Vanda Pharmaceuticals Receives FDA Approval to Proceed with Investigational New Drug VTR-297 a Topical Antifungal Candidate for the Treatment of Onychomycosis

January 31, 2024

WASHINGTON, Jan. 31, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has approved the Investigational New Drug (IND) application to evaluate VTR-297 for the treatment of onychomycosis.

Onychomycosis, or tinea unguium, is a fungal infection of the nail. Onychomycosis can result in discoloration of the nail, onycholysis (nail separation from the nail bed), and nail plate thickening. Onychomycosis accounts for one half of all nail disease with an estimated U.S. prevalence of up to 14%.[1] In addition to cosmetic issues, onychomycosis infection may indirectly decrease peripheral circulation, thereby worsening conditions such as venous stasis and diabetic foot ulcers.[2]

"The initiation of clinical studies with VTR-297 in the treatment of onychomycosis is an important milestone in studying and developing potential new therapies for this common disorder," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

VTR-297 is a small molecule histone deacetylase (HDAC) inhibitor with activity against dermatophytes and fungi, originally isolated from the yeast species Streptomyces hygroscopicus as an antifungal antibiotic, first described in 1976.[3] Current therapies for onychomycosis include topical agents JUBLIA® (efinaconzole), KERYDIN® (tavaborole), and PENLAC® (ciclopirox). There have not been any new onychomycosis treatments approved by the FDA since 2014.[4]

References

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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 Twitter @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding the estimated prevalence of onychomycosis and the development of new antifungals, 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, assumptions 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 reporting and diagnosis of onychomycosis and onychomycosis cases and the ability to successfully complete the clinical development of, and obtain regulatory approval for, VTR-297 in the treatment of onychomycosis. 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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