ADAPT NXT: An Open-Label Study to Assess the Clinical Efficacy and Safety of Efgartigimod to Further Individualize Treatment in Patients With gMG

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Myasthenia Gravis Foundation of America Scientific Session; September 21–24, 2022; Nashville, TN, USA

Disclosures

- The ADAPT NXT study was funded by argenx
- Kelly Gwathmey has received consulting/speaking honoraria from Alexion and consulting honoraria from UCB and argenx

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Introduction: Individualizing Treatment Options With Efgartigimod

Efgartigimod is well tolerated and effective in patients with gMG when dosed using an **individualized cycle approach**[1,2]

Continuous dosing approaches to efgartigimod have been employed in other disease states, including ITP and pemphigus[2]

ADAPT NXT was designed to describe the efficacy and safety of IV efgartigimod 10 mg/kg administered in a continuous regimen (**infusions every 2 or 3 weeks**) and a cyclic regimen **(cycles of 4 once-weekly infusions, with 4 weeks between cycles**)[2]

ADAPT NXT will provide information on further individualization of efgartigimod dosing in patients with gMG[2]

gMG, generalized myasthenia gravis; ITP, primary immune thrombocytopenia; IV, intravenous.

1. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536. **2.** argenx Data on File, 2022.

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Rationale for Dosing Choices

Pharmacodynamic Modeling

- Simulated total IgG modeling, based on existing clinical data, was performed to assess relative reductions in IgG with additional individualized dosing regimens[1]
- Based on these modeling data, continuous dosing of efgartigimod may provide similar reductions in IgG to individualized cycle dosing

Safety

- No serious adverse events were assessed as related to efgartigimod in ongoing clinical studies in which efgartigimod was administered weekly or Q2W[1]
- Q2W continuous dosing of efgartigimod has been used to treat other conditions without notable changes to risk profile[2]

IgG, immunoglobulin G; Q2W, every 2 weeks.

1. argenx Data on File, 2022. **2.** Goebeler M, et al. *Br J Dermatol.* 2022;186(3):429-439.

ADAPT NXT (ARGX-113-2003) Study Design

Efgartigimod IV phase 3b, multicenter, randomized, open-label, parallel-group study in patients with gMG

