FDA APPROVAL CALL | JUNE 21, 2024

VYVGART® HYTRULO

NOW INDICATED FOR CIDP

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Forward Looking Statements

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Approval Overview

TIM VAN HAUWERMEIREN

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VYVGART Hytrulo Now FDA-Approved for CIDP

1958* Corticosteroids

1979* PLEX

1985* IG

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

First and only targeted IgG Fc-antibody fragment†

- Non-plasma derived biologic therapy for CIDP
- Targets FcRn, reducing IgG antibodies, including pathogenic autoantibodies

VYVGART Hytrulo is a coformulation of efgartigimod alfa and hyaluronidase. By depolymerizing hyaluronan, hyaluronidase increases permeability of the subcutaneous tissue.

*Indicates the date of the first published description of positive clinical efficacy in CIDP.
†Human IgG-derived.

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Highlights of U.S. Prescribing Information

INDICATION STATEMENT

VYVGART Hytrulo is a neonatal Fc receptor blocker indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

DOSING AND ADMINISTRATION

- Evaluate need to administer age-appropriate vaccines according to immunization guidelines before initiation of new treatment cycle
- Recommended dosage 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 as once weekly injections

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

CIDP Patients Need New Options

Significant pain, numbness in hands and feet

80%
report **difficulty standing**[1]

>50%
dissatisfied with **symptom burden**[2]

Feelings of **isolation** and **depression**

≤20%
achieve remission on current SOC[3]

88%
have **residual neurological symptoms**[4]

1. Wonink HA et al. 2023
2. Mendoza M, et al. 2023
3. Gorson KC, et al. 2010
4. Bunschoten C et al. 2019

Clinical Data Review

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Innovative ADHERE Study Design

Identify patients with active CIDP

Screening

≤4 WEEKS

Clinical Confirmation Committee

Run-in period

≤12 WEEKS

Patients need to demonstrate disease worsening off-treatment based on INCAT, I-RODS, grip strength

Confirm IgG involvement

Assess efficacy & safety

Treatment Period

Open-label

Randomized, placebo-controlled

Stage A (N=322)

Stage B (N=221)

VYVGART HYTRULO WEEKLY

≤12 WEEKS

Primary analysis: % documented improvement in functional ability and/or strength

RESPONDERS ONLY ADVANCE TO STAGE B

VYVGART HYTRULO OR PLACEBO WEEKLY

≤48 WEEKS

Primary endpoint: relative risk of relapse based on time to first INCAT deterioration

