Fremanezumab Expanded Access Checklist

Expanded Access Program application for former patients for TV48125-CNS-30056/57/58 (ENFORCE)

To request the continued supply of fremanezumab via Expanded Access, this Patient Access Form must be read, completed and signed by the prescribing physician.

Patient eligibility will be determined by Teva Pharmaceuticals in accordance with established policies and procedures. Teva Pharmaceuticals acceptance and processing of this request form does not guarantee that access to the product will be provided.

Please refer to https://www.tevapharm.com/research_development/clinicaltrials/ for more information.

IF THE PATIENT MEETS ALL OF THE ELIGIBILITY CRITERIA LISTED BELOW THEN PLEASE COMPLETE THIS CHECKLIST (IN ADDITION TO THE EXPANDED ACCESS REQUEST FORM LOCATED ON THE WEBPAGE LINK ABOVE) SIGN, SCAN AND EMAIL BOTH DOCUMENTS TO: expandedaccess@tevapharm.com

Treating physician name: _____ _
Name of former study investigator (if applicable): _____
Institution: _____
Address: _____
Phone number: _____
Email address: _____

Previous Study: ☐ **TV48125-CNS-30056** ☐ **TV48125-CNS-30057 or** ☐ **TV48125-CNS-30058**
Subject ID: _____
Date of end of treatment or early termination visit: _____

Please check the boxes below to indicate whether the following criteria continue to be met:

☐ The patient has completed or early terminated Teva-sponsored Study **TV48125-CNS-30056/57/58** without important protocol deviations related to patient safety

☐ The patient is willing to sign informed consent form

☐ There is no other comparable or satisfactory therapy available to treat the patient. Please specify (e.g.other anti-CGRP mABs not approved/reimbursed/tolerated/switching not justified):_____

_____

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☐ The patient is unable to obtain Fremanezumab under another Investigational New Drug or through a clinical study.

☐ The risk/benefit for the patient supports continuing treatment with Fremanezumab**;**

Please specify, e.g. by providing an estimate of the number of attacks at baseline versus the number of attacks at the end of treatment or early termination visit; the use of acute medication and/or oxygen use at baseline versus at the end of treatment or time of early termination

_____
_____
_____
_____
_____
_____

Has the subject experienced during the study AEs and/or SAEs associated with hypersensitivity, rash, pain, or any AESI (ophthalmic adverse event of at least moderate severity; events of possible IMP induced liver injury AST or ALT>=3X the ULN, total bilirubin >=2X the ULN, or INR >1.5; Hy's law events; or events of anaphylaxis and sever hypersensitivity reactions)

☐ NO ☐ YES

If yes, please describe the event(s):

_____
_____

☐ Patient is either sterile or uses highly effective birth control methods for the duration of expanded access and for 7.5 months after discontinuation of Fremanezumab.

☐ The patient is not pregnant or a lactating/nursing female or plans to become pregnant during the expanded access and 7.5 months after discontinuing treatment.

☐ No clinical significant abnormalities assessed by the investigator at the application

_____ _____

Signature of Treating Physician Date

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