Participant Verbal Informed Consent Form and Authorization to Use and Disclose Protected Health Information

For Adult Participants, Parents/Legal Guardians of Minor Participants and Participants Reaching Age of Majority

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**

If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed. When "you" appears in this form, it refers to your child except where it says otherwise.

INTRODUCTION

You are invited to participate in an observational study since you are pregnant, have been diagnosed with migraines and prescribed eptinezumab or other (non-CGRP-targeting) preventive migraine medications. You are being asked to provide data about your pregnancy, which will also include data about your unborn baby and newborn baby. The purpose of this consent form is to obtain your permission to collect data about your pregnancy, your unborn baby and newborn baby for up to 1 year after delivery.

About 844 participants will be enrolled into this study into two cohorts (422 women with migraines exposed to eptinezumab during pregnancy or up to 20 weeks prior to becoming pregnant will be enrolled into one cohort, and 422 women with migraines exposed to non-CGRP targeting preventive migraine medications during pregnancy or up to 1 week (depending on medication) prior to becoming pregnant will be enrolled into a second cohort).

H. Lundbeck A/S (Lundbeck) is the data controller and sponsor of this study and is based in Denmark within the European Union (EU).

The purpose of collecting and processing your data, and data of your unborn and newborn baby is to assess the safety of eptinezumab (Vyepti®) and other preventive migraine medications in pregnancy. As described in this Informed Consent Form, this also includes archiving the data and collecting and processing safety information obtained in the study.

Lundbeck will be using information from you, your unborn baby and newborn baby and/or your medical records to complete this study and is responsible for looking after your information once it has been shared with Lundbeck. Lundbeck will not know your name, the name of your newborn baby, personal identification number, and any other information that allows your or your newborn baby to be directly identified, as this information will have been replaced by a keycode number at United BioSource Corporation (UBC – the study site), meaning that your data and your newborn baby data is "pseudonymized". Lundbeck will only receive pseudonymized personal data about you and your newborn baby. Any references hereafter to "personal data", "data" or "information" should be read as pseudonymized or key-coded data.

If you agree, Lundbeck will ensure your data including data about your unborn baby and newborn baby are handled properly and in accordance with the General Data Protection Regulation (GDPR) as well as any applicable local laws. The GDPR is one of the toughest privacy and security laws in the world and it governs how the personal data of individuals may be processed in and transferred out of the EU and lists the rights of those individuals whose personal data is being processed. Lundbeck will be working closely with UBC, and the specific responsibilities of each party in terms of your personal data are described in more detail in the agreements entered into between the parties. For more information about the way your personal data including data of your unborn child and newborn baby are handled by UBC or Lundbeck, please contact UBC.

Lundbeck will collect, process, and analyze your personal data for this study and future scientific research. Lundbeck has a legitimate interest in conducting scientific research and processing your personal data for scientific research purposes in order to develop safe and efficacious medicine. Further as part of the conduct of the study, Lundbeck will collect and process safety information and store the data derived from the study according to applicable laws and regulations as described in this Informed Consent Form. This processing is a legal obligation for Lundbeck as the sponsor of the study and is further necessary for reasons of public interest in the area of public health, such as ensuring high standards of quality and safety of health care and of medicinal products in accordance with applicable laws and regulations on data protection. The processing may entail combining data derived from this study with data derived from other studies e.g., safety data, if requested by Regulatory Authorities.

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 regular doctors or other licensed medical practitioner's office.

There are no medical risks for you or your baby when you participate in this observational pregnancy study. Eptinezumab has not been investigated for use during pregnancy and it is not known how it may affect pregnant women, an unborn baby or a baby who is breastfed (a nursing infant).

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.

UBC will collect information either directly from you and/or from your medical records from your general practitioner/ordinary doctor in accordance with Lundbeck's Clinical Study Protocol (a document that UBC must follow to correctly conduct the study), and these data will be sent to Lundbeck.

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.