99%

eligible patients rolled over to **Open Label Extension** study

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Key Data from ADHERE Trial

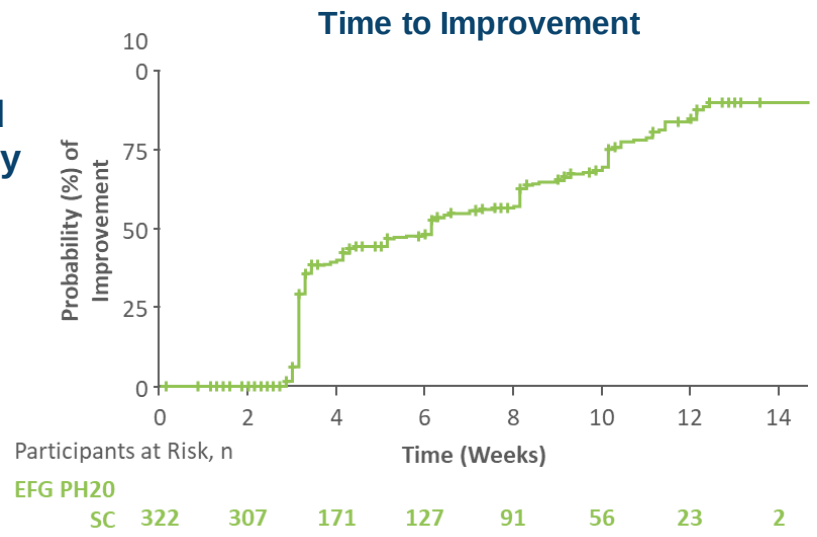
STAGE A

40%

Demonstrated improvement by Week 4

2/3

Improved / progressed to Stage B

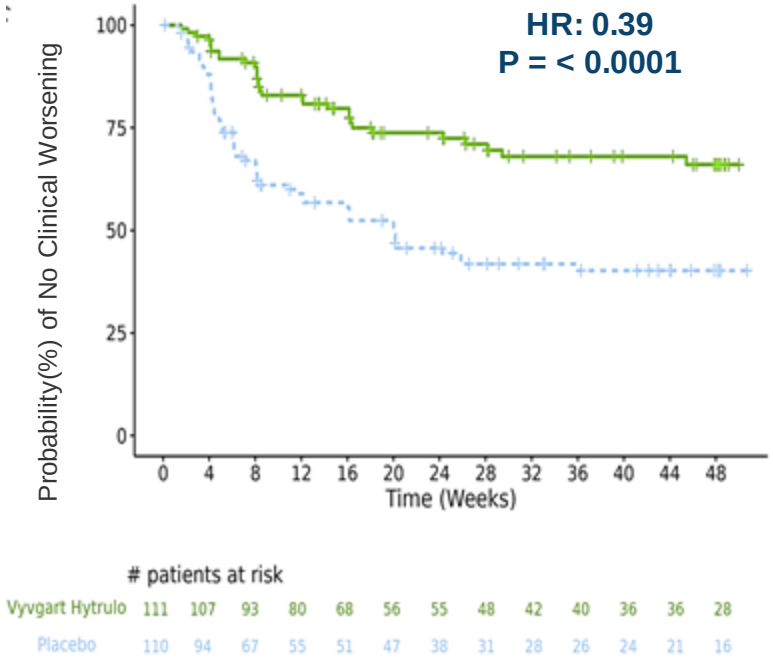


STAGE B

61%

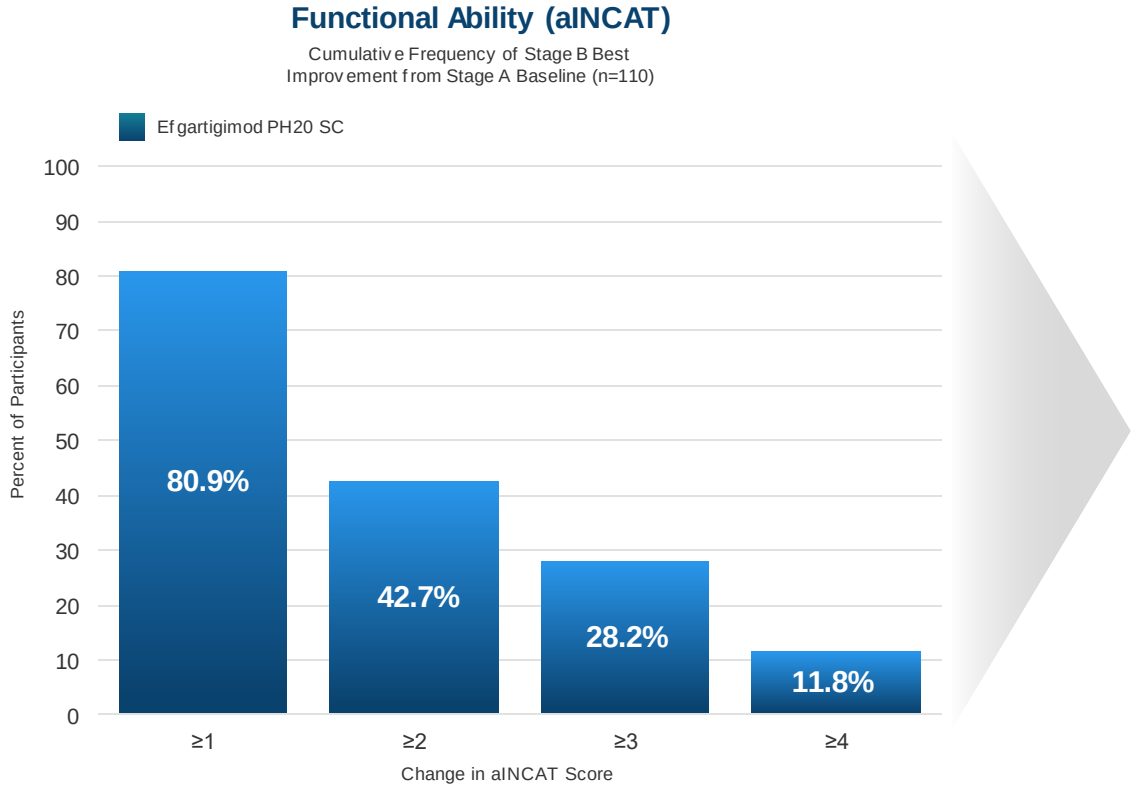
reduced risk of relapse

Consistent response across subgroups



Patients Experienced Deep and Clinically Meaningful Improvements in Functional Ability

