



Vanda Pharmaceuticals Responds to Ruling in HETLIOZ® ANDA Litigation

December 13, 2022

WASHINGTON, Dec. 13, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today responded to the ruling in its HETLIOZ® ANDA Litigation.

Vanda has brought several Hatch-Waxman lawsuits in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. (Teva) and Apotex Inc. (Apotex) asserting infringement of patents covering HETLIOZ® (tasimelteon) 20 mg capsules. A trial was held in March 2022. Today the Court ruled that Teva and Apotex did not infringe U.S. Patent No. RE46,604, and that the asserted claims of U.S. Patent Nos. RE46,604; 9,730,910; 10,149,829; and 10,376,487 are invalid. Vanda intends to appeal the decision to the United States Court of Appeals for the Federal Circuit and to request a stay of market entry by Teva and Apotex while the appeal is pending.

HETLIOZ® is also approved in the European Union and is not subject to this litigation, nor is generic litigation pending outside of the United States. The litigation does not relate to the HETLIOZ LQ® oral suspension formulation.

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.

About HETLIOZ®

For full U.S. Prescribing Information for HETLIOZ® and HETLIOZ LQ®, including indication and Important Safety Information, visit www.hetlioz.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's intention to appeal the decision and request a stay of market entry, 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, whether Vanda appeals the decision and Vanda's ability to obtain a stay of market entry. 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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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