TEVA MIGRAINE PREGNANCY REGISTRY INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: ASSESSMENT OF PREGNANCY OUTCOMES IN PATIENTS TREATED WITH AJOVY (FREMANEZUMAB): PREGNANCY REGISTRY

PROTOCOL NO.: TV48125-MH-50037
IRB Protocol # 20204095

SPONSOR: Teva Branded Pharmaceutical Products R&D, Inc.
145 Brandywine Parkway
West Chester, Pennsylvania 19380
United States

INVESTIGATOR: Sara A Ephross, PhD, MPH
301 Government Center Drive
Wilmington, North Carolina 28403
United States

STUDY RELATED PHONE NUMBER(S): 833-927-2605 (24 hours)

You are being asked to participate in a non-interventional research study. Non-interventional research is limited to data collection and is done to see how a drug performs in real-life situations Your participation is voluntary. If you choose to participate, you may elect to withdraw your consent at any time.

Many women need to take medicine before they realize they are pregnant. However, we know little about the effects of taking most medicines in pregnancy, because pregnant women are often not included in studies that determine the safety of new medicines. A pregnancy exposure registry study is a study that collects health information from women who take prescription medicines when they are pregnant. Information is also collected on the newborn baby. Enrolling in a pregnancy exposure registry can help improve safety information for medicines used during pregnancy and can be used to update drug labeling.

There is a class of drug therapy (collectively known as anti-CGRP monoclonal antibodies or anti-CGRPs) that has been approved by the United States Food and Drug Administration (FDA) for the preventive treatment of migraine in adults. The following is a list of exmples of the anti-CGRPs that are approved: AJOVY® (fremanezumab-vfrm) injection, AIMOVIG® (erenumab-aooe) injection, EMGALITY® (galcanezumab-gnlm) injection, and VYEPTI™ (eptinezumab-jjmr) infusion.

Since there are many women of child-bearing potential (that is, women who can become pregnant) who may be exposed to anti-CGRPs, and since there limited data to show if anti-CGRPs affect the development of fetus (an unborn baby) and infant, the regulatory authorities required that the manufacturing drug companies conduct a pregnancy registry. Teva, who makes AJOVY, is the Sponsor of this Migraine Pregnancy Registry ("Registry").

The purpose of this Registry is to help us learn more about the safety of AJOVY by collecting information on maternal, fetal, infant outcomes and other health events compared to other anti-CGRPs, and compared to other treatments for migraine.

Since you have been exposed to a preventive treatment for migraine during pregnancy or within the required time frame before pregnancy, we are asking for you to be a part of this Registry which collects pregnancy information from women using this class of therapy. It is anticipated that approximately 1,098 pregnant women with migraine will participate in this Registry.

The collection of the information and other activities related to this Registry will be performed by Registry Coordinating Center (RCC) staff at Syneos Health, a research company who has been contracted by Teva to conduct this Registry. A description of this Registry will be available on the EU PASS Register and on the FDA Pregnancy Registry website. These websites will not include information that can identify you. At most, theywill include a summary of the study results.

What do I have to do to participate?
To be a part of this Registry you must be between 18-45 years old (19 in AL and NE and 21 in MS), pregnant with migraine, and either (1) be exposed to AJOVY at any time during pregnancy and/or within 5 months prior to last menstrual period (2) not exposed to AJOVY or similar medication, but exposed to other preventive treatments for migraine at any time during pregnancy and/or within 21 days prior to last menstrual period, or (3) be exposed to a medication similar to AJOVY at any time during pregnancy and/or within 5 months prior to last menstrual period.

Your routine healthcare will remain unchanged. You will not have to make any extra office visits, take any extra tests, or take any additional medications.

For you to participate in this Registry, you must first provide your consent. You can give your consent verbally to the Registry Coordinating Center by calling 1- 833-927-2605.

Alternatively, you can provide your written consent by signing this form, and emailing the form to: TevaMigrainePregnancyRegistry@syneoshealth.com, or mailing the form to Syneos Health, at 301 Government Center Drive, Wilmington, NC 28403, or returning the form to your health care provider where this consent form was received.