BENEFITS

There is no direct benefit for you or your newborn baby for participating in this study. However, your participation in this study will help H. Lundbeck A/S to determine if there are any effects of Eptinezumab in pregnant women or babies whose mothers were exposed to Eptinezumab during pregnancy.

PARTICIPATION INFORMATION

Before any study-related procedures are performed, you will be asked to read this Informed Consent Form and agree to participate in this study. You will also be asked to sign and return a Medical Information Release Form.

During enrollment, the Pregnancy Coordinating Center (PCC) will ask you basic questions about your health and pregnancy, as well as your contact information, including your address and phone number. You will also be asked to identify a secondary contact. The secondary contact must be someone outside of your household who is able to contact you in case the PCC is unable to reach you. You will have the option of signing the Medical Information Release form either digitally or in hardcopy. If you are willing to sign the MIR electronically it will be sent to you during the enrollment call. If you are unwilling or unable to sign the MIR electronically, it will be delivered to you in hard copy and you will need to sign, date, and return via the self-addressed and pre-stamped envelope provided. The signed MIR allows the PCC to reach out to your regular doctor or other licensed medical practitioner who is caring for you during pregnancy to provide the information for the study.

Your information will be collected electronically via an app or directly through the PCC during enrollment and throughout the study.

You will be contacted by the PCC during the last month of the second trimester of your pregnancy, on the estimated date of delivery, when your baby is 6 and 12 months of age, and periodically throughout the study to collect medication usage from your participant diary. The PCC will collect the following information:

- Any changes in the contact information you provided at enrollment
- Any changes in the status of your pregnancy and/or outcome
- Any changes in Vyepti® 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 at birth or when you are contacted when your baby is 6 and 12 months of age

In addition, you will be given a participant medication diary log and be advised at the 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 log will be available electronically via an app, and will also be available as a paper-based version.

In addition, your regular doctor or other licensed medical practitioner who is caring for you during pregnancy will be contacted at the initial pregnancy report, around 34 weeks of your pregnancy and, again, within 2 weeks of your estimated delivery date. The PCC will also contact your baby's doctor or other licensed medical practitioner when your baby is approximately 6 and 12 months old to determine if there are any changes in your baby's health status. Further contacts with you may be initiated by the PCC to clarify questions, for instance on missing information.

CONFIDENTIALITY AND HIPAA AUTHORIZATION

The information below explains which personal details and health data from you and your newborn baby may be used and shared with others.

The personal data collected for the study and processed by Lundbeck via your study investigator will be demographic data (for example, year of birth, body weight), health data (for example, medical history, medication use prior to and/or during pregnancy, diagnosis of disease and severity), The categories of data to be collected and processed are described further in this Informed Consent Form.

Lundbeck may also process and analyze the study data mentioned above and below for the purpose of future scientific research within Lundbeck's area of expertise (please refer to Lundbeck.com for more information).

Conducting future exploratory research allows Lundbeck to maximize the use of already collected data and limit additional data collection from other similar patients. For example, it may entail that Lundbeck may use your data to help Lundbeck to:

- Gain more information and new knowledge about the use and effects of eptinezumab (Vyepti®) and other diseases within Lundbeck's area of expertise (please refer to Lundbeck.com for more information) after the study is ended, and
- Look for connections between data from this study and data from other studies.

Conducting future scientific research may entail that your and pseudonymized data and data of your unborn and newborn baby obtained as part of this study are at a later stage pooled (combined) with data from other studies to learn more about, for example, the cause (pathology) and/or consequences of use of eptinezumab (Vyepti®) and other diseases within Lundbeck's area of expertise. Further, your data may also be shared with Lundbeck's data processors, health authorities, and/or other researchers or collaboration partners; however, at this time, Lundbeck cannot specify who the relevant research and collaboration partners may be or where they are located. Therefore, Lundbeck cannot rule out that some of them may be located outside the European Union (EU) where the level of data protection may not be as good as within the EU. If this is the case, Lundbeck will ensure that measures are in place to ensure an adequate level of data protection compared to that in the EU/EEA. You can read more below under "Will my data be shared with parties outside the EU/EEA?"

