



Together We Discover

VYVGART[®] Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

FDA Approval Call

June 21, 2023



Forward Looking Statements

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VYVGART

for Generalized Myasthenia Gravis

NOW TWO FDA-APPROVED PRODUCTS

VYVGART[®]
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

VYVGART[®] **Hytrulo**
(efgartigimod alfa and
hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

VYVGART and **VYVGART Hytrulo** are indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

ANDREA. Living with gMG

VYVGART® Hytrulo has redefined my experience with gMG. I am grateful to have found a treatment built to my needs, empowering me to return to the activities I love.

GENERALIZED MYASTHENIA GRAVIS PATIENT EXPERIENCE

gMG is characterized by debilitating muscle weakness and fatigue. Despite taking an average of 2.3 current treatments, 61% of patients have poor well-being according to WHO-5 Index

2.6
Years

mean time from symptom expression to diagnosis

1/2
of Patients

have been diagnosed with depression or anxiety in addition to gMG

51%
of Patients

stopped working completely from disease impact

35%
of Patients

need help from a caregiver with daily activities and 33% of caregivers have to cut back or stop working altogether

Redefining What 'Well-Controlled' Means for the Patient

**We want to transform gMG
treatment for patients**

Achieve minimal symptom expression

**Reduce reliance on broad
immunosuppressants**

Minimize treatment burden

**Regain control of their lives, including
professionally and socially**



Innovative Phase 3 Bridging Study

Consistent Responses Across IV and SC

MG-ADL RESPONDERS

69.1%

n=38/55

VYVGART Hytrulo

69.1%

n=38/55

VYVGART

SECONDARY MG-ADL responder: ≥2-point reduction
≥4 consecutive weeks during the first cycle

QMG RESPONDERS

65.5%

n=36/55

VYVGART Hytrulo

51.9%

n=28/54

VYVGART

SECONDARY QMG responder: ≥3-point reduction
for ≥4 consecutive weeks during the first cycle