You can withdraw your participation in this study at any time. Your decision to participate or to withdraw from the study will not have any impact on your care or treatment by your physician.

What kind of information will be given to the Registry?
During the study, the Registry will collect certain personal information about you and your infant. This will include general personal information (for example, your name, contact information, date of birth, gender, height, weight, racial or ethnic origin, last menstrual period and health information (for example, medical history, test results, physical and mental health condition). The collection of this information is essential if you wish to participate in this Registry.

This study will require you to give us some basic information about your migraine and general health status and your permission to contact:

- the healthcare provider(s) you are seeing during this pregnancy to obtain information about you, your pregnancy, and your infant(s) at birth
- your infant(s) healthcare provider(s) to provide the remaining information needed by the registry
- With your permission, we will request information directly from your/your infant(s)' healthcare providers. Your healthcare provider will be contacted at enrollment, end of 1st trimester, mid-2nd trimester, mid-3rd trimester and at your estimated date of delivery. Your infant(s) healthcare provider will be contacted at birth, 6 months and 12 months of age.

How will the Registry keep my information confidential?
The Registry Coordinating Center will collect your name and your contact information in the Registry database, but it will be limited access, and only the Registry staff can access it and it will not be transferred to Teva or to any other third party unless required by law.

Your name, address, telephone number, and identifying information (such as medical record number or health plan number) may need to be used by the Registry Coordinating Center staff to identify you for the purpose of collecting the required information from you and your health care provider(s).

Your name and contact information will be destroyed at the end of this Registry by Syneos Health.

In order to maintain patient confidentiality, each patient will be assigned a unique patient identifier created randomly upon registry enrollment (e.g. your initials and a random code), so that no-one outside the Registry will be able to find out that the data is about you. This patient identifier will be used in place of your name for the purpose of data analysis and reporting.

Teva will be given your patient identifier and HCP contact information in the Teva safety database as required by applicable laws and regulations relating to safety reporting.

In the context of the Registry, Teva has overall responsibility for the Registry and for the personal coded data collected from each participant as part of the Registry.

Data about you will be used by the Registry personnel, regulatory authorities such as the US Food and Drug Administration (FDA), or members of the Institutional Review Board (IRB) who is responsible for ethical oversight of this Registry, representatives from Teva, its affiliated companies and third party contractors working on behalf of Teva (including Syneos Health), and authorized government regulatory authorities as required or permitted by law, for the purpose of studying and investigating migraines, AJOVY and the response to the class of therapies, investigations related to migraines, and response to the class of therapies, as well as for monitoring activities, reporting of adverse events and other regulatory and legal obligations of Teva. All personnel accessing your data are required to respect your confidentiality at all times. Your data will only be processed in accordance with applicable laws and regulations.. If anyone mentioned in this form shares or discloses your information outside of the United States, it may be to a country with privacy laws that do not protect you at the same level as the U.S., however, every effort will be made to ensure that your privacy remains protected by using only coded information.

You may have certain rights under applicable law (e.g. to request access to your personal data and, if needed, to request correction of any information which is wrong or

incomplete, or to correct, delete or restrict (stop any active processing of your data). Note that your right to access personal data about you may be limited (e.g. if fulfilling your request would reveal personal data about another person, or if you ask to delete information which we are required by law to keep or have compelling legitimate interests in keeping, or suspended until the conclusion of the study). This right of access and correction can be exercised through your study representative.

The results of the Registry may also be reported to authorities who approve medicines, like the FDA. Health care providers who participated in the Registry will also receive information about the overall results of this study, but will only have access to identifiable data of their own registered patients. After the study is completed, the data collected in the study will be archived following the applicable regulations and guidances, which is usually a period of 10 years.

In the event of any publication or presentation resulting from the Registry, no personally identifiable information will be disclosed.

