Vanda Applauds White House Issuance of Executive Orders Requiring Federal Agencies to be Transparent in Policymaking and Enforcement

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WASHINGTON, Oct. 16, 2019 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA), a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients, urges federal agencies, particularly the U.S. Food and Drug Administration (FDA), to comply with the release of the White House Executive Orders encouraging transparency and accountability when guidance documents are issued without the notice-and-comment rulemaking process required under the Administrative Procedure Act.

"The recent Executive Orders appropriately identify the issues associated with the issuance of guidance documents. The actions taken by the White House last week confirm that a more aggressive approach is needed to limit the use of guidance documents as a tool to circumvent the federal rule-making process," said Mihael H. Polymeropoulos, M.D., Vanda's President and CEO.

In this year alone, the FDA's Center for Drug Evaluation (CDER) and will issue almost 100 new draft and revised draft guidance documents, spanning 15 different categories. FDA guidance documents, although not legally binding, often serve as the basis for enforcement. The American public deserves scientifically informed, transparent rules from professionals that focus on risk management, patient safety and scientific innovation, rather than blind reliance on often outdated compliance checklists.

In February of this year, Vanda filed a lawsuit asking the U.S. District court in the District of Columbia to prohibit the FDA from requiring an unnecessary animal study on a promising new drug to treat gastroparesis. Vanda's lawsuit cites the FDA's inappropriate use of an underlying guidance document as a shortcut around proper rulemaking. The animal study would result in the killing of dogs with no scientific justification or benefit to human safety. That lawsuit is still pending.

Vanda enthusiastically supports the Executive Order directives, which, among other things, require federal agencies to seek comment on major federal guidance and better explain their guidance to the public and administration officials and put processes in place that permit regulated parties to petition the agencies to rescind guidance that should no longer be effective.

"There is broad agreement that a federal agency's guidance should not be inappropriately used," said Dr. Polymeropoulos. "It is imperative that our industry challenges and helps to improve the way the FDA operates to ensure that the rule making process is done with the common goal of getting safe, effective and accessible medicines to patients as soon as possible."

About Vanda Pharmaceuticals Inc.
Vanda is a 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, please visit www.vandapharma.com.

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