

Together We Discover

Reaching Patients Through
Immunology Innovation

VYVGART™

(efgartigimod alfa-fcab) FDA Approval Call

December 17, 2021



Forward Looking Statements

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Safe Harbor: Certain statements contained in this presentation, other than present and historical facts and conditions independently verifiable at the date hereof, may constitute forward-looking statements. Examples of such forward-looking statements include those regarding its statements related to its the therapeutic and commercial potential of VYVGART; the response to treatment paradigm, including rapid HCP adoption of VYVGART; the estimated number of gMG patients in the U.S.; infrastructure, access and path to bring VYVGART to patients; the expected effect of value-based agreements with participating plans; expected pricing of VYVGART; the intended results of its strategy including global launch preparation; acceptance of efgartigimod for review by PMDA and anticipated approval in first quarter of 2022; that MAA filed with EMA and validated, with anticipated approval in second half of 2022; anticipated pathway for approval in China with NMPA by mid-2022; partnership agreement with Medison and anticipated filing in Israel during first quarter of 2022; its pre-approval programs in Europe and Canada; ambition to be in 15 efgartigimod indications by 2025; its clinical development and regulatory plans, including the timing and outcome of regulatory filings and approvals; the timing, progress and benefits of marketing and commercialization activities; and the expected size of the markets for VYVGART.





VYVGART Approval

Tim Van Hauwermeiren
Chief Executive Officer

VYVGART IS
NOW FDA-APPROVED

**VYVGART**TM
(efgartigimod alfa-fcab)

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

Where critical patient need
meets breakthrough science



That is where we redefine immunology



VYVGART: Highlights of U.S. Prescribing Information

INDICATION STATEMENT

VYVGART is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

DOSING AND ADMINISTRATION

- Evaluate need to administer age-appropriate vaccines according to immunization guidelines before initiation of new treatment cycle
- Recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks
- Subsequent treatment cycles to be administered based on clinical evaluation

WARNINGS AND PRECAUTIONS

- 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 until infection has resolved
- Angioedema, dyspnea, and rash have occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy



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

1/2
of Patients

have been diagnosed with depression or anxiety in addition to gMG

2.6
Years

mean time from symptom expression to diagnosis

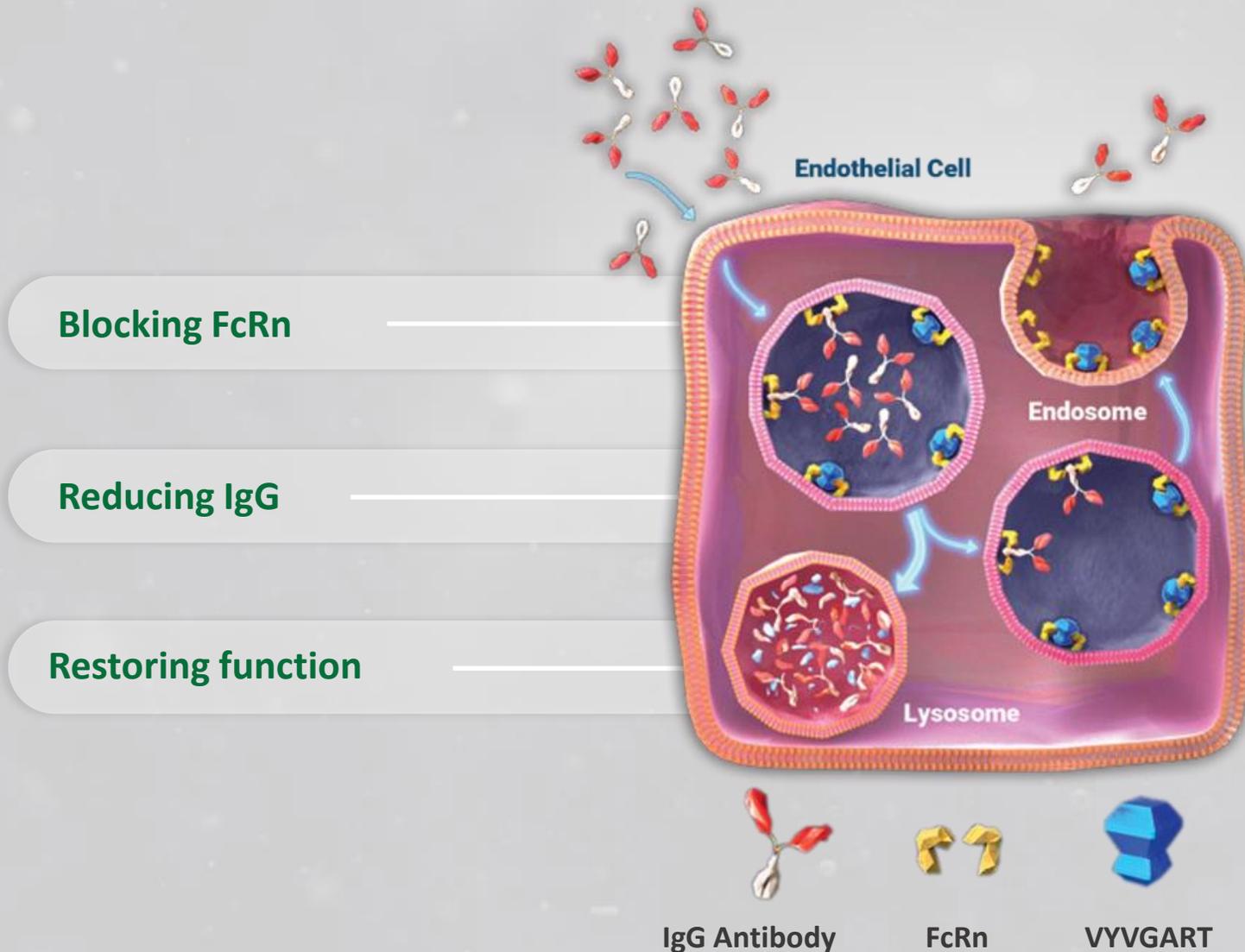
Symptoms can vary from patient to patient, day to day, **or even throughout the same day**...this unpredictability contributes to emotional burden of disease