By signing the consent form, you understand that collection, use and transfer of personal data (including your health data) about you and your baby as described in this form is necessary for the conduct of the Registry. Should you withdraw your consent to participate in the Registry, no additional personal data will be collected about you, but the use of your personal data that was already collected before your withdrawal may be used by Teva to meet its legal and regulatory obligations as well as for the conduct of the Registry.

You may decide not to participate or you may leave the Registry at any time.

Risks, Discomforts and Compensation for Injury

The study uses a series of questionnaires to gather information and does not involve any medical procedures. For these reasons, the only risks or discomforts that are expected are related to the possible loss of confidentiality and/or the emotional discomfort answering some of the questions.

If you or your infant(s) experience an injury or illness unrelated to your participation in the Registry, Syneos Health or Teva will not be held liable for any claim made in respect of such injury or illness.

You should discuss with your doctor whether or not you should breast-feed a baby while on this study.

Benefits

There are no direct benefits for your participation in this Registry, but there may be benefits to other participants like you in the future. The results of this study may

increase medical knowledge about the safety of using AJOVY before or during pregnancy.

Expenses
You will not have any additional expenses as a result of your participation in this Registry.

Payment for Participation
You will be compensated for taking part in this Registry. You will be compensated for your time as follows: $25 for completing the Patient Registration Form, $25 for completing the Follow-up at Estimated Date of Delivery/Pregnancy Outcome Form after delivery, and $25 for completing the Follow-up for Infants at 12-Months Form (as applicable). Payment will be made in the form of Amazon gift cards. If you would like to receive gift card(s), you must provide your email address. Gift cards will be processed on a calendar quarterly basis.

☐ Please check this box if you DO NOT wish to receive these gift cards.

Alternatives
You may choose not to participate in this Registry.

Source of Funding
Funding for this research study will be provided by Teva. Your Healthcare provider(s) should inform you of any possible conflict of interest. Your study doctor will be paid by the sponsor.

What if I decide not to participate?
Your participation in this Registry is voluntary. You may decide not to participate or you may leave the Registry at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Your medical care will not be affected by choosing not to participate in the Registry.

You may withdraw from the Registry at any time. If you choose to be a part of the Registry, and decide later that you want to stop allowing information to be given to the Registry, you may let us know by sending a letter to the study at the address on page one of this informed consent form or you may contact us directly using the phone number(s) listed on page one of this form. We will be allowed to use data collected before withdrawal of your consent. If you decide not to participate or to stop participating later, your/your infant's medical care will not be affected.

Your participation in this study may be stopped at any time at the discretion of your doctor and Teva without your consent for any reason. Teva or the FDA may also end the Teva Migraine Pregnancy Registry early.

New Information
You will be told about new information or findings that develop during the course of this study that might change your decision to participate in this Registry.

Questions
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-855-818-2289 or Researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Do not sign this consent form or give your verbal consent unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. If you agree to be in this study, you will receive a copy of this informed consent form.

Informed Consent
Before making the decision regarding enrollment in this research you should have:

- Discussed this study with the Health care provider(s),
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

By giving informed consent, you have not given up any of your legal rights and you freely consent to participate in the Teva Migraine Pregnancy Registry.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

☐ Verbal consent given by Participant to Registry Coordinating Center staff over the phone on:
OR

☐ Informed Consent process conducted by Participant's Health Care Provider on:

_____ Date (dd/mmm/yyyy)

Name of Participant	Date of Birth (dd/mmm/yyyy)

Address of Participant

Telephone number of Participant

Signature of Participant (optional)	Date (dd/mmm/yyyy)

Printed Name of person who conducted the Informed Consent Process

Person Explaining the Research: Your signature below means that you have explained the study research to the participant and have answered any questions he/she has about the research.

Signature of ☐ Registry Coordinating Center staff or ☐ Health Care Provider	Date (dd/mmm/yyyy)

If written informed consent is provided, please sign and return **one** signed original to Syneos Health at 301 Government Center Drive, Wilmington, NC 28403 in the pre-addressed, postage paid envelope provided. Please keep a copy of this document for your own reference.

