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)

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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

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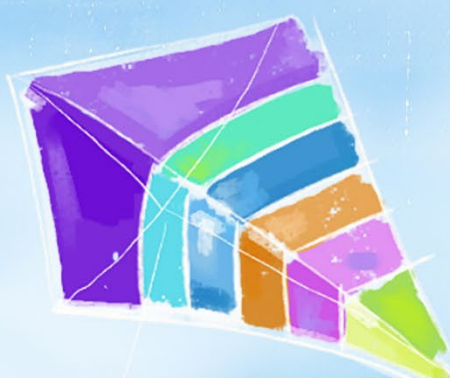
What are the objectives of the study?

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

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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

Interim analysis of results

people can only enter one study part

Part B
100 people with PWS

There is currently no open label extension available

23 weeks

30 days	Screening Period	1 clinic visit
6 weeks	Study Treatment Period	4 clinic visits, 3 phone calls or remote visits
13 weeks	Follow-up Period	1 clinic visit, 2 phone calls or remote visits

21 weeks

30 days	Screening Period	1 clinic visit
15 weeks	Study Treatment Period	6 clinic visits, 3 phone calls or remote visits
2 weeks	Follow-up Period	1 clinic visit

Clinic visit

Phone call or remote visit

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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

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How is the study set up? – Visit schedule

Study visit schedule for Part A

Study Visit #	Date & Time of Visit	Physical Exam	Blood Samples (fasting)	Alcohol Breath Test	Urine Sample	Urine Pregnancy Test (if applicable)	ECG	PK Blood Draws*
2	Day 1							
3	Day 14±1							
4	Day 28±1							
5	Day 42±1							
6	Day 56±2							
7	Day 98±3							
8	Day 133±1							

*Certain participants enrolled in Part A will provide pharmacokinetic (PK) blood samples.

Study visit schedule for Part B

Study Visit #	Date & Time of Visit	Physical Exam	Blood Samples (fasting)	Alcohol Breath Test	Urine Sample	Urine Pregnancy Test (if applicable)	ECG	iDXA	PK Blood Draws
2	Day 1								
3	Day 14±1								
4	Day 28±1								
5	Day 42±1								
6	Day 70±2								
7	Day 105±2								
8	Day 119±3								

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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

Study Visit #	Study Day	Planned Blood Draws	Date & Time
Visit 3	Day 14	1 hour postdose 3 hours postdose 4 hours postdose 5 hours postdose 8 hours postdose	
	Day 15	24 hours postdose	
Visit 5	Day 42	0 hour postdose 1 hour postdose 3 hours postdose 4 hours postdose 5 hours postdose 8 hours postdose	
	Day 43	24 hours postdose	
	Day 44	48 hours postdose	
	Day 46	96 hours postdose	

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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 procdures

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)*

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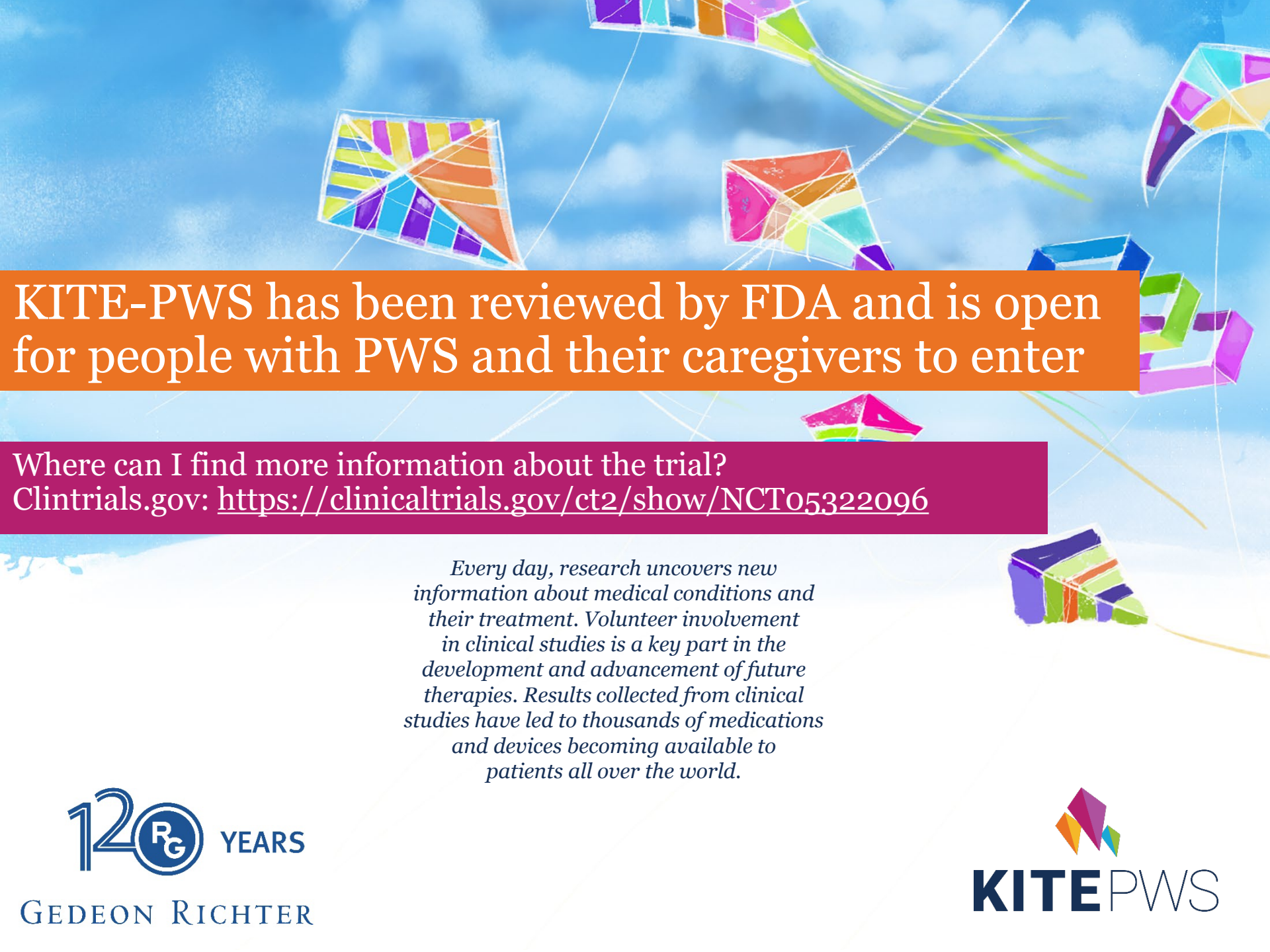

KITE-PWS has been reviewed by FDA and is open for people with PWS and their caregivers to enter

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

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.

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