Vanda Pharmaceuticals Reports Positive Results from a Second Phase III Study of Tradipitant in Motion Sickness

May 15, 2024

- *New Drug Application expected to be submitted in Q4 2024*

WASHINGTON, May 15, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced the results from its second Phase III study of tradipitant in motion sickness, confirming the previously reported results of two efficacy studies demonstrating that tradipitant is effective in the prevention of vomiting associated with motion sickness. This Phase III study was conducted in real-world conditions on boats in the coastal waters of the United States (U.S.).

The Motion Serifos study was a multicenter, randomized, double-blind, placebo-controlled study where 316 participants embarked on boat trips under varied sea conditions and received tradipitant 170 mg, tradipitant 85 mg, or placebo. Study participants had a prior history of motion sickness and were distributed across twenty boat trips that took place between September 2023 and April 2024. Sea conditions and participant evaluation of the symptoms of motion sickness were recorded for each trip. The primary endpoint of the study was the effect of tradipitant 170 mg on vomiting. The key secondary endpoints were: (1) the effect of tradipitant 85 mg on vomiting and (2) the effect of tradipitant in preventing severe nausea and vomiting.

Both 170 mg and 85 mg tradipitant doses were shown to be superior to placebo in preventing vomiting with only 10.4% and 18.3% of participants experiencing vomiting on tradipitant 170 mg and 85 mg respectively, as compared to 37.7% of participants on placebo (p=0.000002, p=0.0014) resulting in reduction of risk of vomiting of over 70% in the tradipitant 170 mg group and of over 50% in the tradipitant 85 mg group.

Tradipitant (170 mg and 85 mg together) was also effective in the endpoint of prevention of severe nausea and vomiting (tradipitant 13.3%, placebo 33.0%, p=0.00003).

Motion sickness remains an unmet need as various pharmacological and non-pharmacological interventions suffer from low efficacy, substantial side effects, or both. The U.S. Food and Drug Administration (FDA) has not approved a new medication for motion sickness in over forty years, since the approval of scopolamine, a transdermal patch placed behind the ear, in 1979.

Vanda expects to submit a New Drug Application (NDA) for tradipitant in the prevention of vomiting induced by motion to the U.S Food and Drug Administration (FDA) in the fourth quarter of 2024.

Table 1: Results of Motion Serifos study for the overall population across all sea conditions

Prevention of vomiting		% Vomiting	Difference v. Placebo	p-value
Tradipitant 170 mg	n=106	10.4 %	27.3 %	0.000002
Tradipitant 85 mg	n=104	18.3 %	19.4 %	0.0014
Placebo	n=106	37.7 %		
Prevention of severe nausea and vomiting		% Severe Nausea and Vomiting	Difference v. Placebo	p-value
Tradipitant	n=210	13.3 %	19.7 %	0.00003
Placebo	n=106	33.0 %		

Motion sickness

Motion sickness is a disorder characterized by a constellation of symptoms, with nausea and vomiting being the primary ones.[1] Motion sickness has plagued travelers for thousands of years, as evidenced by the ancient Greek physician Hippocrates who wrote "sailing on the sea proves motion disorders the body".[1] Historians theorize that motion sickness may have changed the fate of civilization on several occasions, notably the defeat of the Spanish Armada by the English in 1588 and the negative effects on Napoleon's camel corps during the Egyptian campaign in 1798.[2]

It is believed that a discrepancy between actual body position and perceived body position triggers the maladaptive response of motion sickness.[3] Approximately 30% of the general population is reported to suffer from motion sickness under ordinary travel conditions that include sea, air and land travel.[4]

According to IQVIA data, approximately two to three million doses of Dramamine, a common motion sickness remedy, are purchased monthly in the U.S. Dramamine treated patients represent only a fraction of the people treated monthly for motion sickness.

Motion sickness is one of the most prevalent episodic disorders in the world, whose prevalence has dramatically increased with world population mobility over the last 100 years.

The U.S. Department of Transportation reports 10 billion trips per year in mass transit (buses and trains), with an additional 965 million passenger trips in domestic and international air travel.[5]

References

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2. Huppert D, Benson J, Brandt T. A historical view of motion sickness-a plague at sea and on land, also with military impact. Frontiers Neurology. 2017: 8:114.
3. Reason JT. Motion sickness adaptation: a neural mismatch model. Journal of the Royal Society of Medicine. 1988: 71: 819-829.
4. Turner M, Griffin MJ. Motion sickness in public road transport: passenger behavior and susceptibility. Ergonomics. 1999: 42: 444-461.
5. U.S. Department of Transportation, Office of the Secretary of Transportation, Bureau of Transportation Statistics. 2018 Transportation Statistics Annual Report.

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.

About Tradipitant

Tradipitant is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for gastroparesis and motion sickness. The FDA has imposed a partial clinical hold on tradipitant clinical protocols of longer than 12 weeks duration.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's plans to pursue FDA approval for tradipitant for the prevention of vomiting induced by motion, 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, Vanda's ability to prepare and submit a NDA for tradipitant for the prevention of vomiting induced by motion in the fourth quarter of 2024. 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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