



Vanda Prevails in Jet Lag Litigation Against the FDA

March 28, 2023

WASHINGTON, March 28, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced a win in its jet lag FOIA litigation against the FDA.

On March 27, 2023 a federal court granted final judgment in favor of Vanda in its Freedom of Information Act ("FOIA") case requesting records created by the Food and Drug Administration ("FDA") during its review of Vanda's application seeking approval of a new use for its drug, Hetlioz[®] (tasimelteon). Vanda filed the lawsuit, *Vanda Pharmaceuticals, Inc., v. Food and Drug Administration*, case no. 1:22-cv-00938, in the United States District Court for the District of Columbia in April 2022 to compel the FDA to produce, as required by FOIA, certain records relating to its denial of Vanda's supplemental New Drug Application ("sNDA") for HETLIOZ[®] in the treatment of jet lag disorder.

Vanda had repeatedly attempted to obtain these records from the FDA pursuant to a FOIA request it submitted in December 2019, but the FDA had refused to disclose those records, invoking the deliberative process exemption under FOIA.

The court rejected the FDA's claim that it would suffer "foreseeable harm" if it disclosed to Vanda its reviews relating to Vanda's sNDA. In particular, the court held that in the context of this case, contrary to the FDA's assertion, "[d]isclosure cannot chill" the "deliberations" of agency staff.

Dr. Mihael H. Polymeropoulos, Vanda's President, CEO and Chairman of the Board, said: "In order to facilitate the development of promising new therapeutics for unmet patient needs, it is crucial that the FDA work collaboratively with drug innovators. The court's ruling today constitutes an important step to ensure appropriate transparency at the FDA, which is essential to scientific advancement in the service of public health."

As part of its ruling, the federal court issued a final and appealable order in Vanda's favor, which also denied the FDA's cross-motion for summary judgment.

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.

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

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