



Vanda Pharmaceuticals Settles HETLIOZ® Patent Litigation with MSN

January 14, 2022

WASHINGTON, Jan. 14, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: Vnda) today announced it has entered into a License Agreement (the License Agreement) with MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (together MSN) and Impax Laboratories LLC (Impax) to resolve Vanda's patent litigation against MSN regarding MSN's Abbreviated New Drug Application seeking approval of its generic version of Vanda's HETLIOZ® (tasimelteon).

Under the License Agreement, Vanda granted MSN and Impax a non-exclusive license to manufacture and commercialize MSN's version of HETLIOZ® in the U.S. effective March 13, 2035, unless prior to that date Vanda obtains pediatric exclusivity for HETLIOZ®, in which case, the license will be effective July 27, 2035. MSN and Impax may enter the market earlier under certain limited circumstances.

The License Agreement is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The License Agreement provides for a full settlement and release by Vanda, MSN and Impax of all claims that are the subject of the litigation.

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®

HETLIOZ® (tasimelteon) is a melatonin receptor agonist. HETLIOZ® has been granted market authorization by the U.S. Food and Drug Administration and the European Medicines Agency. 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 the License Agreement, 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 regulatory authorities challenge the enforceability of or seek to enjoin the entry into the License Agreement, whether the U.S. District Court for the District of Delaware, where the litigation is pending, will grant orders dismissing the litigation, whether additional third parties may seek to market generic versions of HETLIOZ® and the results of any litigation that Vanda files to defend and/or assert its patents against such third parties. 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, 2020, 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

Elizabeth Van Every
Head of Corporate Affairs
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

View original content: <https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-settles-hetlioz-patent-litigation-with-msn-301461230.html>

SOURCE Vanda Pharmaceuticals Inc.