~30% patients able to improve 3-4 points on INCAT**



INCAT Disability Scale: Arm Disability*

0= No upper limb problems; 1= Symptoms in one/both arms without impacting the ability to perform certain functions
2= Symptoms in one/both arms affecting but not preventing the ability to perform functions; 3= Symptoms in one/both arms preventing the performance of 1-2 functions; 4= Symptoms in one/both arms preventing the performance of ≥3 functions;
5= Inability to use either arm for any purposeful movement

INCAT Disability Scale: Leg Disability*

0= Walking not affected; 1= Walking affected, but walks independently outdoors; 2= Usually uses unilateral support to walk outdoors; 3= Usually uses bilateral support to walk outdoors; 4= Usually uses wheelchair to travel outdoors, but able to stand and walk a few steps with help;
5 = Restricted to wheelchair, unable to stand and walk a few steps with help

*The INCAT disability score[1] is a 10-point scale that assesses activity limitations of arms and legs; both are scored separately from 0–5, with 0 representing no functional impairment and 5 representing inability to make any purposeful movement.
**ADHERE clinical trial data

ADHERE Trial Safety: Summary of Adverse Events

	Open-Label Stage A	Double-Blinded Stage B	
n (%)	Efgartigimod PH20 SC (N=322; PYFU=46.9)	Efgartigimod PH20 SC (N=111; PYFU=56.7)	Placebo (N=110; PYFU=42.1)
PARTICIPANT WITH EVENT			
Any TEAE	204 (63.4)	71 (64.0)	62 (56.4)
Any SAE	21 (6.5)	6 (5.4)	6 (5.5)
Injection site reactions	62 (19.3)	16 (14.4)	7 (6.4)
Discontinued due to AEs[a]	22 (6.8)	3 (2.7)	1 (0.9)
Deaths[b]	2 (0.6)	0 (0)	1 (0.9)
MOST COMMON TEAES (≥5% OF PARTICIPANTS IN ANY GROUP)			
Injection site erythema	33 (10.2)	6 (5.4)	0 (0)
CIDP	17 (5.3)	1 (0.9)	1 (0.9)
Headache	16 (5.0)	4 (3.6)	2 (1.8)
Upper respiratory tract infection	11 (3.4)	2 (1.8)	11 (10.0)
COVID-19	6 (1.9)	19 (17.1)	14 (12.7)
Injection site bruising	4 (1.2)	6 (5.4)	1 (0.9)

AE, adverse event; CIDP, chronic inflammatory demyelinating polyneuropathy; COVID-19, coronavirus disease 2019; PH20, recombinant human hyaluronidase PH20; PYFU, participants years of follow-up; SAE, serious adverse event; SC, subcutaneous; TEAE, treatment-emergent adverse event. [a]TEAEs grouped under Preferred Terms leading to efgartigimod PH20 SC discontinuation were Cardiac arrest (n=1), Injection site rash (n=1), COVID-19 (n=1), COVID-19 pneumonia (n=1), Muscular weakness (n=1), CIDP (n=15), Quadriparesis (n=1), and Pruritus (n=1) in stage A; COVID-19 pneumonia (n=1), Prostate cancer (n=1), and Transitional cell carcinoma (n=1) in stage B efgartigimod PH20 SC; and Pneumonia (n=1) in stage B placebo SC. [b]Two deaths (cardiac arrest and deterioration of CIDP) in stage A were considered not related to efgartigimod PH20 SC by the investigator; one death (pneumonia) in the placebo arm of stage B was considered treatment related by the investigator.

Commercial Strategy

KAREN MASSEY

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Raising Expectations for CIDP Patients

"Every day is your new normal. I had to learn how to continue life - every single day - even though things are going to be different for me."

