Now Enrolling: A Clinical Study for Adults Diagnosed with **Idiopathic Hypersomnia**

Introducing the INTUNE Study

A quick reference guide

Thank you for your interest in learning about the INTUNE study. This fact sheet provides more study details that you can share with potential study participants. If potential participants have any questions or would like to know more, please direct them to call the local study site at the number below or visit **www.intuneihstudy.com**.

What is this study?

In the INTUNE study, researchers will evaluate the safety and efficacy of an investigational study drug, pitolisant, for excessive daytime sleepiness and other symptoms in adults with idiopathic hypersomnia (IH).

Who is this study enrolling?

Approximately 200 participants will be enrolled in approximately 60 study sites across the United States. This study is for adults with IH.

How is the study drug being tested?

After a 28-day screening period, all eligible participants will receive daily doses of the study drug for 8 weeks. After the 8-week period, study staff will evaluate participants to confirm eligibility to continue in the double-blind randomized withdrawal phase for 4 weeks. During this 4-week period, eligible participants will be randomized to receive either study drug or matching placebo. A placebo is a tablet that looks like the study drug but has no study drug in it. Neither the study participant nor the study doctor will know if the participant is receiving the study drug or a placebo.

How long will this study last?

This study will last up to approximately 4 to 5 months. After the final visit, participants will have the opportunity to enroll in an additional long-term safety study. If participants choose not to participate in the long-term safety study, they will have 2 safety follow-up telephone contacts approximately 15 days and 30 days after the last dose of study drug.

How will participants' health be monitored in this study?

During the study, participants will visit the study site regularly for health checks and several types of tests and assessments. They will also be asked to keep records at home. These may include:

- Physical exams
- Vital signs measurements (blood pressure, heart rate, breathing rate, and body temperature)
- Weight measurements
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Questionnaires
- Electronic diaries (records that participants will keep on a handheld device that will be provided to each participant. Study staff will train participants on how to use the electronic diaries)

Not all of these activities will occur at every visit.

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What are the benefits and risks of being in this study?

Your health will be monitored frequently throughout the study; however, there is no guarantee that your symptoms of IH will improve. They may stay the same or they may get worse. As with any drug, the study drug may cause side effects. Any study has risks, which may include things that could make participants feel sick or uncomfortable or could cause harm. The study staff will review potential risks before study enrollment.

Is participating in this study mandatory?

Taking part in a clinical study is voluntary. Those eligible to enroll may choose to join the study but leave at a later date for any reason at any time. Regardless of whether someone chooses to enroll or leave the study early, their future healthcare won't be affected.

How can potential participants learn more about this study?

To learn more, please direct potential participants to call our local study site at the number below or visit **www.intuneihstudy.com** The study team can also schedule a screening appointment to explain the study in detail.

Study site phone number:

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