You may also provide consent to opt in or choose to opt out of enrolling in a Mobile Application (app) or to receive text notices for updates and information during the time you are participating in the Registry. You will be provided with the app link and login information after Enrollment.

I give consent to be enrolled in a Mobile Application and/or to receive text notices for updates while I am participating in the Teva Migraine Pregnancy Registry to the following mobile telephone number:_____

☐ Yes
☐ No

If Applicable
Permission for a Participant who is 18 years old but Under the Age of Majority in her state (Alabama, Nebraska, Mississippi) to Participate in the Registry (Assent)
Statement of person conducting assent discussion:

1. I have explained all aspects of the research to the participant to the best of her ability to understand.
2. I have answered all of the questions of the participant relating to this research.
3. The participant agrees to be in the research.
4. I believe the participant's decision to enroll is voluntary.
5. The Health care provider(s) and study staff agree to respect the participant's physical or emotional dissent at any time during this research and the participant understands that they can chose not to participate in the Registry even if their parent provides consent.

Statement of Parent or Guardian:
My child appears to understand the research to the best of his or her ability and has agreed to participate.

Relationship to Participant: _____

For Participants Under the Age of Majority, Name of Parent/Legal Guardian (person authorized to consent to the child subject's general medical care)

For Participants Under the Age of Majority, Address of Parent/Legal Guardian

For Participants Under the Age of Majority, Phone number of Parent/Legal Guardian:

For Participants Under the Age of Majority, Signature of Parent/Legal Guardian (optional)

_____

Date (dd/mmm/yyyy)

If written assent (by participant) and consent (by parent/legal guardian) are provided, please sign and return **one** signed original originals to Syneos Health Registry Coordinating Center at 301 Government Center Drive, Wilmington, NC 28403 in the pre-addressed, postage paid envelope provided. Please keep a copy of this document for your own reference.

Printed Name of person who conducted the Informed Consent Process

Person Explaining the Research: Your signature below means that you have explained the study research to the participant's parent/legal guardian and have answered any questions he/she has about the research.

Signature of ☐ Registry Coordinating Center staff or ☐ Health Care Provider

Date (dd/mmm/yyyy)

AUTHORIZATION FOR USE OR DISCLOSURE OF HEALTH INFORMATION

The words 'you' and 'your' in this form refer to you and your child.

You hereby authorize Syneos Health to use or disclose health information about you for the AJOVY Pregnancy Registry and other purposes described below. You understand that the health information to be used or disclosed includes "Protected Health Information," as that term is defined in federal regulations called the Privacy Regulations, which were developed under the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). You understand that Protected Health Information is health information that identifies you or that could be used to identify you. You must sign this form to participate in the AJOVY Pregnancy Registry.

Name of research study participant (please print):

_____

Person(s) or class of persons authorized to disclose your health information: Representatives of the following people/groups within Syneos Health may use your health information and share it with other specific groups in connection with the Teva Migraine Pregnancy Registry:

- The Teva Migraine Pregnancy Registry Coordinating Center;
- The Institutional Review Board;
- The Syneos Health Data Privacy Officer or designee ;
- Teva Branded Pharmaceutical Products R&D, Inc. or it's affiliates ("Teva*");*
- Registry Advisory Committee*.*

Person(s) or class of persons authorized to receive your health information:
Representatives of the following people/groups outside Syneos Health may receive and use your health information in connection with the Teva Migraine Pregnancy Registry.

- Funding agencies and relevant government national and international oversight agencies such as the Food and Drug Administration and the Office for Human Research Protections and as otherwise required by law;
- Teva, a manufacturer of pharmaceutical products and sponsor of the Teva Migraine Pregnancy Registry, and its affiliates, agents, subcontractors, and representatives.
- Agents of the study sponsor such as contract research organizations, laboratories, organizations that assist with the analysis of the data (including safety data) and similar agents.

