## What is a clinical study?

In a clinical study, participants are assigned to one or more study drugs to learn more about the study drug, to find out if it works or works better than other treatments, and to find out if it has side effects.

## What is an investigational drug?

An investigational drug (also called a study drug) is a substance that is being tested in a clinical research study. An ethics committee has reviewed the clinical study for testing in people, and the study drug may or may not be approved by the government health agency after study results are made available.

## Why participate in a clinical study?

Study volunteers are an essential part of this important research. Your participation and experience in the ONSTRIDE-2 study may possibly help scientists and researchers gain helpful insights about the investigational drug. Your participation in a clinical study is voluntary. You may decide not to participate or you may leave the study at any time.

## What are my costs to take part in this study?

The study drug or placebo will be given at no cost to you, and you will not be charged for any study-related visits, tests, or procedures. Assistance with study-related expenses may be available to eligible participants.

## What risks are involved?

There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study.

## Why should I join this study?

You're invited to play an active role in the future of idiopathic hypersomnia care. Together, we can be a vital force in advancing idiopathic hypersomnia research.

ONSTRIDE 2
STUDY FOR PEOPLE WITH IDIOPATHIC HYPERSOMNIA

**Thank you for your interest in the ONSTRIDE-2 study for people with idiopathic hypersomnia.**

**For more information, please visit onstride-2.com, scan the QR code, or contact:**

[Study site stamp or contact information]

**FPO**

HARMONY BIOSCIENCES

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# The path forward for idiopathic hypersomnia starts with new research.

## Consider the ONSTRIDE-2 study.

ONSTRIDE 2
STUDY FOR PEOPLE WITH IDIOPATHIC HYPERSOMNIA

## Why is the ONSTRIDE-2 study important?

People with idiopathic hypersomnia may still experience persistent symptoms or unwanted side effects while taking available medicines. Scientists and researchers are actively exploring idiopathic hypersomnia by developing and testing investigational drugs through clinical research studies. The ONSTRIDE-2 study is being conducted to learn more about an investigational drug called HBS-301 (pitolisant delayed-release tablets) for adults with idiopathic hypersomnia.

## What is the purpose of this study?

In the ONSTRIDE-2 study, researchers will evaluate the safety and efficacy of an investigational oral drug (HBS-301) in adults with idiopathic hypersomnia.

## Who can participate in the ONSTRIDE-2 study?

**To qualify for this study, you must be:**

- 18+ 18 years of age or older
- Diagnosed with idiopathic hypersomnia
- If on a stable dose of a current medication, must continue it through study completion
- Not pregnant or planning pregnancy
- Willing to discontinue prohibited medications
- Able to give informed consent

*This is not a complete list of study requirements. The study doctor will review all of the requirements with you.*

## How long will this study last?

Participation in this study is expected to last approximately 16 weeks. After the final study visit, you may have the opportunity to participate in an open-label extension period where all participants will receive HBS-301 for approximately 1 year. The study staff will provide more information about this optional extension period.

## What will happen in the ONSTRIDE-2 study?

**This study consists of the following:**

### SCREENING/BASELINE PERIOD (Up to 28 days)

- Tests and assessments will be done to determine if you meet the requirements to enroll in this study.

### STUDY TREATMENT PERIOD (8 weeks)

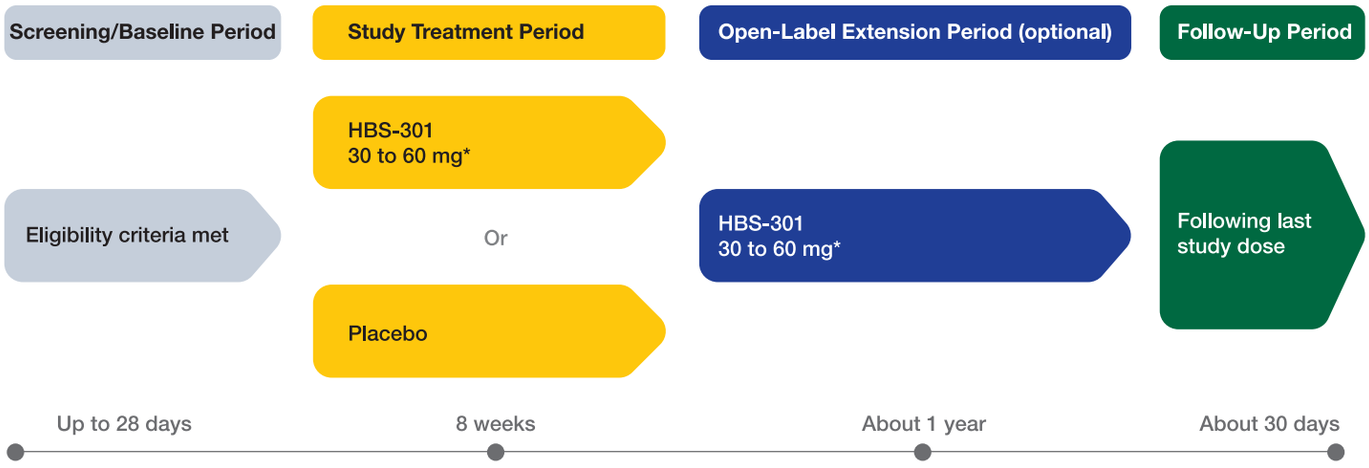
- All eligible participants will be randomly assigned (by chance) to receive the study drug (HBS-301) or placebo oral tablets. A placebo is a tablet that looks like the study drug but has no study drug or active ingredients in it.
- This is a double-blind study, which means that neither you nor the study doctor and study staff will know if you are receiving the study drug or placebo.
- During this period, you will take either HBS-301 or placebo tablets by mouth once daily in the morning when you wake up. You will also attend weekly telehealth (phone) visits or clinic (in-person) visits so your health and safety can be monitored. Laboratory and heart tests, physical examinations, questionnaires, and other assessments may be done at some visits.

### OPEN-LABEL EXTENSION PERIOD (optional; about 1 year)

- If you are eligible and decide to join the optional 1-year Open-Label Extension Period after completing the Study Treatment Period, you will begin taking HBS-301.
- During this period, you will also attend monthly telehealth visits and 3 onsite clinic visits.

### FOLLOW-UP PERIOD (about 30 days after the final dose of study drug)

- During the Follow-Up Period, you will have 2 follow-up telehealth visits approximately 15 days and 30 days after the last dose of study drug or placebo.




**Dose adjustments will be made for participants taking specific medications.*