



Vanda Pharmaceuticals Provides Update on VQW-765 Clinical Development Program

October 14, 2026

- Phase III clinical study of VQW-765 in adults with social anxiety disorder did not meet its primary endpoint
- Consistent with prior studies, VQW-765 was safe and well tolerated

WASHINGTON, Oct. 14, 2026 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today provided an update on its clinical development program for VQW-765, a novel small molecule alpha 7 nicotinic acetylcholine receptor ($\alpha 7$ -nAChR) partial agonist. Vanda's Phase III clinical study, VP-VQW-765-3201 (Study 3201), which evaluated VQW-765 for the on-demand treatment of acute anxiety in adults with social anxiety disorder, did not meet its primary endpoint.

Study 3201 (NCT07221578)¹ was a multicenter, randomized, double-blind, placebo-controlled Phase III study conducted at approximately 30 clinical sites in the U.S. The study randomized 546 adults 18 to 65 years of age with a current diagnosis of social anxiety disorder and elevated baseline scores on the Liebowitz Social Anxiety Scale and Public Speaking Anxiety Scale. Participants received a single oral dose of VQW-765 or placebo in a 1:1 ratio and were then challenged with a psychosocial stress test, the standardized Trier Social Stress Test (TSST). The TSST induces acute stress by having participants prepare (anticipation phase) and then deliver (performance phase) an interview-style presentation to a panel that gives no feedback or encouragement.

The primary endpoint was the level of distress during the performance phase of the TSST in the female population, as measured by the Subjective Units of Distress Scale (SUDS), on which participants rate their nervousness or distress from 0 to 100, with higher scores indicating greater distress. Female participants who received VQW-765 did not show a statistically significant difference from those who received placebo. The study also did not meet the key secondary endpoint of SUDS during the performance phase of the TSST in the full (male and female) population.

Population	SUDS Performance Phase (Std Err)		LS Mean Difference (95% CI)	P-value
	VQW-765	Placebo		
ITT females*	65.6 (1.90)	66.0 (1.96)	-0.4 (-5.32, 4.62)	0.8899
ITT males and females**	64.7 (1.50)	63.8 (1.51)	0.9 (-3.00, 4.73)	0.6605

*Primary endpoint **Key secondary endpoint

Study 3201 was designed to confirm the findings of Vanda's earlier Phase II clinical study, VP-VQW-765-2201 (Study 2201), in which participants with a history of performance anxiety who received VQW-765 reported numerically lower stress levels during the TSST than those who received placebo. The Phase III results did not confirm those findings.

"We are disappointed that Study 3201 did not confirm the earlier Phase II findings² for VQW-765 in patients with social anxiety disorder," said Mihael H. Polymeropoulos, M.D., President, CEO and Chairman of the Board of Vanda Pharmaceuticals. "We thank the participants, investigators and site staff who made this study possible."

Given these results, the VQW-765 program is on hold pending further analysis of the full dataset.

About VQW-765

VQW-765 is a novel small molecule alpha 7 nicotinic acetylcholine receptor ($\alpha 7$ -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 that of nicotine, 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

Over 20% of the U.S. population is estimated to experience debilitating performance anxiety that ranges from public speaking to test taking, writer's block and musical performance. 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.

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.

References

1. ClinicalTrials.gov NCT07221578.
2. He Y, Polymeropoulos CM, Mohrman MA, et al. Efficacy and safety of an alpha 7-nicotinic acetylcholine receptor agonist, VQW-765, in subjects with performance anxiety: randomised, double-blind, placebo-controlled trial. *Br J Psychiatry*. 2025;227(1):473-480. doi:10.1192/bjp.2025.84

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including but not limited to statements regarding Vanda's clinical development plans for VQW-765; Vanda's clinical development plans for the rest of its late-stage pipeline and the estimated prevalence in the U.S. of performance anxiety 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 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 outcome of Vanda's analysis of the full dataset from Study 3201; and the accuracy of the estimates of the prevalence in the U.S. of performance anxiety. 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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