Description of the health information that may be used and/or disclosed: The study will need information about you, your current pregnancy throughout the entire pregnancy and information about your infant(s) through 12 months of age. We will ask you/your healthcare provider about your use of any migraine drugs you are taking up to 5 months prior to your last menstrual period. Your healthcare providers will be asked to provide information about your obstetric history, medical conditions and medications, prenatal testing information, general personal information, any pregnancy complications/adverse outcomes for you, and all other individually identifiable information, whether or not contained in your medical records, regarding any past, present, or future medical or mental health conditions for the provision of health care treatment or services to you.

Your infant(s) healthcare provider will be asked to provide information about growth, developmental milestones and any birth defects.

Information about you will be collected at the start of your participation, end of 1st trimester, mid-2nd trimester, mid-3rd trimester and at your estimated date of delivery. Your infant(s) healthcare provider will be contacted at

birth, 6 months and 12 months of age. You have the right to know what information is being collected and have the right to correct it as needed.

The information will be used and/or disclosed for the following purpose(s):

- To conduct the Teva Migraine Pregnancy Registry as described in the Informed Consent Form that was provided to you by Syneos Health
- To Teva, for purposes of conducting, evaluating, overseeing or otherwise assisting with this research study and the related research activities;
- For uses and disclosures required by law.

Revocation and Miscellaneous:

1. You understand that you will receive a copy of this Authorization.
2. You understand that you may revoke this authorization at any time by notifying Syneos Health in writing at the following address:

   Registry Coordinating Center
   301 Government Center Drive
   Wilmington, NC 28403

   - You understand that if you revoke this authorization, it will not apply to actions taken consistent with this authorization before such revocation. Information that has already been gathered may still be used and given to others.
   - Syneos Health and the others described above as authorized to receive your information may continue using and sharing the information obtained prior to your revocation if it is necessary for the soundness of the overall research. If you withdraw your permission, no new health information will be gathered.
   - If you revoke this authorization, you understand that you will no longer be able to participate in the Teva Migraine Pregnancy Registry.

3. You understand that information disclosed pursuant to this authorization may be re-disclosed by recipients of the information and may no longer

be protected by federal privacy regulations. These groups are committed to keeping your health information confidential.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

You do not have to sign this form. If you do not sign this form, you cannot take part in this Registry.

You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

By signing below, you acknowledge that you have read and understand this form.

☐ Authorization for Use or Disclosure of Health Information obtained by Registry Coordinating Center staff over the phone on:
OR
☐ Authorization for Use or Disclosure of Health Information obtained by Participant's Health Care Provider on:

_____

_____ _____
Signature of participant (or parent/legal guardian as applicable) Date

Printed name of participant

Printed name of Parent/Legal Guardian

Printed Name of person who obtained the Authorization for Use or Disclosure of Health Information

Signature of ☐ Registry Coordinating Center staff or ☐ Health Care Provider

Date (dd/mmm/yyyy)

IRB Approved at the Protocol Level
Dec 15, 2020

MEDICAL INFORMATION RELEASE FORM

I HEREBY REQUEST THAT MEDICAL INFORMATION RELATED TO MY PARTICIPATION IN THE REGISTRY BE RELEASED TO:

Teva Migraine Pregnancy Registry Coordinating Center
301 Government Center Drive Wilmington, NC 28403
Phone number: 1-833-927-2605
Fax number: 800-800-1052
Email: TevaMigrainePregnancyRegistry@syneoshealth.com

RECORDS TO BE RELEASED FROM:

Name of Health Care Provider: _____

Name of Practice: _____

HCP Specialty: ☐Obstetric HCP ☐Prescribing HCP ☐Other: _____ (please specify)

Address: _____

_____

Telephone number: _____ Fax number (if available): _____

Email (if available): _____

Comments: _____

Patient Date of Birth: _____

☐Verbal Consent given by Patient to Registry Associate over the phone on:

_____
Date

_____
Signature of Registry Associate obtaining verbal consent Date

_____
Printed/Typed Name of Patient

_____
Signature of Patient (optional) Date

Address of Patient: _____

_____

Telephone number of Patient: _____

Email of Patient (if available): _____