FDA Bureaucrats Unlawfully Delay Hearing on Vanda Drug and Falsely Blame Commissioner Makary and the reductions in force at FDA

April 23, 2025

WASHINGTON, April 23, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. ("Vanda") (Nasdaq: VNDA) today announced that FDA bureaucrats have committed to delay Vanda's request for a hearing on the approvability of tradipitant for gastroparesis. Rather than take accountability, FDA bureaucrats identify a new scapegoat: newly appointed Commissioner, Dr. Martin Makary, and reductions in force.

FDA last night represented to a federal court that the April 1 reduction in force is partially to blame for the Center for Drug and Evaluation and Research's delay of at least 6 more months to provide its recommendation on whether the Commissioner should hold a hearing. But this cannot be true. Commissioner Makary said that any cuts were not to scientists or reviewers, the very individuals who supposedly need more time. This excuse is also suspect because CDER, in prior matters, has requested the same or longer delay to provide hearing recommendations: CDER took six months to submit a proposed order on the Hetlioz jet lag hearing request and likewise requested six months for the Hetlioz insomnia application.

It is unfair for CDER and its lawyers to blame the recent reductions in force for their habitual institutional delays on hearing requests. These statements also conceal the extraordinary fact that FDA has denied every hearing request on new drug approvability for at least the past decade.

FDA bureaucrats have created policies to avoid scrutiny of their decision-making by habitually denying hearings. FDA's office of chief counsel and DOJ have repeatedly defended FDA's right to act unlawfully when confronted by federal judges. When considering FDA's delay in resolving Vanda's hearing request in a prior instance, a federal judge pointedly asked FDA whether it was "conceding that the [HHS] Secretary is presently not complying with the statute," and a DOJ lawyer replied, "Yes, your Honor".

We urge Commissioner Makary to step in and restore adherence to the law at FDA; targeted RIFs are not to blame for FDA's culture of delay and closemindedness. Commissioner Makary and Secretary Kennedy have been clear that "radical transparency and common sense" should be the operating culture of the Agency. We also urge Attorney General Bondi to stop DOJ lawyers from defending unlawful Agency actions.

"Vanda has fought for 'transparency and common sense' for years because rational innovation can only thrive in a democracy and not in a bureaucracy. It is time for FDA and DOJ to stop fighting innovators like Vanda, focus on what is broken and listen to ideas of how it can be fixed, and usher in a new era of rational and transparent decision making," said Dr. Mihael Polymeropoulos, Vanda's President, CEO and Chairman of the Board.

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 X @vandapharma.

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

Jim Golden/Jack Keleher/Dan Moore
Collected Strategies
VANDA-CS@collectedstrategies.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/fda-bureaucrats-unlawfully-delay-hearing-on-vanda-drug-and-falsely-blame-commissioner-makary-and-the-reductions-in-force-at-fda-302436404.html

SOURCE Vanda Pharmaceuticals Inc.