51%
of Patients

stopped working completely from disease impact

Surveyed neurologists ranked severe gMG only behind ALS as most severe disease they treat

VYVGART: First FDA-Approved FcRn Antagonist



Mechanism of Action: VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG.



ADAPT Clinical Data Review

Wim Parys, M.D.
Chief Medical Officer

VYVGART Clinical Development



Randomized, double-blind
placebo-controlled Phase 3 trial
of 167 adult gMG patients



Ongoing single-arm
open-label extension study



Results from ADAPT
published in July 2021

ADAPT Study Design

Individualized Treatment Cycles

DESIGN

167 adult gMG patients

MGFA Class II, III, IV

Anti-AChR antibody positive and negative

MG-ADL score $\geq 5^a$

On ≥ 1 stable gMG treatment^b

2 weeks screening

Patients randomized 1:1 to receive 10 mg/kg VYVGART or placebo



All patients receive initial treatment cycle

(1-hour infusion once weekly for 4 weeks)

Individualized treatment cycles

(≤ 3 cycles in 26 weeks)

Time between cycles determined by duration of clinically meaningful improvement^c

Primary Endpoint

MG-ADL responder: ≥ 2 -point reduction for ≥ 4 consecutive weeks, with the first reduction occurring by week 4 during the first cycle (8 weeks) in anti-AChR antibody positive patients

Open-label extension (≤ 3 years of treatment)

151 patients who completed ADAPT entered ADAPT+ study

AChR, acetylcholine receptor; MG-ADL, Myasthenia Gravis Activities of Daily Living; NSIST, nonsteroidal immunosuppressive therapy; MGFA Myasthenia Gravis Foundation of America

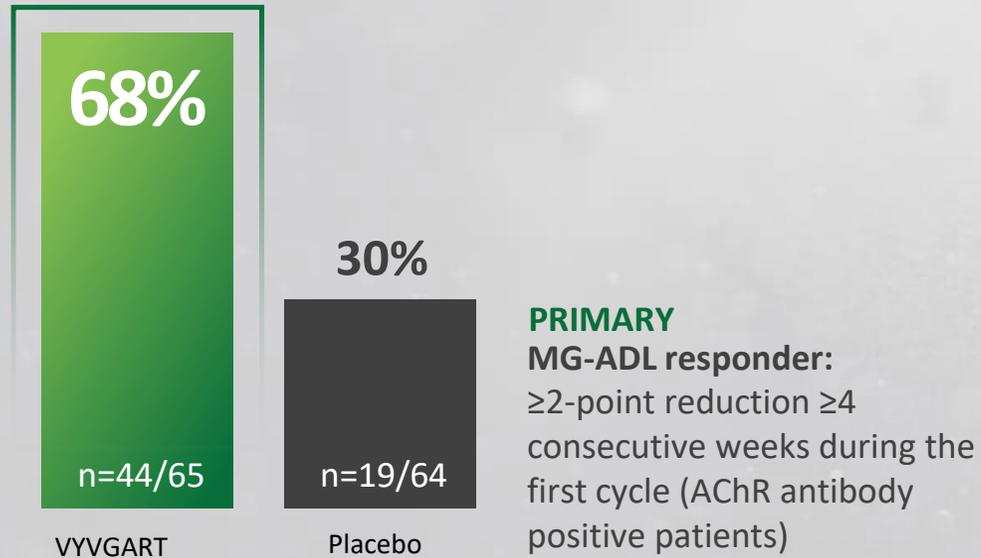
^a50% of score attributed to nonocular items; ^bAcetylcholinesterase inhibitor, steroid, and/or NSIST for the duration of the trial. ^cCriteria for initiation of next cycle: ≥ 8 weeks from start of previous cycle, total MG-ADL ≥ 5 points, MG-ADL ≤ 2 points of baseline

