## A Summary of the FirST-4-LEMS Study

Medical condition under study: Lambert-Eaton Myasthenic Syndrome (LEMS); purpose of the study is to determine the degree of LEMS symptom control with amifampridine phosphate treatment

Eligibility criteria: Adult patients with a confirmed diagnosis of LEMS who are currently taking amifampridine phosphate

Participant benefits: All treatment and participation costs, (travel, hotel, meals, etc) are covered; no cost health examination, short term study (5 - 12 days); 24/7 access to expert medical care for the duration of the study

Time commitment: The FirST-4-LEMS study will be continuous for at least 5 and up to 12 days plus travel to the study site

Study locations: Miami, FL and Los Angeles, CA

**BY TAKING PART IN THIS IMPORTANT STUDY YOU CAN HELP CHANGE THE FUTURE OF THE LEMS COMMUNITY**


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Amifampridine phosphate is an investigational drug and not currently commercially available.
This study is being sponsored by Catalyst Pharmaceuticals



### Introducing the FirST-4-LEMS Study

# YOUR PARTICIPATION CAN HELP CHANGE THE LIVES OF PEOPLE WITH LAMBERT-EATON MYASTHENIC SYNDROME (LEMS)

*As someone living with LEMS and taking amifampridine phosphate, you have the opportunity to help EXPAND DRUG ACCESS FOR ALL PEOPLE WITH LEMS BY PARTICIPATING IN THE FirST-4-LEMS (Firdapse Strength Trial for LEMS) study.*

- Your participation in the FirST-4-LEMS study could help others by participating in medical research. In fact, every prescription medicine you've taken has been investigated in studies that were only possible because of volunteer participants.
- You'll have the reassurance of your support person accompanying you and healthcare personnel monitoring you in a safe, comfortable environment throughout the study.

**YOU CAN BE PART OF THE PROCESS OF OBTAINING FDA APPROVAL FOR AMIFAMPRIDINE PHOSPHATE. SECURING LONG-TERM AVAILABILITY FOR ALL THOSE LIVING WITH LEMS AND POTENTIALLY RELIEVING THEM OF THEIR SYMPTOMS**

**INSIDE:** Learn more about how you can be part of the FirST-4-LEMS study

## YOUR PARTICIPATION CAN MAKE A POWERFUL DIFFERENCE TO PEOPLE LIVING WITH LEMS

*Because you are taking amifampridine phosphate, you may be eligible to participate in the **FirST-4-LEMS** study. Your EAP physician will recommend your eligibility. Please contact him/her if you are interested.*

### What is the FirST-4-LEMS study?

The **FirST-4-LEMS** study evaluates the effectiveness of amifampridine phosphate in controlling, reducing, and/or eliminating symptoms of LEMS. It is a "phase 3" study, and is needed to gain FDA approval.

Your participation can potentially help all people with LEMS benefit from a treatment manufactured to meet FDA requirements -- and ensure that therapy is available long-term.

**THE RESULTS OF THE FirST-4-LEMS STUDY ARE A NECESSARY PART OF TRYING TO OBTAIN FDA APPROVAL AND MAINTAIN ACCESS TO EFFECTIVE THERAPY FOR THE LEMS COMMUNITY**

### Who can participate in the FirST-4-LEMS study?

Only adults with a confirmed diagnosis of LEMS who are currently taking amifampridine phosphate are eligible to participate.

### Where is the study being conducted?

The **FirST-4-LEMS** study will be done in two locations – in Miami and in Los Angeles. Participants will stay at a comfortable hotel that is focused on patient well being. Hotel accommodations and details will be provided separately by the study coordinator.

All study related testing and evaluation will be conducted at the respective university clinical research centers.

### Why is the study being conducted?

The study is an additional clinical requirement that the FDA has asked Catalyst Pharmaceuticals to perform in order to further demonstrate that the medication you are taking is effective in treating LEMS symptoms. That's why your participation is so important, because when the study is completed, the FDA may have the information needed to approve the medication so that it can be made available to all those living with LEMS in the United States.

### What can I expect during the FirST-4-LEMS study ?

This is a short study (from 5 to 12 days, plus travel to/from the site), where you would stay at a hotel and have 3 to 4 required clinical evaluations at the medical center. Dates are flexible to work around your schedule and availability. The study procedures are limited, and all travel and hotel details will be arranged.

This is a "wash out" study, in which you may be be off amifampridine phosphate for only 4 consecutive days. Half of the participants will be taken off their medication and given a placebo that looks like your medication. Your health is our primary concern, so you will be monitored closely throughout the study.

### What happens in the clinical evaluation?

The following will occur:

- Strength and walking tests
- Questions about how you are feeling
- Urine samples
- Vital signs
- Medical history
- No EMG
- Optional screening for lung cancer

### Will I need to sign an Informed Consent Document in order to participate?

Yes, this document is necessary for participation in all clinical trials. You'll receive it from the study physician and have time to review it and ask questions. Your physician will also help answer any questions you may have.

### Can I bring my spouse, a friend, or a support person?

Yes, you may bring a support person as part of the study, to help assist you. Their travel, hotel, and meal costs will also be provided.

### Will I be compensated for my time participating in this study?

There may also be compensation available to offset financial hardships resulting from study participation, so please ask about possible availability.

**YOUR PARTICIPATION GIVES YOU THE POWER TO IMPROVE THE FUTURE FOR ALL PEOPLE LIVING WITH LEMS**