Total anticipated enrollment = 72

Eligibility criteria

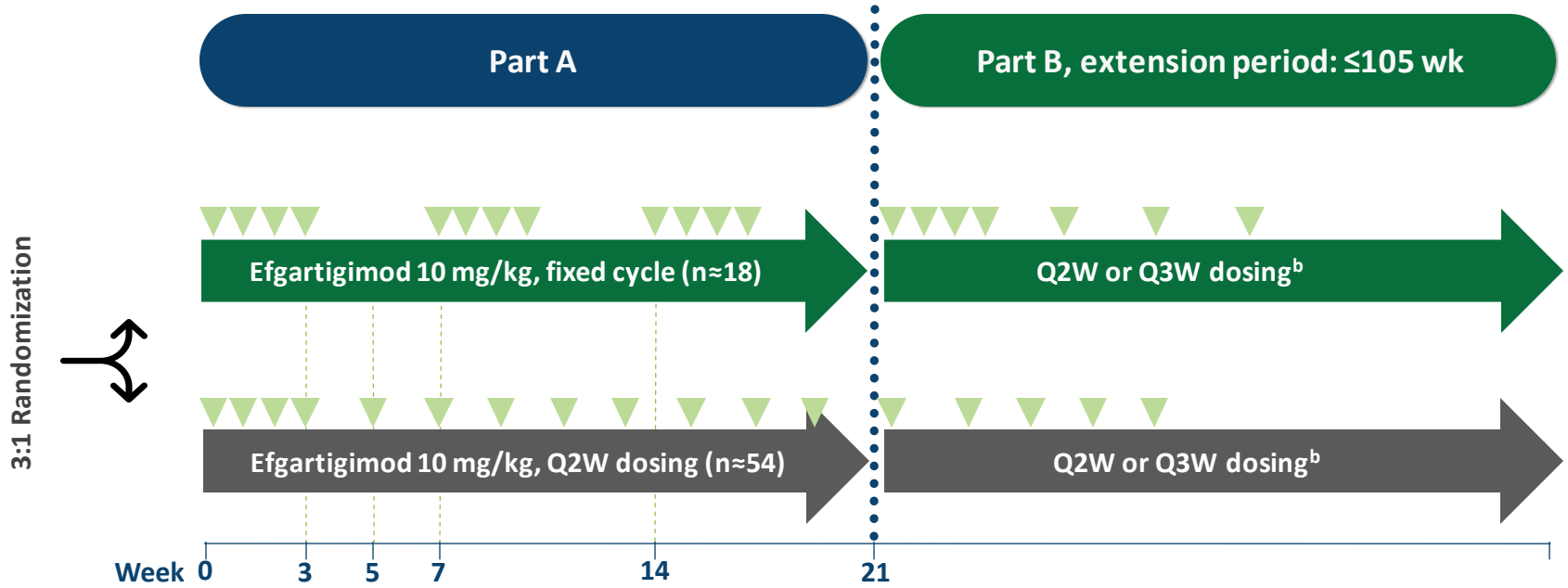
Age ≥18 y

AChR-Ab positive

MG-ADL score ≥5 (>50% nonocular)

Stable background treatment permitted[a]

IgG ≥6 g/L



gMG, generalized myasthenia gravis; IgG, immunoglobulin G; IV, intravenous; NSIST, nonsteroidal immunosuppressive therapy; Q2W, every 2 weeks; Q3W, every 3 weeks.
[a]Concomitant gMG therapy permitted, but not required (NSISTs, steroids, and/or acetylcholinesterase inhibitors; stable dose for ≥1 month before screening for NSISTs and/or corticosteroids). [b]During Part B, participants who maintain clinical improvement receiving the Q2W dosing regimen can switch to the Q3W dosing regimen. Participants in Part B who do not maintain clinical improvement on the Q3W dosing regimen will be able to switch back to the Q2W dosing regimen.
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ADAPT NXT Primary and Secondary Endpoints

PRIMARY ENDPOINT

Mean of the average MG-ADL total score change from Week 1 through Week 21 by regimen arm[a]

SECONDARY ENDPOINTS

- Incidence and severity of adverse events, serious adverse events, adverse events of special interest, laboratory test results, vital signs, and electrocardiogram results
- Change from baseline in the MG-ADL total score over time
- Percentage of participants who have a ≥2-, 3-, 4-, or 5-point improvement in MG-ADL total score over time
- Participants achieving minimal symptom expression, defined as MG-ADL total score 0–1, over time

MG-ADL, Myasthenia Gravis Activities of Daily Living.
[a]MG-ADL will be completed weekly until the end of Part A.
argenx Data on File, 2022