1. Howard JF, et al. *Lancet Neurol.* 2021;20(7):526-536.

Treatment Benefit Demonstrated with MG-ADL and QMG Disease Scores

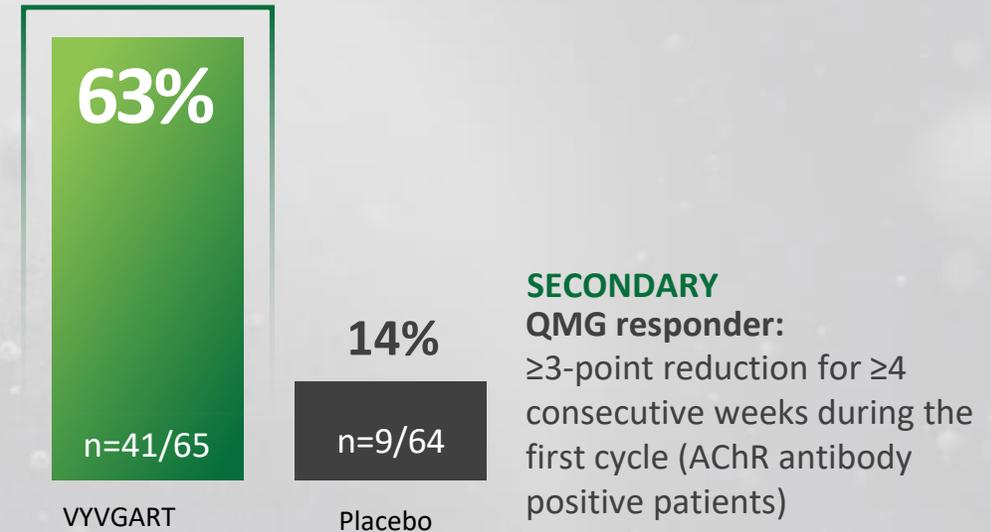
MG-ADL RESPONDERS

$P < .0001$



QMG RESPONDERS

$P < .0001$



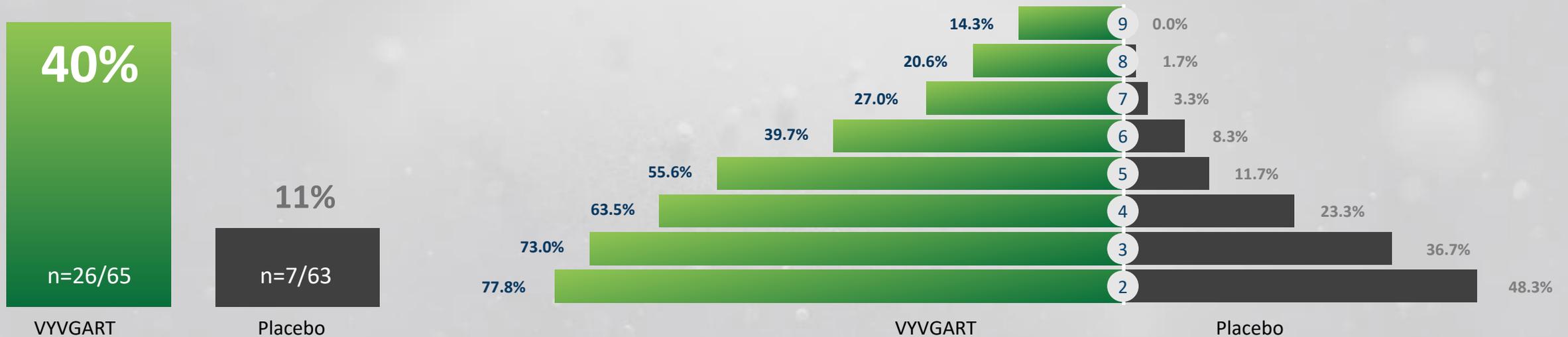
Treated Patients Demonstrated Depth of Response

Exploratory Endpoints

Proportion of AChR-Ab+ patients with MSE (MG-ADL 0 or 1) during cycle 1

Proportion of AChR-Ab+ patients with increasing MG-ADL improvement (week 4)

Minimum Improvement in Total MG-ADL Score



AChR-Ab, acetylcholine receptor antibody; MG-ADL, Myasthenia Gravis Activities of Daily Living; MSE, minimal symptom expression
 *Howard JF, et al. Lancet Neurol. 2021;20(7):526-536.