MINIMAL SYMPTOM EXPRESSION

37.0%

n=20/54

VYVGART Hytrulo

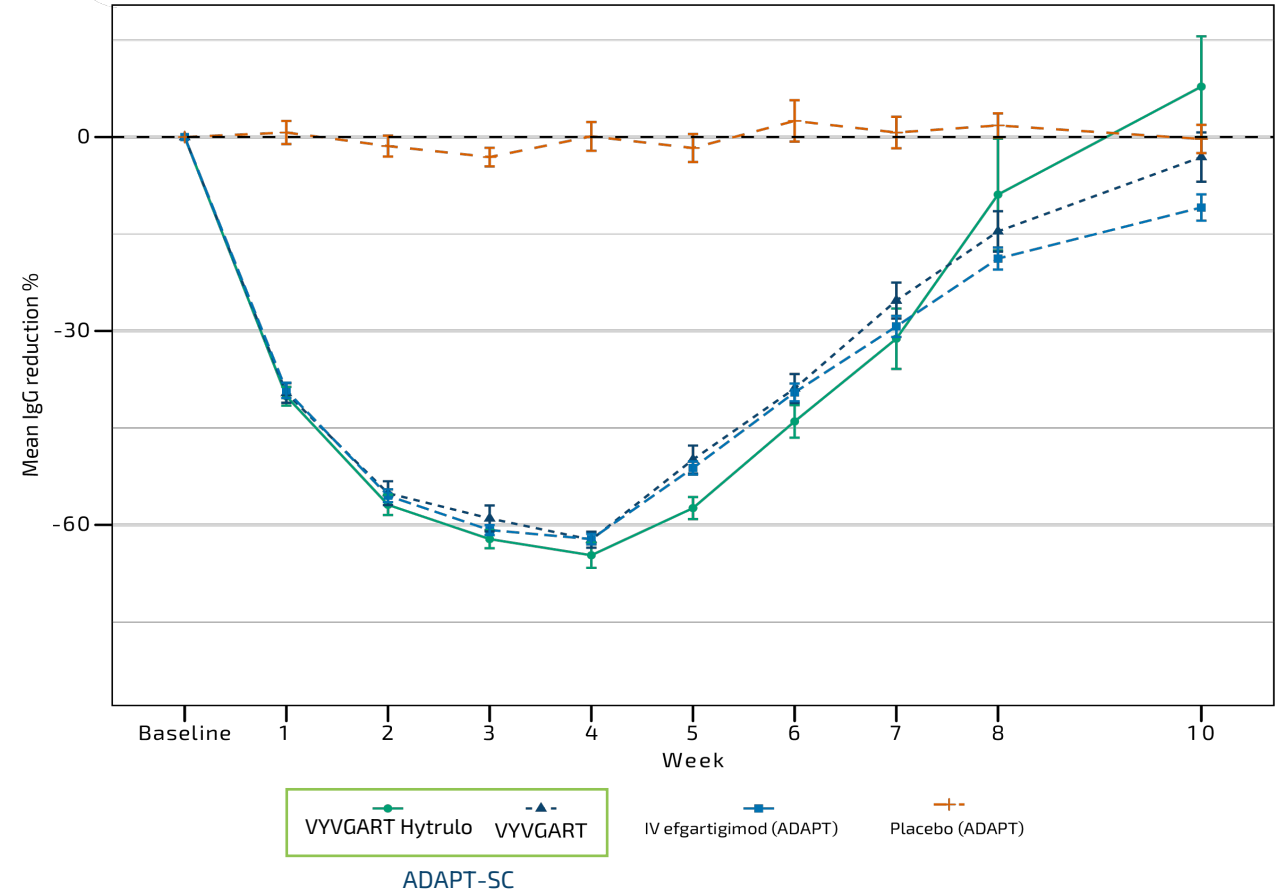
38.2%

n=21/55

VYVGART

EXPLORATORY MSE: MG-ADL score of 0 or 1

Primary endpoint of noninferiority met [$p < 0.0001$]



IgG reduction (%) in all ADAPT-SC and ADAPT participants

VYVGART® Hytrulo

(efgartigimod alfa and hyaluronidase-qvfc)

Injection for Subcutaneous Use

INDICATION STATEMENT

VYVGART Hytrulo is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

DOSING AND ADMINISTRATION

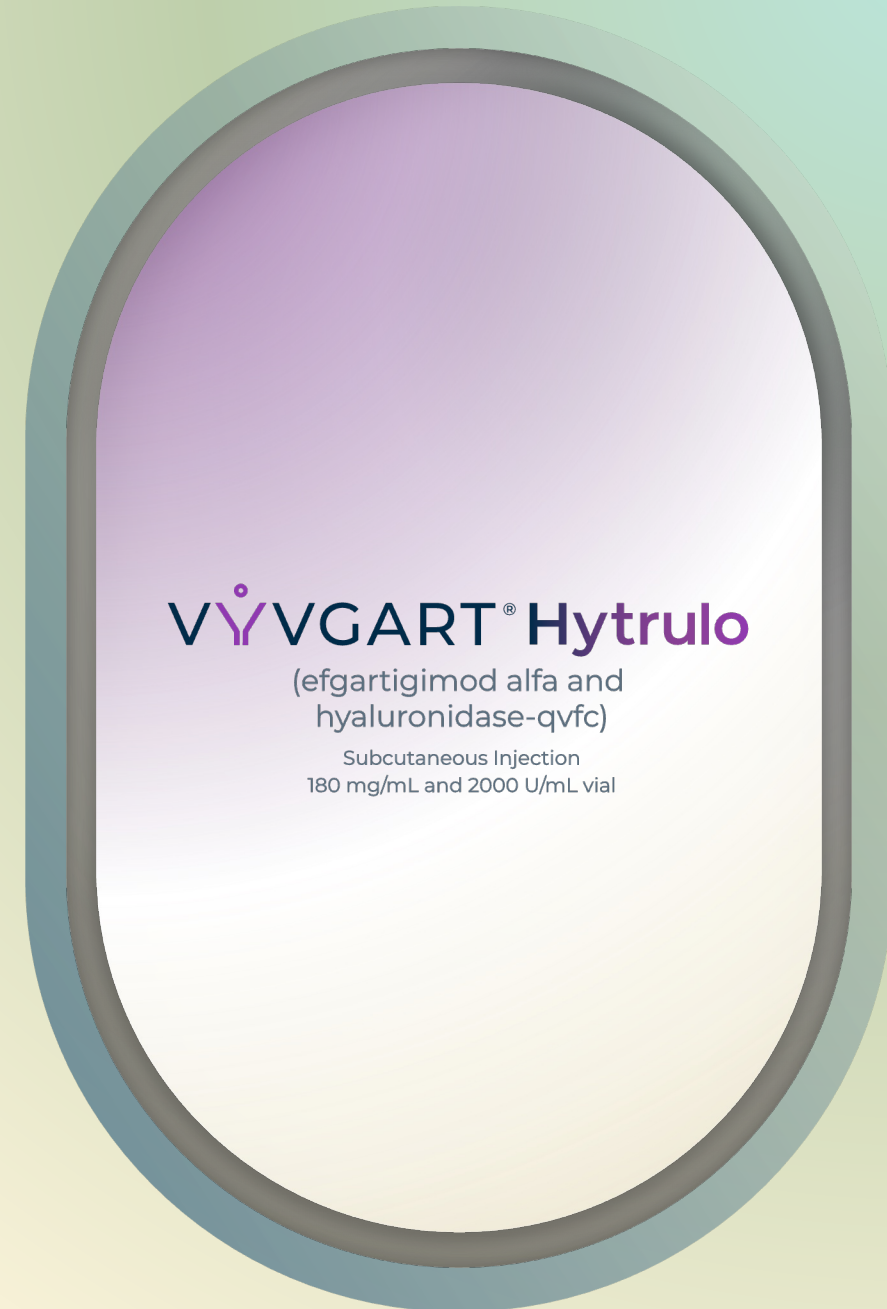
- Administer by a healthcare professional only
- Recommended dose is 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously over approximately **30 to 90 seconds** in cycles of once weekly injections for 4 weeks
- Subsequent treatment cycles to be administered based on clinical evaluation
- Safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established

