Our goal is to help people with Prader-Willi syndrome reach new heights

Learn more about KITE-PWS, a research study testing an investigational drug that may help to control appetite.

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Representing: Gedeon Richter Plc. (Sponsor)
What is the purpose of the study?

- To learn about an experimental drug called RGH-706 in people with PWS that may help to control hyperphagia (increased appetite) in people with PWS

What is RGH-706?

- An experimental drug that blocks a hormone called melanin-concentrating hormone (MCH)
- When MCH attaches to specific receptors in the brain it increases the desire to eat
- RGH-706 aims to be the first MCH blocker to be studied in people with PWS

KITE-PWS will help us understand if RGH-706 is safe and effective in blocking MCH and reducing appetite in people with PWS
What are the objectives of the study?

Primary objectives

• To understand if RGH-706 is effective in reducing hyperphagia in people with PWS in the short- and longer run

Hyperphagia for Clinical Trials Questionnaire (caregiver reported)

Secondary objectives

• To assess safety and tolerability of RGH-706
• To assess how much and how quickly the study treatment gets into the bloodstream, (pharmacokinetics)
• To explore the effect of RGH-706 on weight, body composition and metabolic biomarkers (e.g. fasting glucose, insulin, uric acid, etc.)
• To explore the effect of RGH-706 on caregiver burden and caregiver impressions of severity and change

Medical examinations Laboratory tests Questionnaires DEXA measurement

Exploratory objectives

• To explore the effect of RGH-706 on exploratory metabolic biomarkers (leptin, ghrelin, adiponectin)

KITE-PWS is a multicenter study with 25 research sites (6 sites in the USA) in 5 countries
How is the study set up? – Study duration and visits

Participants will be randomized to RGH-706 or placebo for both parts (capsules)

**Part A**
60 people with PWS

- **30 days** Screening Period
- **6 weeks** Study Treatment Period
- **13 weeks** Follow-up Period

**Part B**
100 people with PWS

- **30 days** Screening Period
- **21 weeks** Study Treatment Period
- **15 weeks** Follow-up Period

Interim analysis of results

People can only enter one study part

There is currently no open label extension available

Participants will be randomized to RGH-706 or placebo for both parts (capsules)

Clinic visit

Phone call or remote visit

Participating in the study:

60 people in Part A

100 people in Part B

Clinic visit

Phone call or remote visit

There is currently no open label extension available.
How is the study set up? – Visit schedule

Procedures that occur at every visit in both Part A and B

- weighing
- waist circumference measurement
- questions about any symptoms, illness and medical changes
- vital signs (blood pressure, pulse, temperature)
- questionnaire for caregiver

Visit schedule

- The primary caregiver should accompany the participant to every visit
- For blood draws, the participant should be in fasting state (no food or drink but water 10 hours before the visit)

- The sponsor of the study will pay for costs of the study drug, tests and procedures during study
- Reimbursement for travel expenses will be provided
- A participant may qualify for travel accommodations and reimbursement for out-of-pocket expenses
- A stipend for participating in the study will be provided
How is the study set up? – Visit schedule

**Study visit schedule for Part A**

<table>
<thead>
<tr>
<th>Study Visit #</th>
<th>Date &amp; Time of Visit</th>
<th>Physical Exam</th>
<th>Blood Samples (fasting)</th>
<th>Alcohol Breath Test</th>
<th>Urine Sample</th>
<th>Urine Pregnancy Test (if applicable)</th>
<th>ECG</th>
<th>PK Blood Draws*</th>
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<tbody>
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*Certain participants enrolled in Part A will provide pharmacokinetic (PK) blood samples.

**Study visit schedule for Part B**

<table>
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<tr>
<th>Study Visit #</th>
<th>Date &amp; Time of Visit</th>
<th>Physical Exam</th>
<th>Blood Samples (fasting)</th>
<th>Alcohol Breath Test</th>
<th>Urine Sample</th>
<th>Urine Pregnancy Test (if applicable)</th>
<th>ECG</th>
<th>iDXA</th>
<th>PK Blood Draws</th>
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<td>4</td>
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How is the study set up? – Visit schedule

Optional pharmacokinetic sub-study for participants in Part A

- People in Part A can participate in optional PK testing
- Blood samples would be collected during the 8 hours after receiving a dose of study drug (see table below)
- Travel accommodations and reimbursement for out-of-pocket expenses provided
- An adjusted stipend is provided for participating in the PK sub-study

<table>
<thead>
<tr>
<th>Study Visit #</th>
<th>Study Day</th>
<th>Planned Blood Draws</th>
<th>Date &amp; Time</th>
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<tbody>
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<td>3 hours postdose</td>
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<td>Day 15</td>
<td>24 hours postdose</td>
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<td>Visit 5</td>
<td>Day 42</td>
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<tr>
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<td>1 hour postdose</td>
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<td>3 hours postdose</td>
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<td>5 hours postdose</td>
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<td>8 hours postdose</td>
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<td>Day 43</td>
<td>24 hours postdose</td>
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<td>Day 44</td>
<td>48 hours postdose</td>
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<td>Day 46</td>
<td>96 hours postdose</td>
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</table>
Who can be in the study?

- People with genetic diagnosis of PWS
- At least 17 years of age
- Body weight > 88 lbs (40 kg) and < 450 lbs (200 kg)
- Stable body weight for the past 3 months (weight change ≤5% in the previous 3 months)
- Have a consistent and reliable caregiver who can evaluate changes in participants’ hyperphagia symptoms, mood, health and behaviour during the study (caring for the participant for at least 3 months prior to study entry, is anticipated to be the participant’s primary caregiver for the duration of the study and must spend at least 4 waking hours per day on average with the participant)
- No uncontrolled diabetes or diabetes that requires insulin
- Medical history and other criteria will be reviewed to determine eligibility*

What should be considered before joining the study?

Possible risks:
- RGH-706 might not help your symptoms
- Side effects*
- Discomfort and time commitment related to study procedures

Possible benefits:
- RGH-706 might help your symptoms
- Receive regular health check-ups
- Help doctors learn about RGH-706 which may help others with PWS in the future

*for detailed information regarding study entry criteria and potential side effects please refer to the research sites and investigators participating in the study (https://clinicaltrials.gov/ct2/show/NCT05322096)
KITE-PWS has been reviewed by FDA and is open for people with PWS and their caregivers to enter.

Where can I find more information about the trial?
Clintrials.gov: [https://clinicaltrials.gov/ct2/show/NCT05322096](https://clinicaltrials.gov/ct2/show/NCT05322096)

Every day, research uncovers new information about medical conditions and their treatment. Volunteer involvement in clinical studies is a key part in the development and advancement of future therapies. Results collected from clinical studies have led to thousands of medications and devices becoming available to patients all over the world.