Safety: Summary of Adverse Events

	VYVGART (n=84) n (%)	Placebo (n=83) n (%)
AEs^a	65 (77)	70 (84)
SAEs^b	4 (5)	7 (8)
≥1 infusion-related reaction event^c	3 (4)	8 (10)
Infection AEs^d	39 (46)	31 (37)
Discontinued study treatment due to AEs^e	3 (4)	3 (4)
Severe AEs (grade ≥3)	9 (11)	8 (10)
Most frequent AEs		
○ Headache	24 (29)	23 (28)
○ Nasopharyngitis	10 (12)	15 (18)
○ Nausea	7 (8)	9 (11)
○ Diarrhea	6 (7)	9 (11)
○ Upper respiratory tract infection	9 (11)	4 (5)
○ Urinary tract infection	8 (10)	4 (5)

ECG, electrocardiogram; SAE, serious adverse event; ^aAEs were predominantly mild or moderate in severity. ^bSAEs efgartigimod group: thrombocytosis, rectal adenocarcinoma, MG worsening (each leading to treatment discontinuation), and depression; SAEs placebo group: 1 case each of myocardial ischemia, atrial fibrillation, spinal ligament ossification (that led to treatment discontinuation); remaining events were URTI, spinal compression fracture, MG worsening, and MG crisis. ^cAll infusion AEs were mild in severity. ^dAll infections were mild to moderate in severity except for 3 severe events: influenza and pharyngitis (efgartigimod) and URTI (placebo). ^eEfgartigimod group: MG worsening, rectal adenocarcinoma, thrombocytosis (all SAEs); placebo group: myocardial ischemia, atrial fibrillation, spinal ligament ossification (all SAEs). Howard JF, et al. *Lancet Neurol.* 2021;20(7):526-536.