ADVERSE REACTIONS

- The most common adverse reactions ($\geq 10\%$) in patients treated with intravenous VYVGART were respiratory tract infections, headaches, and urinary tract infection. Additional common adverse reactions with VYVGART Hytrulo are injection site reactions.

WARNINGS AND PRECAUTIONS

- Infections: delay administration to patients with active infection. Monitor for signs and symptoms of infection. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART Hytrulo until infection has resolved
- Hypersensitivity reactions: angioedema, dyspnea, and rash have occurred. If a hypersensitivity reaction occurs, discontinue the administration and institute appropriate supportive measures if needed



Chronic autoimmune diseases are complicated

VYVGART makes treatment simple



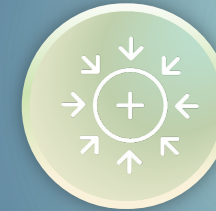
Flexibility and
Choice for
Patients



Broad HCP Use
and Adoption



Best-in-Class
Patient Support



Simplicity of
Access

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Injection for Intravenous Use
400 mg/20 mL vial

VYVGART[®] Hytrulo
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VYVGART Simplifies Treatment of gMG in the Community

Predictable safety and tolerability:
18 months and over 3000* real world patients

Simple Treatment Initiation:
broad access, no vaccination requirements

Choice in HOW to be treated:
IV infusion or SC injection

Demonstrated Efficacy:
78% responders across first two treatment cycles in ADAPT

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Options for site of care:
infusion center, HCP office, home administration

Lowering the bar for treatment initiation and expanding access for the

~17,000

current gMG patients we can address with VYVGART

Simplicity of Access: Driving Choice By Value to the Patient

ESTABLISHED VALUE TO PATIENTS

Creating a new standard for
gMG treatment

Flexibility and choice for
patients

IV has broad and early access

PARITY PRICING

Annual net price to be
similar across IV and SC
treatment options

PRODUCT CHOICE BY MARKET

Patient

Payor

HCP

Expected annual **SC** and **IV** net price for typical
VYVGART patient is approximately \$225,000

Price to vary based on individualized dosing and specific insurance
coverage, and mandatory government rebates and discounts

