



Vanda Pharmaceuticals Intends to Petition the U.S. Supreme Court in its HETLIOZ® ANDA Litigation

October 20, 2023

WASHINGTON, Oct. 20, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced its intention to file a petition for a writ of certiorari in its HETLIOZ® Abbreviated New Drug Application litigation against Teva Pharmaceuticals USA, Inc., Apotex Inc. and Apotex Corp.

Vanda seeks to demonstrate that the United States Court of Appeals for the Federal Circuit (Federal Circuit) applied a flawed standard in assessing obviousness when it affirmed a lower court decision finding several of Vanda's HETLIOZ® patents invalid. Vanda's petition seeks to show that the Federal Circuit's approach to obviousness has deviated materially from *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007), which trains the obviousness inquiry on whether the claimed innovations "do more than yield a predictable result." Vanda believes that the Federal Circuit's approach improperly invalidates critical patent rights, which are necessary to ensure robust pharmaceutical research and development.

"Properly calibrated patent protection is essential to pharmaceutical innovation, which is in turn critical for advances in public health. Vanda intends to pursue its interest in this matter and the interests of innovators, patients and the American public in the proper interpretation of the U.S. patent laws," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

Chief Justice Roberts extended the time for the filing of Vanda's forthcoming petition, which Vanda expects to file by January 12, 2024.

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®, 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 intentions to petition the U.S. Supreme Court and continue to protect its HETLIOZ® patents, the expected timing of the petition filing and the substance and intended effect of the petition, 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, Vanda's ability to file the petition by January 12, 2024, have certiorari granted and prevail in proceedings before the U.S. Supreme Court. 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.

Corporate Contact:

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

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