The **S**tudy in **P**ediatrics with Hyp**ERE**osinophilic syndrome **(SPHERE)**

A quick reference guide for potential participants

Thank you for your interest in the SPHERE study. This fact sheet provides more details about the study so you can decide if you want to find out more information.

What is the SPHERE study?

In this clinical research study, doctors are testing an investigational drug to see how it works long-term on hypereosinophilic syndrome (HES) symptoms in pediatric patients. An investigational drug is one that is not yet approved for use by the general public. The SPHERE study will last for about 64 weeks (approximately 1 year and 3 months) and all participants will receive the investigational drug during the study while continuing their usual medications.

Who can participate in this study?*

The SPHERE study is looking for approximately 25 participants between the ages of 6 and 17 years old who have a current diagnosis of HES for at least 6 months.

**This is not a full list of requirements. The study doctor will review the full requirements for this study with you and your child.*

Why is this study important?

This study can help doctors research the possibility of long-term relief of HES symptoms in pediatric patients. Clinical studies (also called "clinical trials") help doctors learn more about investigational drugs and answer questions about how they work, if they work better than other treatments, and if they have side effects. Current treatments for diseases are only available because of research study volunteers.

What should I know about the SPHERE study?

- You or your child's health and safety will be monitored throughout the study
- You or your child's data and information will be kept confidential
- You or your child will receive all study-related procedures and the study drug at no cost
- The study doctor will provide you or your child with a letter to their school to explain absences during any study visits

How long will this study last?

You or your child will be followed in the SPHERE study for approximately 1 year and 3 months. Eligible participants may enter an expanded access program (EAP), where available, immediately after completion of the 52-week treatment period. Sometimes called "compassionate use," expanded access is a potential pathway for a patient with an immediate life-threatening or serious condition to gain access to an investigational drug outside of a clinical trial.

When you or your child stop or complete the study, the study doctor will continue to assess you or your child's health condition. Participants will have a follow-up visit approximately 12 weeks after the last dose of the study drug (only if you or your child did not enter the EAP).

How will participant's health be monitored in this study?

During the study, you or your child will visit the study site regularly for health checks and several types of tests and assessments. These may include:

- Physical examinations
- Vital signs measurements (body temperature, breathing rate, blood pressure, and heart rate)
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Assessments and questionnaires

Not all of these activities will occur at every visit.

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

One benefit of taking part in this study is that you or your child's health will be monitored frequently. However, there is no guarantee that this study will improve you or your child's health, and it may stay the same or get worse. Also, as with all drugs, the study drugs may cause side effects. We may be able to prevent or manage some of these side effects, and many go away quickly. Any study has risks, which may include things that could make you or your child feel sick or uncomfortable. The study staff will review potential risks before study enrollment.

Can participants decide not to be in the study?

Taking part in a clinical study is voluntary. If participants are eligible to enroll, they may choose to join the study but leave at a later date for any reason at any time. Regardless of whether participants choose to enroll or leave the study early, their future healthcare will not be affected.

How can we learn more about this study?

For more information about your nearest study site, please visit **www.sphereclinicaltrial.com** and click on your location on the world map where you can contact us. You can also call the local study site at the number below and the study team can schedule a screening appointment to explain the study in detail.

Study site phone number: _____

Office hours: _____

This content has been reviewed by APFED and CURED for language clarity and readability. For more information about hypereosinophilic syndrome and to find support, please visit apfed.org.

sphere | gsk | Apfed American Partnership for Eosinophilic Disorders | CURED Campaign Urging Research for Eosinophilic Disease www.CuredFoundation.org