The Vibrance Studies

Two Clinical Research Studies for Narcolepsy Type 1 and Narcolepsy Type 2

Purpose of the Vibrance Studies

The Vibrance Studies are researching the safety and effectiveness of an investigational study drug taken orally once daily and how it may work in adults 18–70 years of age with narcolepsy type 1 (NT1) or narcolepsy type 2 (NT2) for the potential treatment of excessive daytime sleepiness symptoms. Individuals with NT1 may be eligible for the Vibrance-1 Study, and individuals with NT2 may be eligible for the Vibrance-2 Study.

About the Study Drug

The study drug, called ALKS 2680, is an orexin-2 receptor agonist that may improve symptoms of sleep disorder, such as excessive daytime sleepiness (EDS) in adults with narcolepsy type 1 (NT1) or narcolepsy type 2 (NT2) and cataplexy in adults with NT1. ALKS 2680 is an investigational treatment that has not been approved by any health authority, such as the Food and Drug Administration (FDA) in the US.

During the studies, participants will be chosen at random to receive either the study drug or a placebo, which looks just like the study drug but contains no active medicine. The study drug and placebo are tablets taken once daily.

Study Participation

	Vibrance-1 Study	Vibrance-2 Study
In-person visits	7	8
Phone calls	12	9
Mandatory overnight visits	2	
Length of participation	21 weeks	
Completing electronic diaries and questionnaires	Yes, at home	

The Vibrance Studies consist of:

- **Screening Period:** This period lasts up to six weeks. Participants will be evaluated to see if they are eligible to join one of these studies. A two-week medication washout occurs during this period, meaning participants will stop taking their standard narcolepsy medication for two weeks and will be closely monitored by the study team. During this period, one mandatory in-clinic overnight stay is required, and participants will undergo a sleep study (polysomnography) and a Maintenance of Wakefulness Test.
- **Treatment Period:** This period lasts six weeks for the Vibrance-1 Study and eight weeks for the Vibrance-2 Study. Participants will be randomized to receive one of three doses of the study drug or a placebo to be taken once daily. During this period, one mandatory in-clinic overnight stay is required, and participants will undergo a sleep study (polysomnography) and a Maintenance of Wakefulness Test.
- **Open-Label Extension Period:** This optional period lasts seven weeks for the Vibrance-1 Study and five weeks for the Vibrance-2 Study and will allow all participants to receive the study drug, even if they were initially assigned the placebo.
- **Safety Follow-Up Period:** After participants stop taking the assigned study drug or placebo, the study team will check on the participants' health during this two-week period.

Each participant will receive either the study drug or the placebo, as well as study-related medical exams and study-related laboratory tests, at no cost. Compensation for time and travel may be available. Talk to the study doctor or visit **VibranceStudies.com** to learn more.

Eligibility Criteria

Eligible participants must:

- Be 18–70 years of age
- Experience excessive daytime sleepiness
- Have a primary diagnosis of NT1 or NT2
- Have a body mass index (BMI) between 18 and 35 kg/m^2
- Not have symptoms of narcolepsy due to another medical condition
- Not have untreated or uncontrolled sleep apnea

There are additional eligibility criteria, which the study team will discuss with participants.

For more information, please visit VibranceStudies.com.

Clinical research studies aim to answer specific questions about whether medicines work in the volunteers who take them.

Vibrance Studies