

**Participant ID:**

**TEVA MIGRAINE PREGNANCY REGISTRY  
INFORMED CONSENT/ASSENT FORM**

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

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

**SPONSOR:** Teva Branded Pharmaceuticals Products R&D, Inc.

**INVESTIGATOR:** Sara A Ephross, PhD  
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United States  
TevaMigrainePregnancyRegistry@syneoshealth.com

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

In this form, “you” and “your” refers to the participant. If you are completing this form on behalf of a participant that is under the age of majority, “you” and “your” refers to the registry participant.

If the participant is at least 18 years old, but under the age of majority in her state (Alabama, Nebraska, Mississippi), an Assent will also need to be completed by the Registry participant.

**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 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 examples 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, and infant outcomes, and other health events compared to other anti-CGRPs and 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, they will include a summary of the registry results.

***What do I have to do to participate?***

To be a part of this Registry you must meet these qualification criteria:

- 1) Be between the ages of 18 – 45 years; **and**
- 2) Be currently pregnant or have a pregnancy outcome within the last 12 months; **and**
- 3) Have taken AJOVY or any other preventive anti-CGRP migraine medication at any time during pregnancy and/or within 5 months prior to your last menstrual period; **or**
- 4) Have taken a non-CGRP preventative migraine medication at any time during your pregnancy and/or within 5 half-lives (about 1-2 months).

(A half-life is a time range that will be specific to the medication you are taking and the Registry Coordinator will assist you in making this determination.)

Although designed primarily as a prospective registry, the Registry will accept retrospective enrollment, which includes up to 1 year after a live birth. 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](mailto:TevaMigrainePregnancyRegistry@syneoshealth.com), fax to 800-800-1052, or returning the form to your health care provider where this consent form was received.

You can withdraw your participation in this registry at any time. Your decision to participate or to withdraw from the registry 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 registry, 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 registry 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 1<sup>st</sup> trimester, mid-2<sup>nd</sup> trimester, mid-3<sup>rd</sup> 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).

In order to maintain patient confidentiality, each patient will be assigned a unique patient identifier created upon registry enrollment, 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 registry). This right of access and correction can be exercised through your registry 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 registry, but will only have access to identifiable data of their own registered patients. After the registry is completed, the data collected in the registry 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 registry 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.

### ***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 registry 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 Baseline Data 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 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 give consent that we share your email address to deliver the gift card(s).

**Alternatives**

You may choose not to participate in this Registry.

**Source of Funding**

Funding for this research registry will be provided by Teva. Your Healthcare provider(s) should inform you of any possible conflict of interest. Your registry 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 registry 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 registry 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 registry 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 [clientcare@wcgclinical.com](mailto:clientcare@wcgclinical.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 registry, you will receive a copy of this informed consent form.

**Informed Consent**

*I have read the information in this consent form (or it has been read to me). The Registry representative from the Registry Coordinating Center, or my healthcare provider, whose signature is given below, has informed me about the nature of the Teva Migraine Pregnancy Registry. I have had enough opportunity to ask questions. All my questions about the registry and my participation in it have been answered. I freely consent to be in this Registry, and if applicable provide consent for my minor to participate in this Registry.*

*By giving informed consent, I have not given up any of my legal rights.*

☐ Verbal consent given by Participant/Parent/Guardian to Registry Coordinating Center staff over the phone on: \_\_\_\_\_ Date (dd/mmm/yyyy)

**OR**

☐ Verbal consent given to Participant's health care provider on: \_\_\_\_\_ Date (dd/mmm/yyyy)

Verbal consent obtained by:

☐ Registry Coordinating Center staff or

☐ Health care provider

Signature: \_\_\_\_\_

\_\_\_\_\_  
Date (dd/mmm/yyyy)

**OR**

☐ Written consent given by Participant.

*If written informed consent is provided, please sign and return one signed original to Syneos Health at [TevaMigrainePregnancyRegistry@syneoshealth.com](mailto:TevaMigrainePregnancyRegistry@syneoshealth.com), or fax to 800-800-1052. Please keep one copy of this form for your records.*

\_\_\_\_\_  
Signature of study participant or legally acceptable representative\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of parent or legally acceptable representative (use all CAPITALS)

\*If this form is signed by a legally acceptable representative, please describe the basis of your authority to act for the study participant:



## Participant Information

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Name of Participant

Date of Birth (dd/mm/yyyy)

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Address of Participant

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Telephone number of assented/consented participant

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## Parental Permission and Assent

☐ *Participant **has not** reached age of majority (legally an adult) therein parental permission and assent **are** required.*

Parents/Guardians of Participant not reaching age of majority: You have the option of having the participant, join a research study. This is a parental/guardian permission form. It provides a summary of the information the research team will discuss with you. If you decide that the participant can take part in this registry, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

As parent or guardian, I authorize \_\_\_\_\_ (participant's name)  
to become a participant in the Registry described in this form.