UBC will not have access to data included in Lundbeck's future scientific research.

Your name, your personal identification number, and any other information that allows your direct identification will be replaced by a code number at UBC. UBC will keep this information confidential and will not pass this information to Lundbeck. UBC will use this information as needed, to contact you about the study, and make sure that relevant information about the study is recorded for your care.

The following parties may also be able to identify you by name when they access your personal data at UBC or check the accuracy of the data:

- Selected Lundbeck employees
- National health authorities such as the United States Food and Drug Administration (FDA)
- Selected staff from assisting organization(s).

The following people may review the health records of your newborn baby, to make sure that the data collected about him/her are correct:

- Government health agencies and their staff
- Pharmaceutical Sponsor, H. Lundbeck A/S, or its collaborators, licensees, and authorized representatives from e.g., Sponsor and/or health authorities, who check that the study is being performed correctly and that the information collected about you and your newborn baby is accurate
- The Institutional Review Board (IRB) that reviewed the study and ensures that your, your unborn baby and your newborn baby's rights and well-being are safeguarded
- Employees or students of Lundbeck or its authorized agents, who may be with the study monitors and auditors for quality and training purposes
- All staff with access to your and your newborn baby's records are required to keep your and your newborn baby's data confidential.

Your, your unborn and your newborn baby's data will be stored by Lundbeck for at least 25 years after the end of the clinical study, or longer if required by national laws, or as long as the data are considered by Lundbeck to have scientific value, whichever is longer.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be

gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Subject to exceptions and restrictions set out in applicable legislation, you have the right to request access to your personal data, to object to the processing, to have your personal data rectified, deleted, or processing thereof restricted, and to data portability. However, your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to give permission to use and share health data as described above, you will not be able to take part in the study.

COMPENSATION AND STUDY-RELATED EXPENSES

Potential participants who provide informed consent that do not meet the study's enrollment criteria and complete but subsequently do not pass the screening process will receive compensation in the amount of $25.00.

Enrolled participants that successfully attend and complete the data collection requirements at the specified timepoints, as described in the "Participation Information" section of this document will receive $100.00 at each timepoint up to $500.00 for completing the study.

This pregnancy surveillance program is being sponsored by H.Lundbeck A/S; the PCC is being paid by Lundbeck to conduct the study.

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 or your insurance.

POSTING OF RESEARCH STUDY ON WEB

Lundbeck registers the study in the EU PAS register (https://www.encepp.eu/encepp/studiesDatabase.jsp). In addition, it will be included in the FDA list of pregnancy registries (https://www.fda.gov/science-research/womens-health-research/pregnancy-registries)

YOUR RIGHTS

You have the right to be informed about the study results after the data from the study have been subject to statistical analyses and reported. If you are interested in receiving the study results, you should contact UBC. It is your own decision.

If you choose to withdraw from this study, the data already collected will be used in relation to the primary purposes of the study.

If you experience that your rights in relation to your personal data have been violated, you have the right to file a complaint with the competent supervisory authority, such as the Danish Data Protection Agency. You can contact the Danish Data Protection Authority at dt@datatilsynet.dk.

As mentioned above, Lundbeck, as sponsor, only holds pseudonymized data of study participants and cannot ascertain whether a particular individual participated in a study. Lundbeck therefore recommends you contact UBC if you have any questions about the processing of your personal data. UBC will direct your requests, as needed, to Lundbeck using your assigned code number.

This will ensure that your request is dealt with in the most confidential way and that your identity is not revealed to Lundbeck. If you feel that UBC is not able to address any question you have about the processing of your personal data and your rights, you can contact Lundbeck's Data Protection Officer using the contact details below.

Contact details of Lundbeck:

H. Lundbeck A/S

Ottiliavej 9

2500 Valby

Denmark

Tel: +45 36 30 13 11

Data Protection Officer: Dataprivacy@lundbeck.com (Support and advice in various European languages is available.

Providing data on your pregnancy and newborn baby as described in this form does not limit your rights to legal assistance. By agreeing to participate, you are not giving up your or of your newborn baby's legal rights.

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary). While using these, information about you may be collected and shared with the researchers or people outside of the study. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the application. If you would like to read these documents, request a copy or instructions about how to access this information from the pregnancy coordinating center. While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app and eDiary,you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

YOUR PARTICIPATION

Enrollment in this observational Vyepti 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, H. Lundbeck A/S., 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.

Study data collected by UBC through interviews and/or study questionnaires will be processed via secure systems provided by Lundbeck's data processors, and all the data will only be identified by the assigned code number, as mentioned above; your information will not be directly identifiable by Lundbeck or Lundbeck's data processors.

Once Lundbeck receives your data from UBC, your data will be shared with the following categories of recipients:

- Lundbeck's data processors, for example, entities acting on Lundbeck's behalf, for example, consultants, IT service providers and/or data analytics specialists.
- Individual data controllers: After your pseudonymized data are entered into Lundbeck's systems, Lundbeck may share the study data, including your pseudonymized data, with the relevant ethics committees and national health authorities for reporting or approval purposes.

A list of the third parties involved in the study conduct and/or reporting can be provided upon request.

UBC is responsible for storing your data and the code list securely for as long as required by national laws. The pseudonymized personal data from all study participants, including the personal data processed for future scientific research, will be archived in the secure systems held by Lundbeck for at least 25 years after the end of the study, or longer if required by national laws, or as long as the data are considered by Lundbeck to have scientific value, whichever is longer as mentioned above.

Will my data be shared with parties outside the EU/EEA?
Some countries outside the EU / European Economic Area (EEA) may not have the same level of data protection as within the EU/EEA. Once Lundbeck has received your and/or your newborn baby's pseudonymized data, Lundbeck may transfer your data to countries outside the EU/EEA as part of the conduct of the study or for the conduct of future scientific research. Lundbeck will ensure that such transfers are done in accordance with applicable legislation.
If the recipient country is not a country providing adequate data protection (see the list of countries on the EU Commission's website: https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en#documents Lundbeck will ensure that measures are in place to provide an adequate level of data protection compared to that in the EU. For more information, please see the https://commission.europa.eu/publications/standard-contractual-clauses-international-transfers_en.
Transfers made to ethics committees or national health authorities in countries outside the EU will be made, as the transfer is necessary for important reasons of public interest. Transfers made to other Lundbeck entities outside the EU will be based on Lundbeck's set of internal agreements, which can be provided upon request.

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 such as:

- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (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, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., 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 Subject Adviser: Pro00074481.

CONSENT

I have read and understood the information given in this Participation Sheet and Informed Consent Form. The information has been explained to me and I have had the opportunity to ask questions. Based on this I voluntarily agree, that;

- I understand that my participation in this study is voluntary and that I have the right to withdraw my consent to participate in this study at any time by contacting UBC, without giving a reason or losing any rights.

- I understand that if I withdraw my consent then no more data will be collected; however, the data already collected will still be used.

- I understand that by participating in this study I allow for Lundbeck, its representatives, as well as Regulatory Authorities, to compare the data reported in the study to those contained in my medical records.

- I understand and agree to the processing of my (pseudonymized) personal data obtained via my participation in the study for the purpose of clinical research (scientific research) in the form of a scientific evaluation of the use and effects of eptinezumab and other diseases within Lundbeck's area of expertise. I understand that my personal data may be shared with IRBs and national health authorities for reporting or approval purposes, as well as Lundbeck's collaboration partners for scientific research purposes.

- I understand that Lundbeck will process my (pseudonymized) personal data obtained via my participation in the study for future scientific research within Lundbeck's area of expertise and that Lundbeck may share my personal data with other researchers or collaboration partners for this purpose. I understand and acknowledge that Lundbeck cannot at this time specify who the relevant research and collaboration partners may be or where they are located, as this will depend on the specific future scientific research.

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

Vyepti® PCC Associate reviewing this Informed Consent Form:

_____ _____

Printed name of PCC Associate Date Signed

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Signature of PCC Associate