Vanda Pharmaceuticals Calls for Stronger FDA Action to Accelerate Shift from Animal Testing to Human-Relevant Methods

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WASHINGTON, March 19, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA), a leader in innovative drug development and a vocal advocate for reducing unnecessary animal testing, today voiced serious concerns over the U.S. Food and Drug Administration (FDA)'s new draft guidance, "General Considerations for the Use of New Approach Methodologies in Drug Development," released March 18, 2026, by the Center for Drug Evaluation and Research (CDER).

The FDA's draft guidance aims to support the use of New Approach Methodologies (NAMs)—advanced non-animal tools like in vitro assays, organ-on-chip systems, computational models, and human cell-based platforms—to modernize nonclinical testing and move away from traditional animal models. While Vanda welcomes the FDA's stated commitment to improving human predictivity and ethical standards in drug development, the current draft falls short of delivering the bold, practical reform needed to make this transition a reality.

Vanda has a proven track record of pushing for science-driven change, including legal efforts to challenge FDA requirements for prolonged animal studies—such as nine-month dog toxicity tests—that lack strong scientific justification. These efforts highlight the ethical imperative to minimize anima suffering, particularly in dogs, while advancing more predictive human-relevant methods.

"While we applaud the FDA's direction toward human-centric science, the draft guidance must strike a better balance between regulatory caution and the much-needed scientific reform that modern tools demand," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda Pharmaceuticals. "Patients deserve faster access to safer drugs, and ethical progress requires us to prioritize methods that better reflect human biology without unnecessary reliance on animals."

Key shortcomings in the draft include:

- Not a single concrete example of any NAM that the FDA currently accepts today to fully replace a required animal test—despite mentioning general categories like in vitro assays for skin sensitization or eye irritation, the document provides zero specific, real-world illustrations, zero named assays or models with acceptance details, zero case studies of waived animal studies, and zero performance benchmarks from actual regulatory submissions or approvals.
- Limited scientific references and practical examples of validated NAMs, leaving developers without clear benchmarks for success.
- Insufficient transparency in authorship and limited citations, falling below the standards expected in credible scientific discourse.
- Vague validation requirements that lack streamlined approval pathways or concrete criteria, potentially creating uncertainty and slowing adoption of innovative tools.
- FDA leadership has repeatedly emphasized the limitations of animal studies in predicting human outcomes. Vanda urges the Agency to fully embrace this perspective by ensuring the final guidance removes barriers rather than introducing new ones.

To help realize the promise of NAMs and accelerate safer, faster drug development, Vanda calls on the FDA to:

1. Withdraw the current draft and substantially revise it with stronger scientific grounding.
2. Incorporate robust citations to validated NAMs, peer-reviewed studies, and specific, concrete examples of NAMs that have been accepted to replace animal tests, including details on endpoints, performance data, and submission outcomes.
3. Provide clear, expedited pathways for regulatory acceptance that prioritize human relevance and evidence-based confidence over outdated precedents.
4. Actively collaborate with industry innovators, scientists, and animal welfare groups during the comment period to refine the guidance.

Vanda stands ready to partner with the FDA, HHS, and stakeholders across the ecosystem to advance regulatory policies that harness cutting-edge science, protect patient safety, reduce animal suffering—including in dogs—and align with both ethical and scientific imperatives.

About Vanda Pharmaceuticals

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding future regulatory developments and changes to current policies and practices regarding animal testing, 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, future FDA or HHS policymaking. 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.

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