Saniona's Expanded Access Policy (EAP)

Saniona is committed to supporting global and equitable access to our treatments. Our approach to expanded access programs, which provide a pathway for patients to receive investigational drugs without participating in clinical trials, reflects this.

In the U.S., the Food and Drug Administration (FDA) requires companies to establish and communicate an expanded access policy when an investigational medicine enters Phase 2 clinical trials. Currently, the only product Saniona is studying in Phase 2 clinical trials is Tesomet™. We have recently started a Phase 2b clinical trial for hypothalamic obesity (HO) and expect to start a Phase 2b clinical trial for Prader Willi syndrome (PWS) before the end of the year.

Saniona has decided not to provide expanded access to Tesomet at this time. We believe the most appropriate way to deliver on our commitment to patients is through participation in our clinical trials. Clinical trials, and the subsequent approval of a therapy, provide the best way to provide long-term access to as many patients as possible. If you have questions, we encourage you to speak with your physician and potentially participate in one of Saniona's clinical trials.

You can learn more about our clinical trials on our website or www.clinicaltrials.gov

According to the FDA Expanded Access guidelines, expanded access may be appropriate when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

At this time, Saniona does not meet all of the above criteria. Our work is ongoing to generate a robust data package to support safety and efficacy for Tesomet. Additionally, we have enough supply of Tesomet to support only our ongoing clinical trial efforts.

We will, however, continue to evaluate this policy as our clinical development program progresses.