Commercial Strategy

Keith Woods
Chief Operating Officer

Challenge the gMG Treatment Paradigm

Meeting our stakeholders where they are



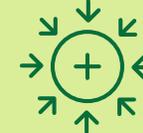
Empower Patients
to Demand Better



Best-in-Class
Patient
Support

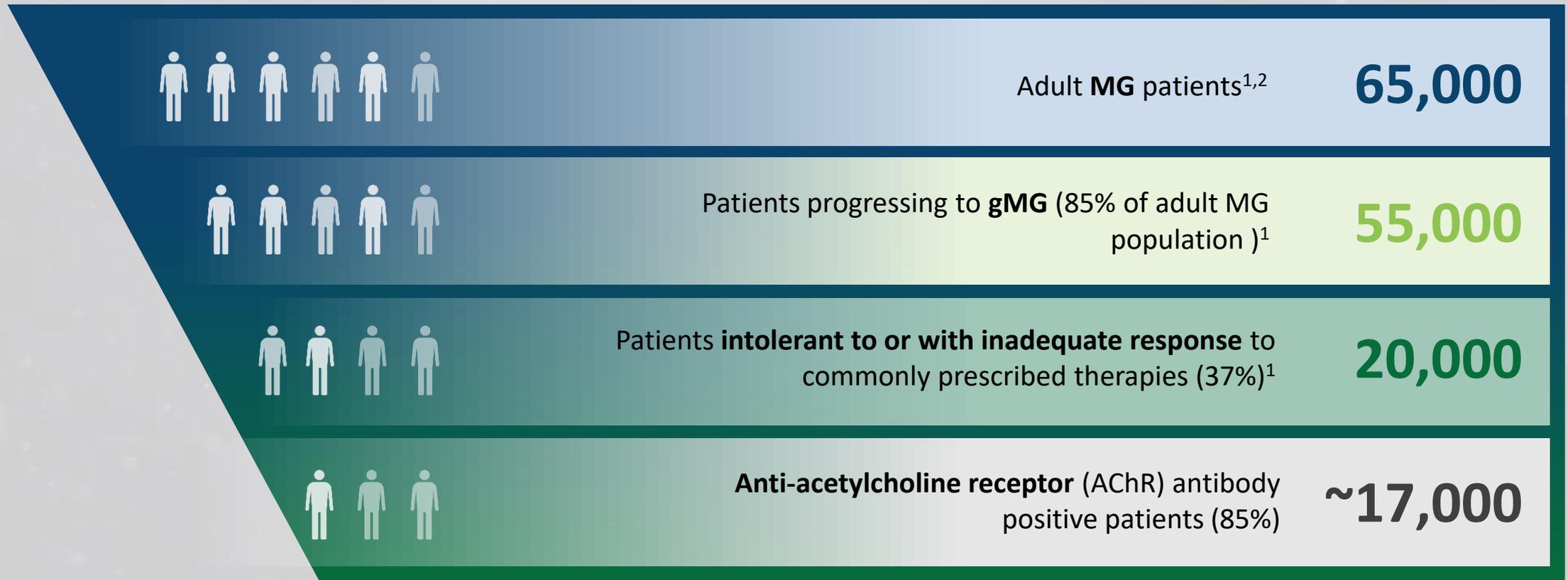


Rapid HCP
Adoption of
VYVGART



Enable
Appropriate
Access

~17,000 Adult gMG Patients in U.S. Not Well-Managed with Current Treatment Options



* Patients intolerant to or with inadequate response to prior treatment with conventional therapies based on claims analysis that found that 36.7% of MG patients had progressed past treatment with an acetylcholine esterase inhibitors and/or steroids.
1. Gilhus N, et al. *Nat Rev Neurol*. 2016;12(5):259-268. 2. Meriggioli M, et al. *Lancet Neurol*. 2009;8(5):475-490. 3. argenx. Data on File from IQVIA PharMetrics Database.

Infrastructure to Bring VYVGART to Physicians and Patients

* **7.7K Neurologists** treat **97%** of gMG patients

VYVGART Field Teams

- **71** Territory Business Managers
- **10** Thought Leader Liaisons
- **16** Medical Research Liaisons
- **10** Nurse Case Managers
- **13** Market Access Professionals
- **10** Field Reimbursement Managers