Relationship to Participant: \_\_\_\_\_

**Parental Permission** (For Participants Under the Age of Majority)

<i>Name of Parent/Guardian</i>	
<i>Address of Parent/Guardian</i>	
<i>Phone number of Parent/Guardian</i>	
<i>Printed Name of Parent/Guardian</i>	
<i>Signature of Parent/Guardian</i>	<div><div></div><div><i>Date (dd/mmm/yyyy)</i></div></div>

**Assent** (For Participants Under the Age of Majority)

<i>Signature of Participant</i>
<div><div></div><div><i>Date (dd/mmm/yyyy)</i></div></div>

## SYNEOS HEALTH

### Authorization for Use or Disclosure of Health Information

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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 HIPAA part of the form in order to participate in the AJOVY Pregnancy Registry.

Name of study participant (please print or type):

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**Person(s) or class of persons authorized to disclose health information about you:**

Representatives of the following people/groups within Syneos Health may use health information about you and share it with other specific groups in connection with the Teva Migraine Pregnancy Registry.

- The Teva Migraine Pregnancy Registry Coordinating Center
- Institutional Review Board;
- The Syneos Health Human Subjects Protection Office;
- Teva Branded Pharmaceutical Products R&D, Inc. or its affiliates ("Teva");
- Registry Advisory Committee.

**Person(s) or class of persons authorized to receive health information about you:**

Representatives of the following people/groups outside Syneos Health may receive and use health information about you 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;
- Sponsor of the Teva Migraine Pregnancy Registry and its affiliates, agents/vendors, subcontractors, and representatives such as contract research organizations, laboratories, insurance companies, organizations that assist with the analysis of the data (including safety data) and similar agents.

The Sponsor may re-disclose or share your protected information in an anonymized form (de-identified) as required by law, regulatory agencies, or in/for scientific meetings/research or published journals. Once your protected health information has left the study site, HIPAA may no longer protect your privacy. If the Sponsor 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, the Sponsor will make every effort to ensure that your privacy remains protected by using only coded information.

**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 Sponsor, its affiliates and vendors, for purposes of conducting, evaluating, overseeing or otherwise assisting with this research study and the related study 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 have a right to access information that is collected about you in order to correct errors. However, this right may be suspended during the research study to protect the integrity of the data.
3. You understand that this authorization will continue indefinitely.
4. You understand that you may withdraw this authorization at any time by notifying Syneos Health in writing at the following email address:  
TevaMigrainePregnancyRegistry@syneoshealth.com
  - You understand that if you withdraw this authorization, data that was collected before you revoked your authorization will continue to be used as previously described. However, no new data will be collected.
  - For US (except sites in state of California): Your permission for the study doctor and the Sponsor to use and disclose personal data about you will not expire unless you withdraw it. [Note to master/country level ICF author: remove this section from ICF

for sites in California as it conflicts with the required California mandate that expiration must have a 'date'. i.e., the ICF cannot state that there is no expiration.]

- You understand that under certain circumstances (such as you are experiencing an ongoing side effect) that your medical records may continue to be reviewed by the Sponsor and/or its affiliates, agents, subcontractors, and representatives for the purpose of monitoring such side effects and so that Sponsor can meet its legal obligations for safety information gathering.
  - If you revoke this authorization, you understand that you will no longer be able to participate in the Teva Migraine Pregnancy Registry.
5. 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.

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

<input type="checkbox"/> <i>Verbal consent given by Participant/Parent/Guardian to Registry Coordinating Center staff over the phone on: _____ Date (dd/mmm/yyyy)</i>	
<b>OR</b>	
<input type="checkbox"/> <i>Verbal consent given to Participant's health care provider on: _____ Date (dd/mmm/yyyy)</i>	
<i>Verbal consent obtained by:</i>  <input type="checkbox"/> <i>Registry Coordinating Center staff or</i> <input type="checkbox"/> <i>Health care provider</i>  <i>Signature:</i>	<div style="border-bottom: 1px solid black; margin-bottom: 5px;"></div> <i>Date (dd/mmm/yyyy)</i>

**OR**

☐ *Written consent given by Participant.*

*If written informed consent is provided, please sign and return one signed original to Syneos Health at [TevaMigrainePregnancyRegistry@syneoshealth.com](mailto:TevaMigrainePregnancyRegistry@syneoshealth.com), or fax to 800-800-1052. Please keep one copy of this form for your records.*

\_\_\_\_\_  
Signature of study participant or legally acceptable representative\*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of parent or legally acceptable representative (use all CAPITALS)

\*If this form is signed by a legally acceptable representative, please describe the basis of your authority to act for the study participant: