Vanda Announces Submission of Biologics License Application to the FDA for Imsidolimab for the Treatment of Generalized Pustular Psoriasis

December 15, 2025

WASHINGTON, Dec. 15, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for imsidolimab, a novel IgG4 IL-36 receptor antagonist, to treat generalized pustular psoriasis (GPP). Imsidolimab inhibits IL-36 receptor signaling, addressing the deficiency in the endogenous IL-36RA regulator commonly seen in GPP patients due to IL36RN gene mutations.

The BLA is supported by positive results from the global Phase 3 GEMINI-1 and GEMINI-2 studies, where a single intravenous dose of imsidolimab led to rapid disease clearance, achieving clear or almost clear skin, with efficacy maintained throughout an approximately 2-year maintenance study period with monthly doses. Imsidolimab demonstrated a favorable safety profile with no clinically meaningful safety signals.

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. Driven primarily by loss-of-function mutations in IL36RN, GPP represents a significant unmet medical need, with prevalence estimates varying widely by region, ranging from approximately 2 to 124 cases per million worldwide (e.g., lower in Europe and higher in parts of Asia).[1,2,3,4]

"The submission of the BLA 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, including Ponvory®, which is approved for the treatment of relapsing forms of multiple sclerosis and is in clinical development for the treatment of psoriasis and ulcerative colitis. We look forward to potential FDA approval and leveraging our commercial infrastructure to address this debilitating condition."

Vanda has requested priority review for the BLA, citing GPP's status as a rare orphan disease with significant unmet need. If granted, priority review would establish a six-month review cycle, with a potential FDA approval of imsidolimab for the treatment of GPP as early as mid-2026.

References:

1. 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).
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. Sachen, K. L., Arnold Greving, C. N. & Towne, J. E. Role of IL-36 cytokines in psoriasis and other inflammatory skin conditions. Cytokine 156, 155897 (2022).

About GEMINI-1 and GEMINI-2 Studies

In the 45-patient GEMINI-1 Phase 3 trial, patients were randomized 1:1:1 to a single intravenous infusion of 750 mg imsidolimab, 300 mg imsidolimab, or placebo on Day 0. At Week 4 (primary endpoint), 53% of patients receiving either dose of imsidolimab achieved a GPPGA score of 0/1 (clear or almost clear skin), compared to 13% on placebo (p=0.0131 for 750 mg dose).

Responders from GEMINI-1 were re-randomized in GEMINI-2 to monthly subcutaneous maintenance dosing with 200 mg imsidolimab or placebo, followed for up to 116 weeks. All patients on active maintenance therapy maintained clear or almost clear skin with no flares, compared to 25% maintenance and 63% flare rate in the placebo group. Across both studies, imsidolimab demonstrated a favorable safety profile, with no treatment-related serious adverse events or discontinuations due to adverse events.

About Imsidolimab and GPP

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).

GPP flares involve painful pustules over large skin areas, accompanied by redness, itching, and systemic symptoms, and can be life-threatening if untreated.

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 estimated prevalence of GPP, the potential for FDA approval of the imsidolimab BLA, the commercial availability of imsidolimab to treat patients with GPP, the potential to extend regulatory and patent exclusivity for imsidolimab into the late 2030s, and the potential timing of FDA approval of imsidolimab for the treatment of GPP, 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 accuracy of the estimates of the number of patients with GPP worldwide, Vanda's ability to obtain regulatory approval of, and successfully commercialize, imsidolimab for the treatment of GPP, Vanda's ability to satisfy the conditions necessary to extend imsidolimab's regulatory and patent exclusivity into the late 2030s and the FDA's determination that the BLA and its supporting documentation meet the criteria for priority review. Therefore, no assurance can be given that the results or developments anticipated by Vanad 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.

Corporate Contact:
Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Jim Golden / Jack Kelleher / Dan Moore
Collected Strategies
VANDA-CS@collectedstrategies.com

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