Fremanezumab Expanded Access Checklist

Expanded Access Program application for former TV48125-CNS-30051 (HALO) / -30068 (FOCUS)

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 Branded Pharmaceutical Products R&D Inc. (TEVA) in accordance with established policies and procedures. TEVA 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-30051** ☐: or **TV48125-CNS-30068** ☐

Subject ID: _____

Date of last study visit: _____

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

☐ The patient must have completed Teva-sponsored Study TV48125-CNS-30051 or Study TV48125-CNS-30068 as defined in the study protocol and without major protocol violations.

☐ For a patient who did not complete Study TV48125-CNS-30068, as defined in the study protocol (i.e., dropped out after the treatment phase), please provide a detailed reason(s) for not completing the study below:

_____

_____

_____

Version date: 14May2019

☐ 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):_____

_____

☐ 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 the reason for requesting expanded access for this patient.

_____
_____
_____

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

☐ 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

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_____ _____

Signature of Treating Physician Date