Infusion Sites
of Care



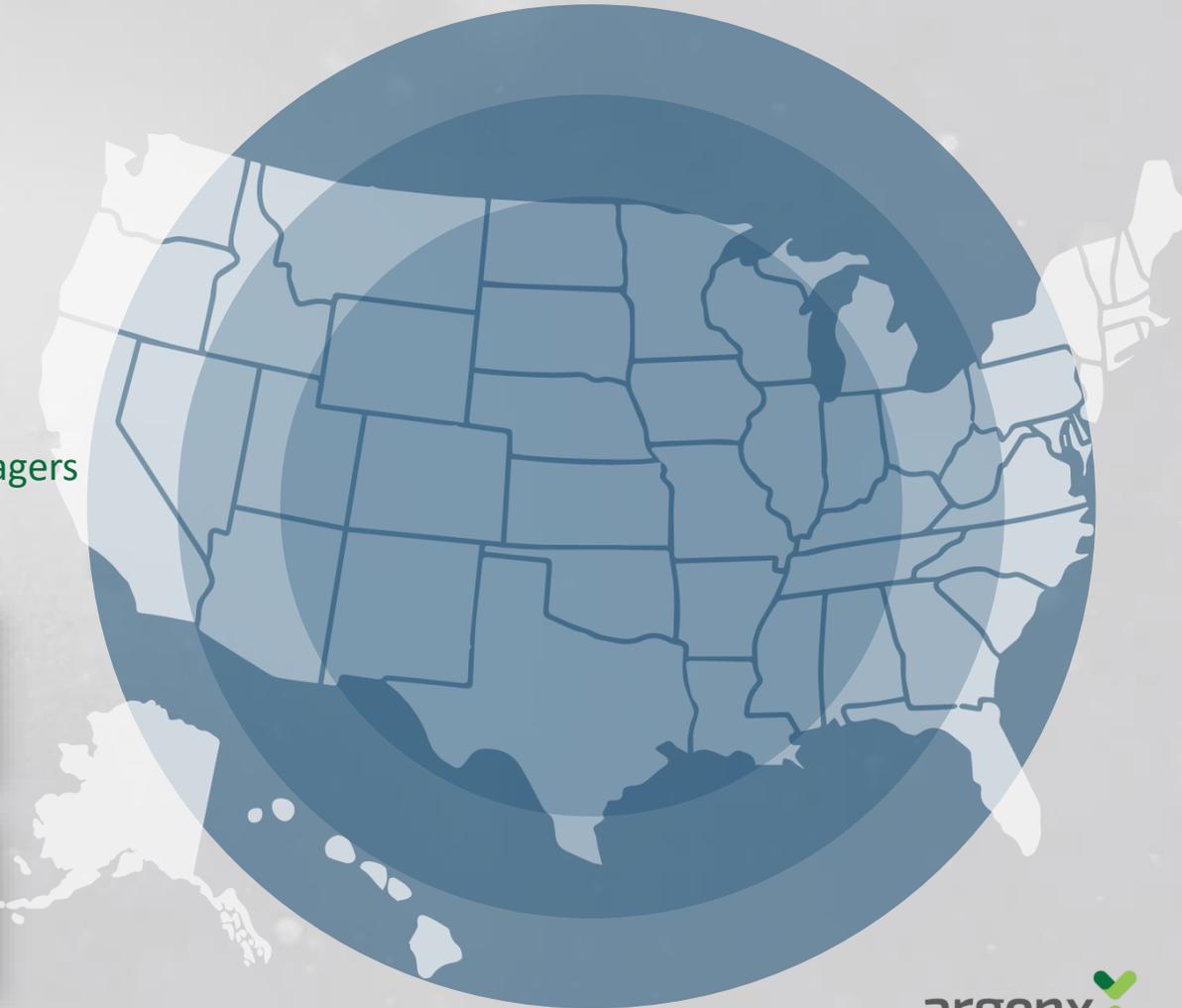
National Specialty
Pharmacies



Home Infusion
Nurses



Access in all **50**
States



Increasing Physician Awareness

- Peer-to-peer speaker programs
- Multi-channel HCP activation
- Integrated HCP input into activation plan



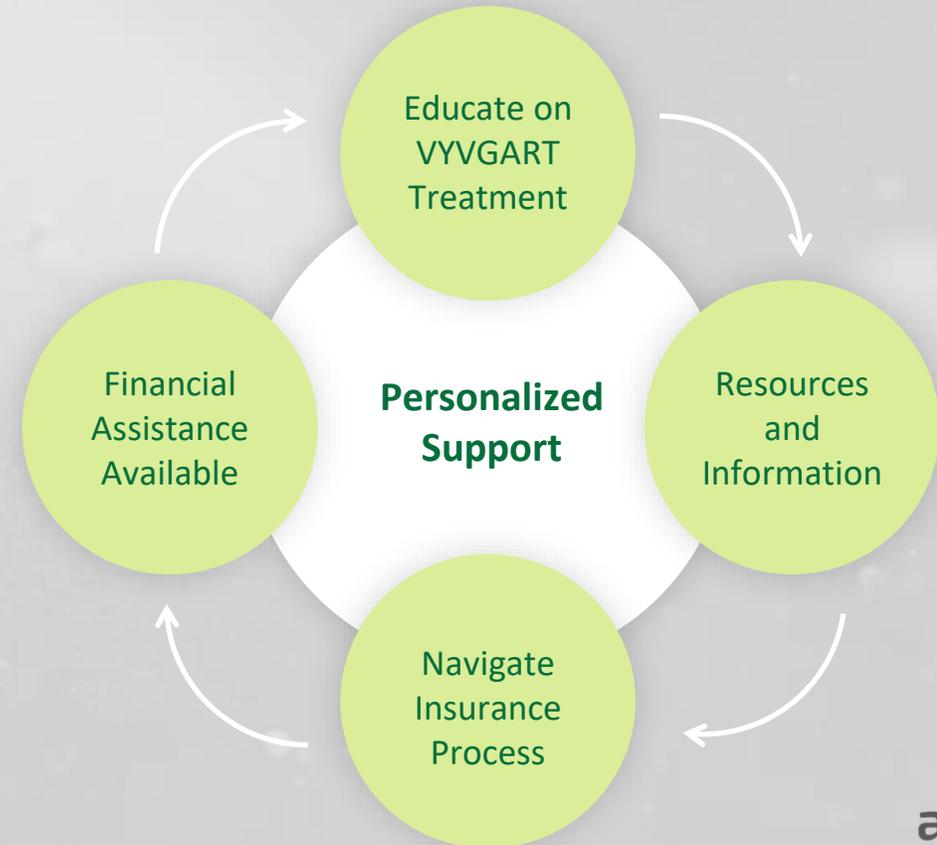
Build experience curve to drive HCPs from awareness to adopting use of VYVGART where appropriate

