Participant Informed Consent Form
For Participants in Canada

Sponsor / Study Title:	**Catalyst Pharmaceuticals, Inc. / "PREGNANCY SURVEILLANCE PROGRAM OF WOMEN AND INFANTS EXPOSED TO FIRDAPSE® DURING PREGNANCY"**
Protocol Number:	**LMS-004**
Principal Investigator: (Study Doctor)	**Amy Miller, RPh, PharmD**
Telephone:	**1-855-212-5856(24-Hours)**
Address:	**UBC** **933 Canyon Road** **Morgantown, WV 26508**

INTRODUCTION

Catalyst Pharmaceuticals, Inc., the study Sponsor, has set up this voluntary observational pregnancy study to describe the pregnancy complications and outcomes of women and their infants who were exposed to at least 1 dose of Firdapse at any time during pregnancy. It is anticipated that approximately 5 pregnancies will be reported over the data collection period. Catalyst Pharmaceuticals, Inc. has contracted and is working with United BioSource (UBC) / Pregnancy Coordinating Center (PCC) to conduct this research study.

You and your baby resulting from your pregnancy are being asked to participate in this research study because you have been exposed to at least one dose of Firdapse®, or because you have Lambert-Eaton myasthenic syndrome (LEMS) and you were not exposed to Firdapse during pregnancy. This form will explain the purpose of this research study and other important information. You need to provide your consent to enroll in the study; therefore, with your permission we would like to record our consent discussion for the study's files. At the end of the discussion about joining the study, your healthcare provider will ask if you would like to consent to enroll in the study.

RISKS

This is an observational study. There is no additional medical intervention outside of your normal standard of care that you are receiving at your doctor or other licensed medical practitioner's office. All data that is collected as part of this study is taken from the information that your doctor has documented in your medical notes during your normal doctor's visits, as well as the results of any tests that were performed during these visits.

There are no additional medical risks for you or your baby when you participate in this observational pregnancy study. While every effort will be made to safeguard your personal information, there is a small risk that your and your baby's information may be unintentionally disclosed. For this reason, absolute confidentiality cannot be guaranteed.

BENEFITS

There is no direct benefit for you or your baby for participating in this study. However, your participation in this study will help Catalyst Pharmaceuticals, Inc. to determine if there are any effects of Firdapse® on pregnant women or babies whose mothers were exposed to Firdapse® during pregnancy. The study data will be provided to regulatory agencies so that other women who become pregnant while being treated with Firdapse® can better understand the effects of Firdapse® on pregnant women and their babies.

PARTICIPATION

Your participation in this study is strictly voluntary. To participate in the study, you will be asked to do the following:

- At the end of your discussion about joining the study, your healthcare provider will ask if you would like to consent to enroll in the study by signing and dating this consent form. We will be mailing/giving you a copy of this consent to you for your files.
- Provide information to your healthcare provider at the time of enrollment (at time of consent) and additional information once per trimester during your pregnancy and at the following timepoints:
    - Pre-natal follow up visit at 34 weeks (Obstetric health care provider will be contacted)
    - At the estimated date of delivery, and;
    - When your baby is 3, 6, 9, and 12 months of age.

INFORMATION

During enrollment, your healthcare provider will ask you basic questions about your health and pregnancy, as well as your contact information, including your address and phone number. Your healthcare provider will also ask you to identify two secondary contacts. The secondary contacts must be someone outside of your household who are able to contact you in case your healthcare provider is unable to reach you.

You will be contacted by your healthcare provider one time during each trimester of your pregnancy, on the estimated date of delivery, and when your baby is 3, 6, 9 and 12 months of age, as needed. Your healthcare provider will collect the following information:

- Any changes in the contact information you provided at enrollment
- Any changes in the status of your pregnancy
- Any changes in Firdapse® treatment, if applicable, and changes in other medications
- Any pre-natal testing at the pre-natal follow up visit
- Any changes to your baby's health status when you are contacted when your baby is 3, 6, 9 and 12 months of age

COMPENSATION AND STUDY-RELATED EXPENSES

This pregnancy surveillance program is being sponsored by Catalyst Pharmaceuticals, Inc.; the PCC is being paid by Catalyst Pharmaceuticals, Inc., to conduct the study.

During your participation, you will not be paid for the study-required phone calls described in this informed consent form.

There are no additional costs for your participation in this study. While you are in this study, the cost of your usual medical care, procedures, medications and doctor visits, will continue to be billed to you, the public health plan, or your private insurance (if any).

POSTING OF RESEARCH STUDY ON WEB

A final study report will be reported at the conclusion of the study and will be available on *http://www.ClinicalTrials.gov*, as guidance provided by (STROBE). This Web site will not include information that can identify you. At most, the Web site will include a summary of the final study results.

A description of this study will also be available on FDA-Pregnancy-Registries@fds.hhs.gov, the Food and Drug Administration (FDA) Women's Health Research web site.

PRIVACY

There is a small risk that your and your baby's information may be inappropriately disclosed. This means absolute confidentiality cannot be guaranteed.

This study will remain open for a minimum of 10 years. Your information will remain at the PCC until approximately 2 years after the end of the study.

Information from this study will be submitted to the Sponsor, the U.S. Food and Drug Administration (FDA), and possibly to Health Canada and governmental agencies in other countries. The results of this research study may be presented at meetings or in publications, but your and your baby's identity will not be disclosed.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your and your baby's medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- a limited number of representatives from the Sponsor (namely its monitors and auditors),
- the research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants),
- government regulatory authorities including Health Canada, the U.S. Food and Drug Administration (FDA), and other foreign regulatory agencies.

Your study records, including confidential information about you and your baby collected during the study, will be kept at a secure location.

While every effort will be made to protect the privacy of your and your baby's information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use and disclosure of your and your baby's information as described above.

WITHDRAWAL

Enrollment in the Firdapse Pregnancy Study is completely voluntary. You may leave the study for any reason at any time. If you decide to stop participating, the quality of your and your baby's medical care will not be affected, and you and your baby will not be penalized or lose any benefits that you and your baby may be entitled to. If you decide to leave the study before your participation has ended, Catalyst Pharmaceuticals, Inc., will still use the information collected before your withdrawal. The request for withdrawal from the study must be made to the PCC by you or your health care provider. The study investigator or the Sponsor can stop the study at any time without your consent.

The Investigator or the Sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you in a timely manner.

ALTERNATIVES TO PARTICIPATION

This pregnancy follow-up is for research purposes only. The only alternative is to not participate in this study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An IRB is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Participant Adviser
  Advarra IRB
  6100 Merriweather Drive, Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00045362.

A copy of this Participant Informed Consent Form will be provided/mailed to you for your records. You and your healthcare provider will sign and date this form if you choose to participate.

We will also include the MIR form that you will need to sign, date and return in the self-addressed and pre-stamped envelope.

By signing and dating below, you agree that you have read and understood all pages of this form.

Healthcare Provider reviewing Participant Informed Consent Form:

Printed name/Signature of Healthcare Provider	Date Signed

Participant:

Printed name/Signature of Study Participant	Date Signed