milsaperidone).

References

1. Online Mendelian Inheritance in Man, OMIM®. Johns Hopkins University, Baltimore, MD. MIM Number: 614204: 12/16/2020. Available at: https://omim.org/
2. Marrakchi, S. et al. Interleukin-36–Receptor Antagonist Deficiency and Generalized Pustular Psoriasis. New England Journal of Medicine 365, 620–628 (2011).
3. Sugiura, K. et al. The Majority of Generalized Pustular Psoriasis without Psoriasis Vulgaris Is Caused by Deficiency of Interleukin-36 Receptor Antagonist. Journal of Investigative Dermatology 133, 2514–2521 (2013).
4. Johnston, A. et al. IL-1 and IL-36 are dominant cytokines in generalized pustular psoriasis. Journal of Allergy and Clinical Immunology 140(1), 109–120 (2017).
5. Sachen, K. L. et al. Role of IL-36 cytokines in psoriasis and other inflammatory skin conditions. Cytokine 156, 155897 (2022).
6. Prinz, J. C. et al. Prevalence, comorbidities and mortality of generalized pustular psoriasis: A literature review. Journal of the European Academy of Dermatology and Venereology 37, 256–273 (2022).

About Imsidolimab

Imsidolimab is a fully humanized IgG4 monoclonal antibody that inhibits IL-36 receptor signaling and is being developed for GPP, a rare orphan indication. Regulatory and patent exclusivity for imsidolimab is expected to extend into the late 2030s. Vanda holds an exclusive global license for the development and commercialization of imsidolimab from AnaptysBio (Nasdaq: ANAB).

About Vanda Pharmaceuticals

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 anticipated timing of the completion of the FDA's review of the imsidolimab BLA; imsidolimab's mechanism of action; the potential for imsidolimab to address a significant unmet medical need; the prevalence

of GPP; potential FDA approval of imsidolimab; Vanda's plans to leverage its commercial infrastructure to address GPP; and the potential to extend regulatory and patent exclusivity for imsidolimab into the late 2030s, 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, the FDA's ability to complete its review of, and reach a decision with respect to, the imsidolimab BLA by December 12, 2026; Vanda's assumptions regarding how imsidolimab achieves its therapeutic effect; Vanda's ability to obtain FDA approval of imsidolimab for the treatment of GPP; Vanda's ability to successfully execute the commercial launch of imsidolimab and to leverage its commercial infrastructure to reach patients with GPP; the ability of imsidolimab to safely and effectively treat GPP; the accuracy of the estimates of the prevalence 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 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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