My VYVGART® Path

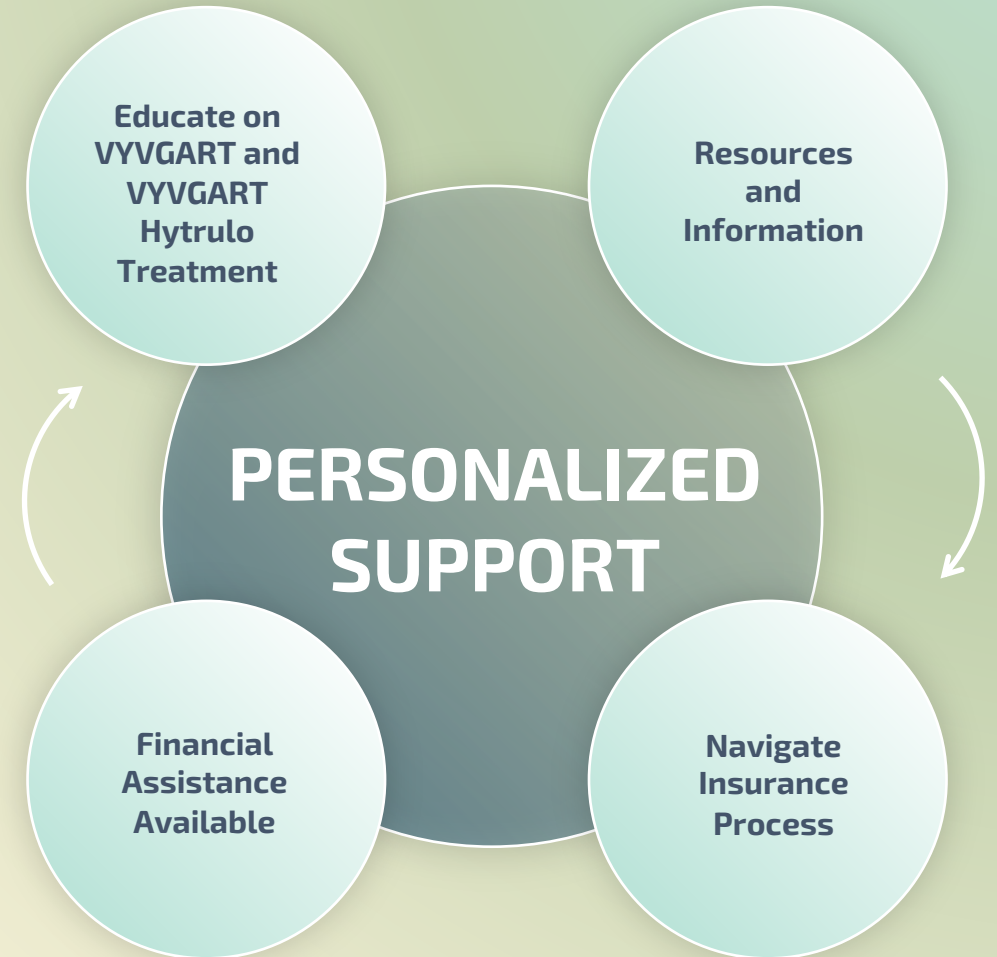
Here for you during your
VYVGART treatment journey



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VYVGART® Hytruo
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My VYVGART Path is Available to Provide Access Support and Education



