

## **Assent Form for Minors Ages 15 to Age of Majority (AOM)**

**Sponsor / Study Title:** H. Lundbeck A/S (Lundbeck) / “Vyepti Pregnancy Registry: A prospective, comparative cohort study of maternal, fetal and infant safety in pregnant women exposed to eptinezumab in the United States”

**Protocol Number:** 19419N

**Principal Investigator:** Amy Miller, RPh, PharmD

**Telephone:** (855) 810-8549 (24-Hour)

**Address:** United BioSource Corporation  
933 Canyon Road  
Morgantown, WV 26508

You are being invited to take part in an observational study because you are/were pregnant while being diagnosed with migraines and treated with Vyepti® or other medications during your pregnancy. In an observational study you will not be asked to change your medical treatment or care for the study. Your treatment or care, including any prescription of medicines, will be decided by you and your regular doctor based on standard medical practice and independently of the study.

Please ask the Pregnancy Coordinating Center (PCC) to explain anything you do not understand. They will answer all the questions you have. You can ask questions about the study at any time.

If you want to talk to the principal investigator alone please ask.

There will be 844 adolescents and adults in this study.

### **What it would mean for you to participate:**

To be part of this observational study you will not have to make any extra office visits, take any extra tests, or take any additional drugs. Your participation in this study will last until your baby turns 12 months at maximum. If your regular doctor or your baby's doctor does not answer our calls, we may also ask you for some of this information directly.

You will be placed into 1 of 2 cohorts depending on which medicines(s) you are taking for your migraines before and during your pregnancy. Your information will be collected electronically through an app or directly through a PCC associate. In addition, you will

be given a participant medication diary log and advised at a baseline visit to record all relevant information (such as dosage, frequency, name of prescription and nonprescription medication taken for migraine, and reason that a medication was taken, among other fields). The participant medication diary will be available electronically via an app, and will also be available as a paper-based version. Your parent/legal guardian can help you fill out this information.

**Will I get hurt in this study?**

Since this is an observational study, there are not any expected medical risks to you for participating in this study.

**WILL WHAT I SAY BE KEPT PRIVATE?**

What you tell the principal investigator or anything else about you may be written down. What is written down about you will be seen by the principal investigator, and other people who run and manage the study. People who make sure that the study is being done the right way may also see it. If the information about the study is sent anywhere else, it will not have your name on it.

What the principal investigator learns about you may also be shared with your parents or legal guardian.

**Important things to know:**

You do not have to be in this study if you don't want to. You have the right to stop your participation at any time. Tell your principal investigator or parent/legal guardian if you want to stop being in the study. No one will be mad at you and your medical care will not change.

**Assent:**

I have read or someone has read to me the informed consent along with this form, called the assent form. The PCC has explained the study to me and has answered my questions. I agree to be in this study.

You will be given a copy of this assent form to keep.

**Vyepti® PCC Associate reviewing this Assent Form:**

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Printed name of PCC Associate

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Date Signed

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Signature of PCC Associate