The ALKS 2680-301 Study is now enrolling individuals who have completed one of the Vibrance Studies. To learn more, talk to your doctor today.

FPO

Clinical Research Study Reminders

Clinical research studies aim to answer specific questions about how medicines work in the volunteers who take them. They are part of the process to approve new medicines.

Researchers use studies to:

- Learn about the safety and effects of investigational medicines
- Help find new ways of using certain medications
- Answer specific health questions

Participation in any clinical research study is voluntary. The study team will inform you of the potential risks and benefits of study participation, as well as possible side effects. To make an informed decision, talk to your healthcare providers about any questions you may have.

All clinical research studies are:

- Developed to protect the rights, safety, and well-being of participants
- Conducted according to strict scientific and ethical principles
- Reviewed and approved by an institutional review board (IRB) or ethics committee (EC)

Thank you for taking this time to learn more about the ALKS 2680-301 Study.

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A Long-Term Extension of the Vibrance Studies Is Now Enrolling

IRB Approved at the Protocol Level
Mar 12, 2025

ALKS 2680-301 Study

Transitioning to the ALKS 2680-301 Study

The ALKS 2680-301 Study is an open-label extension of the Vibrance Studies. This study is meant to continue evaluating the investigational study drug, ALKS 2680. Any individual who has completed one of the Vibrance Studies is eligible to enroll in the ALKS 2680-301 Study and will continue to receive the study drug. All participants will receive the study drug in this open-label, long-term extension study, regardless of whether they received the study drug or placebo in the Vibrance Studies. “Open label” means that all participants and the study team will know what drug is being given.

The purpose of the ALKS 2680-301 Study is to evaluate the long-term safety and effectiveness of the once-daily oral study drug (ALKS 2680) in adults 18–70 years of age for the potential treatment of excessive daytime sleepiness (EDS) symptoms in individuals with central disorders of hypersomnolence who participated in one of the Vibrance Studies. This study is also evaluating the study drug for the potential treatment of cataplexy in participants with narcolepsy type 1 (NT1).

Many of the tests and assessments that occurred in the Vibrance Studies will also happen in the ALKS 2680-301 Study.

There are two ways that an individual who has completed one of the Vibrance Studies can join the ALKS 2680-301 Study:

- **Rollover:** Occurs when individuals immediately enter this study after completing their participation in one of the Vibrance Studies.
- **Re-entry:** Occurs when less than six months have passed since an individual has completed their participation in one of the Vibrance Studies.

As a reminder, orexin is a chemical in the brain that helps regulate the sleep/wake cycle. The investigational study drug, ALKS 2680, is an orexin-2 receptor agonist that may improve symptoms of sleep disorders, such as EDS in adults with NT1 or narcolepsy type 2 (NT2) or cataplexy in adults with NT1.

Study Design

The ALKS 2680-301 Study is enrolling the participants who completed one of the Vibrance Studies. This study will last a little under two years and consists of the following periods:

- **Screening Period:** The length of this period and the number of visits needed will depend on whether an individual entered this study immediately after their participation in one of the Vibrance Studies (rollover), or if time has passed since they completed one of the Vibrance Studies (re-entry).
  - **Rollover:** Consists of one visit to the study site.
  - **Re-entry:** Consists of up to two visits to the study site over four weeks.
- **Treatment Period:** This period lasts a little under two years with 27 visits, including 19 telephone visits and a required overnight stay at the study site. Participants will receive the study drug as an oral tablet once daily and will perform various tests to assess their narcolepsy, including wakefulness tests and completing a daily sleep diary.
  - Participants who received the study drug or placebo in one of the Vibrance Studies will receive the investigational study drug in this open-label, long-term extension study.
- **Follow-Up Period:** After a participant’s final dose of the study drug, they will have two visits (one in person and one via telephone) over two weeks to have their health checked by the study team.

What to Expect

There will be at least 29 visits during this study. Of these, 20 will be performed via telephone call and nine will occur at the study site. One visit requires an overnight stay at the study site. This overnight visit will take place at six months after enrollment. During this visit, participants will undergo an overnight polysomnography (PSG) and a series of sleep trials (known as a Maintenance of Wakefulness Test) the next day. You will also have an eye exam around the time of this visit.

Participants will also be completing electronic diaries and questionnaires while at home. At study visits, the study team will perform tests and procedures, including:

- Vital sign measurements
- Physical exams
- Blood and urine sample collections for lab tests
- Body weight measurements
- Electrocardiograms (ECGs)
- Questionnaires about quality of life and narcolepsy symptoms

Who Can Participate?

Eligible participants must:

- Be 18–70 years of age
- Have completed one of the Vibrance Studies
- Be willing to stay off the medications used for their sleep disorder during the duration of the study
- Not have developed a significant health condition (such as a condition affecting the heart or eyes) before starting this study

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

For more information, talk to your doctor or contact the research site staff listed here.