My VYVGART™ Path
Here for you during your
VYVGART treatment journey



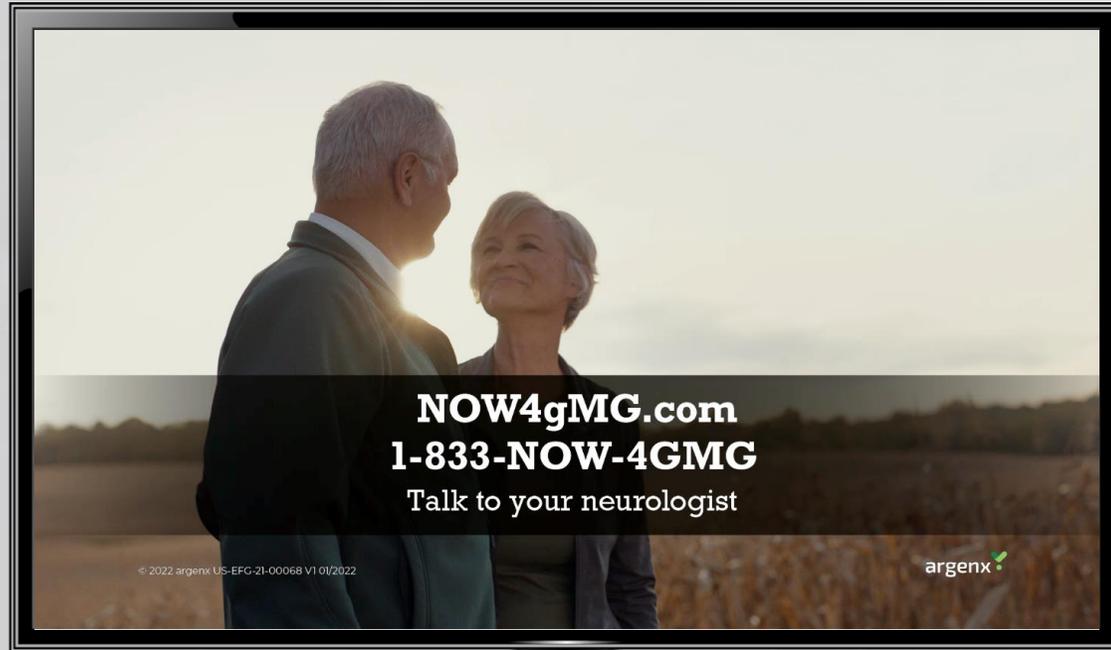
VYVGART™
(efgartigimod alfa-fcab)

My VYVGART Path is Available to Provide Access Support and Education



Activating the Patient

Disease Awareness



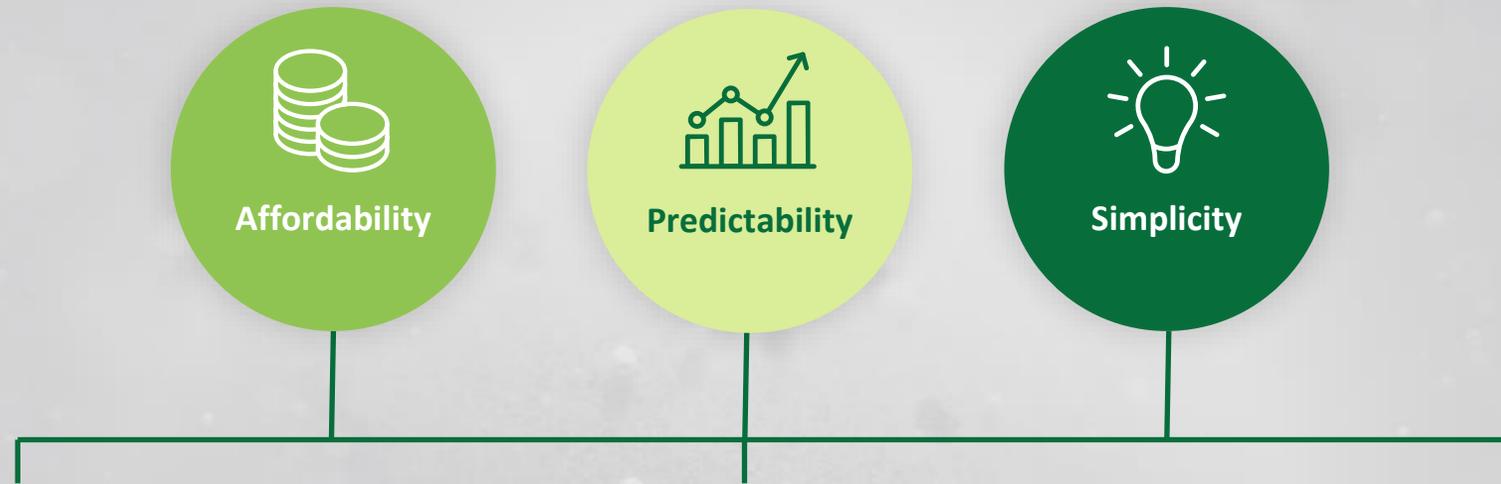
NOW4gMG.com
1-833-NOW-4GMG
Talk to your neurologist

Direct-to-Consumer Campaign



VYVGARTTM
(efgartigimod alfa-fcab)

Key Pillars of VYVGART Value-Based Agreement



The value-based agreement helps provide cost predictability to participating plans aligning interests between patients, physicians and payers

Pricing Based on Value to Patients

ADAPT Clinical Data

Significant
Response
Rates
(MG-ADL and
QMG scales)

