Vanda Pharmaceuticals Reports Results in a Phase II Clinical Study of VQW-765 in the Treatment of Acute Performance Anxiety

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WASHINGTON, Dec. 2, 2022 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today reported results in a Phase II clinical study of VQW-765, a novel small molecule alpha 7 nicotinic acetylcholine receptor (α7-nAChR) partial agonist, in the treatment of acute performance anxiety in social situations, such as public speaking.

In clinical study VP-VQW-765-2201 (Study 2201), 230 volunteers with prior history of performance anxiety were randomized to receive a single dose of VQW-765 or placebo and were challenged with the standardized Trier Social Stress Test (TSST). The TSST creates an acute stress by requiring participants to make an interview-style presentation in front of a panel who provides no feedback or encouragement. Participants who received VQW-765 showed numerically lower stress levels compared to those who received placebo.

In Study 2201, the stress level was assessed by the Subjective Units of Distress Scale (SUDS), a self-rating scale of level of nervousness or distress ranging from 0 to 100 at multiple timepoints during the duration of the TSST. In particular, female participants (approximately 70% of the total participants) reported a larger magnitude and statistically significant response to VQW-765. A higher stress reaction in females (as well as higher prevalence of performance anxiety) as compared to male participants is consistent with prior reports in this particular test of acute performance anxiety.[1] A significant relationship was also seen between exposure to VQW-765 (amount of drug measured in blood) and the clinical response.

This is the first time that an alpha 7 nicotinic acetylcholine receptor (α7-nAChR) partial agonist has shown efficacy in a clinical study of performance anxiety. The observed significant relationship between exposure and clinical outcome further supports the hypothesis that VQW-765 could be effective in treating performance anxiety and creates a valuable roadmap to future confirmatory studies. Clinical data gathered indicates an adverse event profile similar to placebo and there were no observed negative cognitive effects reported by any participant in Study 2201. If the results of the current study are confirmed, VQW-765 could be the first drug in the class of nicotinic receptor agonists approved to treat performance anxiety.

About VQW-765

VQW-765 is a novel small molecule alpha 7 nicotinic acetylcholine receptor (α7-nAChR) partial agonist, with potential use for the treatment of psychiatric disorders. VQW-765 binds and enhances the activity of one type of nicotinic receptors composed of a pentameric assembly of the alpha 7 subtype. While nicotine can also bind this receptor, the binding affinity of VQW-765 is much higher than nicotine itself making it a potent and specific molecule for the alpha 7 receptor. VQW-765, formerly known as AQW-051, was licensed to Vanda from Novartis.

About Performance Anxiety

An estimated over 20% of the U.S. population experiences debilitating performance anxiety that ranges from public speaking to test taking, writer's block and musical performance.[2, 3] The most common type of performance anxiety is public speaking anxiety. People with performance anxiety report that the condition can hinder or even threaten their professional career of choice. Similarly, musicians report that performance anxiety makes them perform at levels below their capabilities. Currently, there is no FDA-approved drug treatment available for performance anxiety and general anti-anxiolytic drugs tend to be sedating which is not preferred in a performance situation.

References

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3. Ebrahimi, O. V., Pallesen, S., Kenter, R. M., & Nordgreen, T. (2019). Psychological Interventions for the Fear of Public Speaking: A Meta-Analysis. *Frontiers in Psychology*, *10*. https://doi.org/10.3389/fpsyg.2019.00488

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's clinical development plan and strategies for VQW-765 and the safety and efficacy of VQW-765, are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, the ability of VQW-765 to safely and effectively treat performance anxiety and Vanda's ability to complete the clinical development of, and obtain regulatory approval for, VQW-765. There

can be no assurance that the actual 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. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved. 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, 2021, 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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