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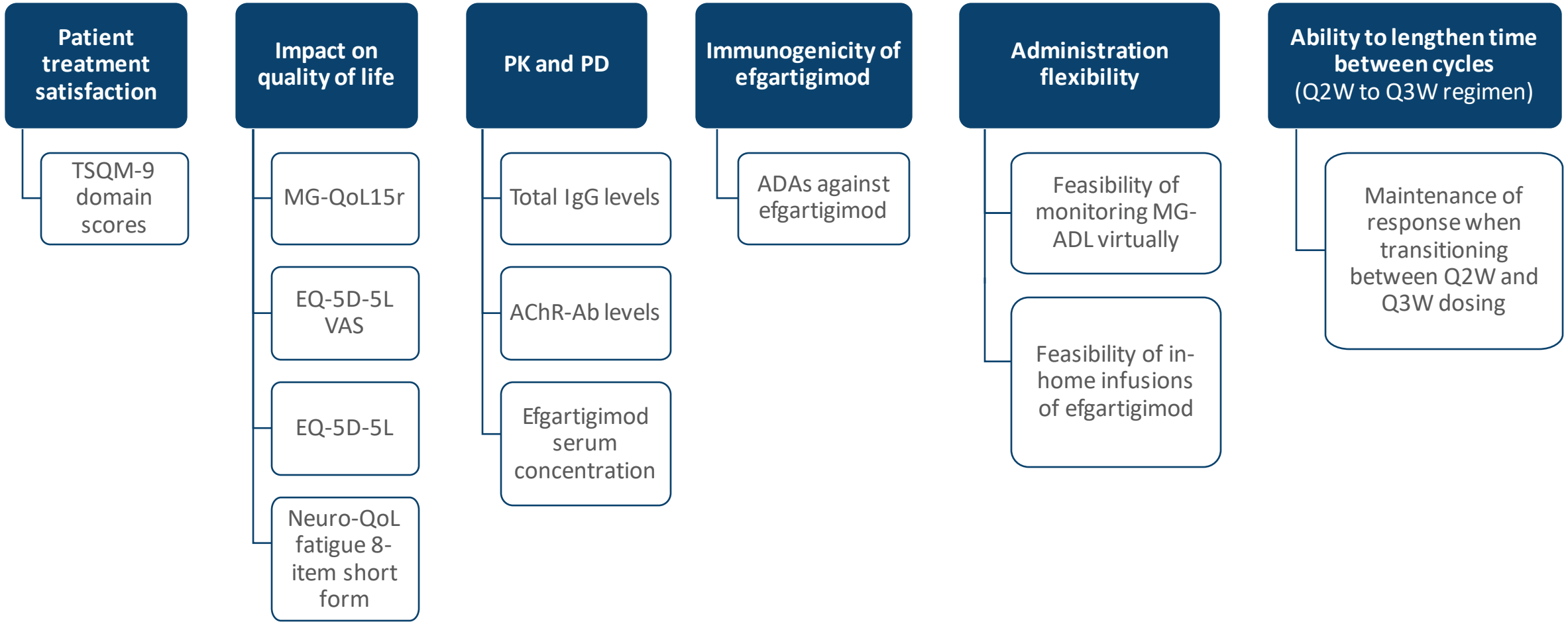
ADAPT NXT Exploratory Objectives



AChR-Ab, anti-acetylcholine receptor antibody; ADA, antidrug antibody; EQ-5D-5L, EuroQoL 5-Dimension, 5-Level; EQ-5D-5L VAS, EuroQoL 5-Dimension, 5-Level Visual Analog Scale; IgG, immunoglobulin G; MG-ADL, Myasthenia Gravis Activities of Daily Living; MG-Qol15r, Myasthenia Gravis Quality of Life 15-Item Questionnaire, Revised; Neuro-QoL, Adult Quality of Life in Neurological Disorders; PD, pharmacodynamic; PK, pharmacokinetic; Q2W, every 2 weeks; Q3W, every 3 weeks; TSQM-9, Treatment Satisfaction Questionnaire for Medication–9 Items.

argenx Data on File, 2022.

Summary

ADAPT NXT is a phase 3b, multicenter, randomized, open-label, parallel-group trial evaluating different dosing regimens of IV efgartigimod in patients with gMG[1]

ADAPT NXT is designed to determine the efficacy, safety, and tolerability of 10 mg/kg IV efgartigimod administered in additional dosing regimens[1]

Recruitment for this study is ongoing[2]

IV, intravenous; gMG, generalized myasthenia gravis.

1. argenx Data on File, 2022. **2.** ClinicalTrials.gov. An open-label study to investigate the clinical efficacy of different dosing regimens of efgartigimod IV in patients with generalized myasthenia gravis (ADAPT NXT). July 28, 2021. Updated September 1, 2022. https://clinicaltrials.gov/ct2/show/NCT04980495?term=ARGX-113-2003&draw=2&rank=1.