Demonstrated
Safety

Individualized
Dosing

Real World Evidence Data

- gMG imposes significant burden on patients and HCPs
- >70% of gMG patients not well managed on current treatments

Expected annual net price
for typical VYVGART patient is
\$225,000

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

Global Launch Preparations Underway

Global



Japan

J-MAA for IV efgartigimod for treatment of gMG accepted for review by PMDA
Anticipated decision in 1Q 2022

EU

MAA filed with EMA and validated
Anticipated decision in 2H 2022

China

Zai Lab to discuss potential accelerated regulatory pathway for approval in China with NMPA
Anticipated filing by mid-2022

Israel

Partnership agreement with Medison
Anticipated filing in 2Q 2022



United States

VYVGART Approved by
FDA on
December 17, 2021

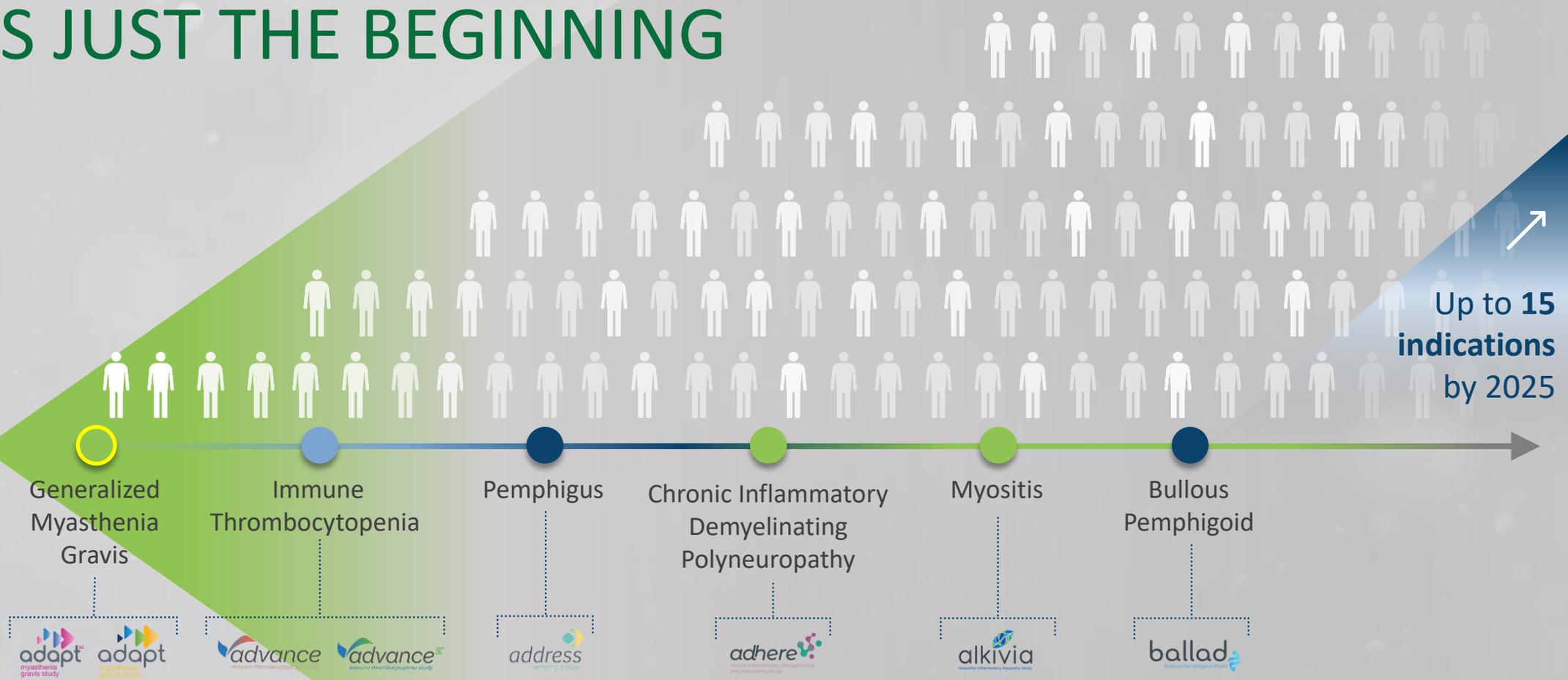


**Pre-Approval Access Program Open
in Europe and Canada**

First Approval In Neuromuscular Franchise

THIS IS JUST THE BEGINNING

VYVGART™
(efgartigimod alfa-fcab)



Key: ■ NEURO ■ HEME ■ SKIN ■ KIDNEY

Together We Discover

Reaching Patients Through
Immunology Innovation

