

Fremanezumab Expanded Access Checklist

Expanded Access Program application for former TV48125-CNS-30057/58 (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 http://www.tevapharm.com/research_development/rd_focus/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-30057** : or **TV48125-CNS-30058** _____

Subject ID: _____

Date of study early termination visit: _____

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

The patient has early terminated Teva-sponsored Study **TV48125-CNS-30057/58** 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

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 early termination visit; the use of acute medication and/or oxygen use at baseline versus at 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 $\geq 3X$ the ULN, total bilirubin $\geq 2X$ the ULN, or INR > 1.5 ; Hy's law events; events of anaphylaxis and severe hypersensitivity reactions)

YES NO

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