Reaching gMG Patients Across the Globe

US



**VYVGART
Approved**
December 2021



**VYVGART Hytrulo
Approved**
June 2023

Global



Japan
Approved January 2022

United Kingdom
Approved March 2023

China (Zai Lab)
Expected approval in 2023

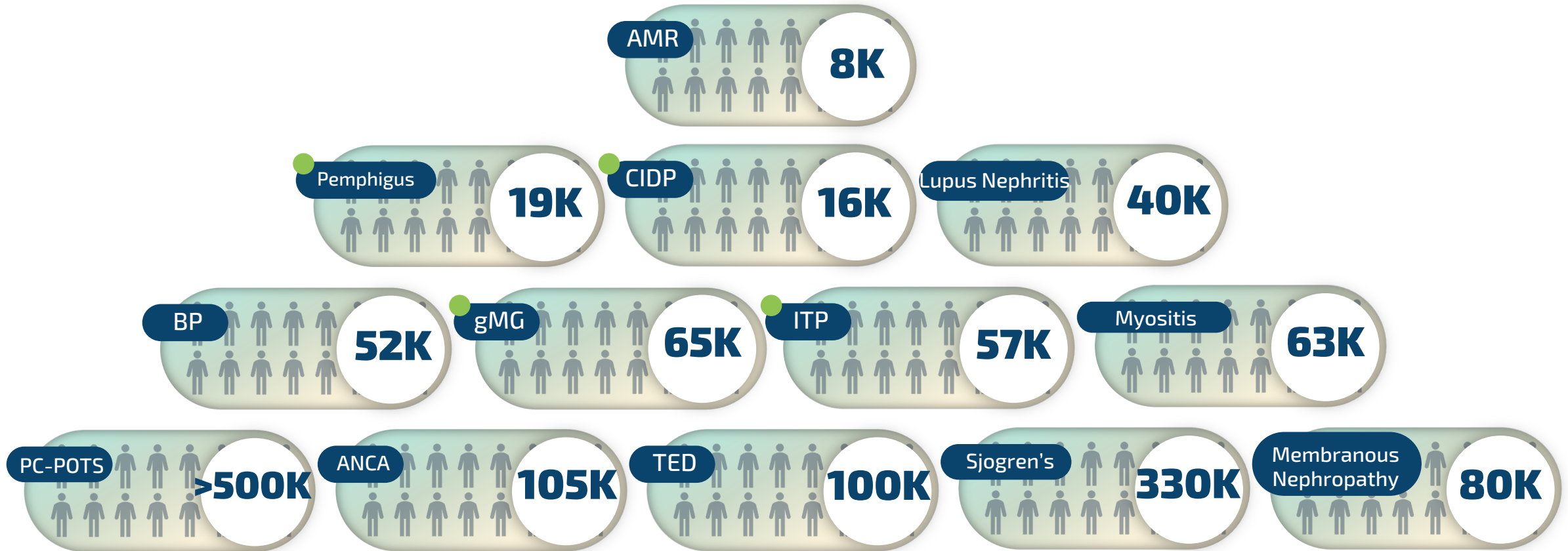
Europe
Approved September 2022

Israel (Medison)
Approved April 2023

Canada
Expected approval in 2023

Subcutaneous efgartigimod approval decisions expected in Europe and Japan by 1Q24

gMG is just the beginning

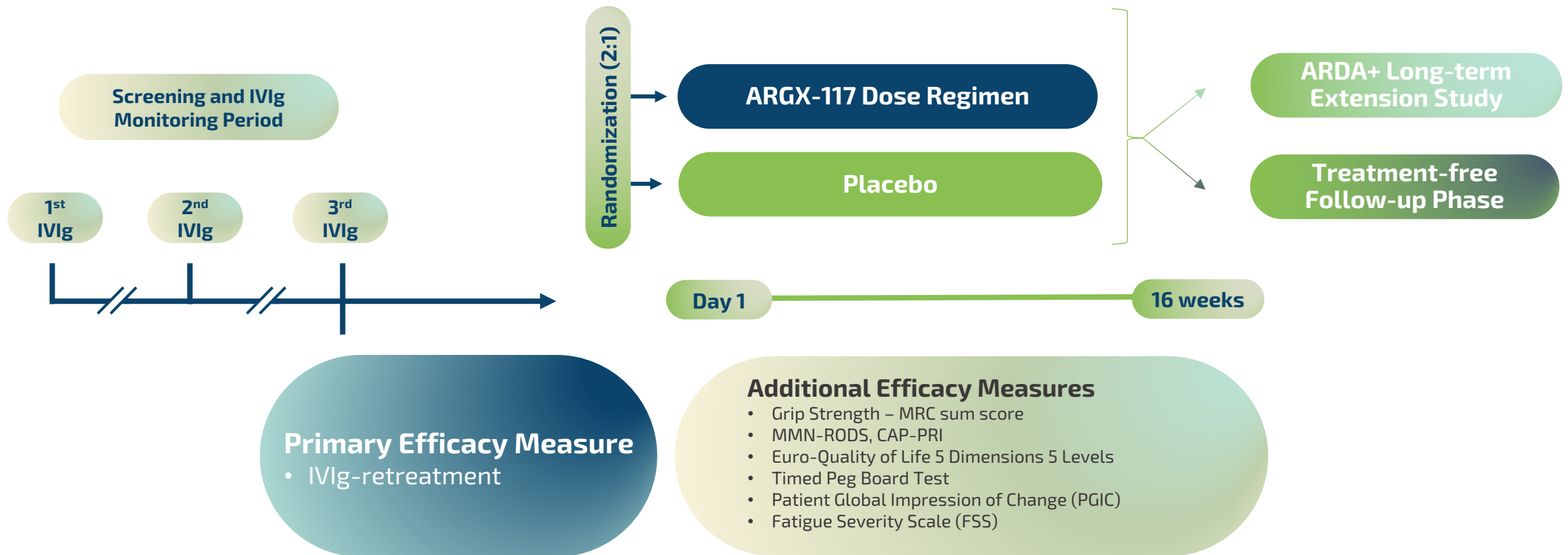


● indications with successful proof-of-concept or Phase 3 data

Empasiprubart for Multifocal Motor Neuropathy Advancing Phase 2 ARDA Study to Cohort 2



A phase 2, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the safety and tolerability, efficacy, pharmacokinetics, pharmacodynamics, and immunogenicity of two dose regimens of empasiprubart (ARGX-117) in adults with multifocal motor neuropathy



Our mission continues...