SCOTT- CIDP PATIENT

Maximizing Impact of VYVGART Hytrulo

Empower Patients to Demand more from their Treatment

Provide Best in Class Patient Support

Drive Rapid Healthcare Provider Adoption

Deliver Broad Access

12,000 Adult CIDP Patients in U.S. Not Well-Managed with Current Treatment Options

Diagnosed CIDP Patients — ~41K

Treated CIDP Patients
Includes all patients treated on IVIG/SCIG, PLEX, steroids, biologics, other — ~24K

Patients Not Well-Managed on Current Therapy* — ~12K

*This is defined as patients who either are not responding well to current treatment or experiencing negative side effects
Source: argenx market research, IQVIA LAAD data

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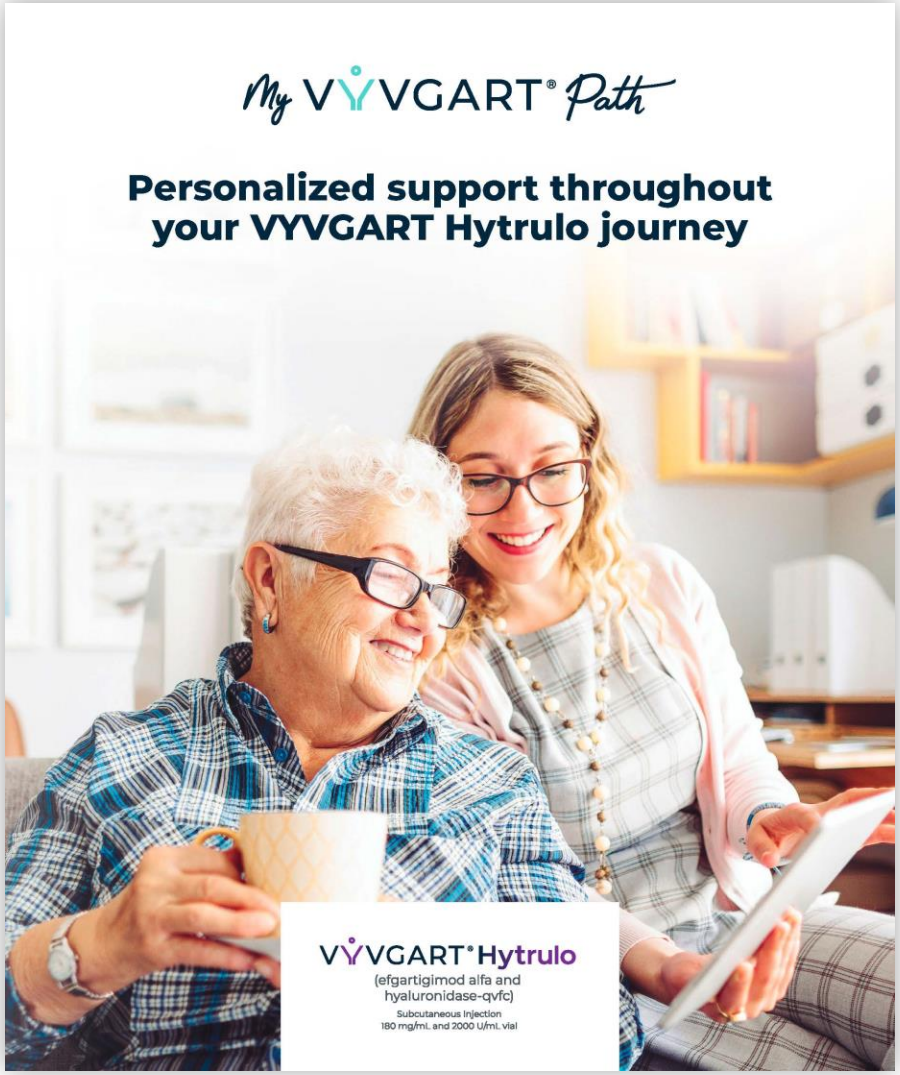
Activating an Empowered Patient Community

NAVIGATING HEALTHCARE

Discussion Guide: Talking to Your Doctor About Your Experience With CIDP

Discover a guide to track symptoms and abilities aimed to help you have more productive conversations with your doctor.



Driving Rapid Adoption with Neurologists

Neurology Landscape

10K
Target Neurologists

72%
CIDP/MG Prescriber Overlap

Reaching the Right Physicians

- Expansion of deeply experienced sales force
- Strong relationships with existing VYVGART prescribers

Leveraging the Strength of ADHERE data

- First innovation in 30 years
- Compelling combined safety, efficacy, convenience

Providing Reimbursement Support

- Support navigating the reimbursement process

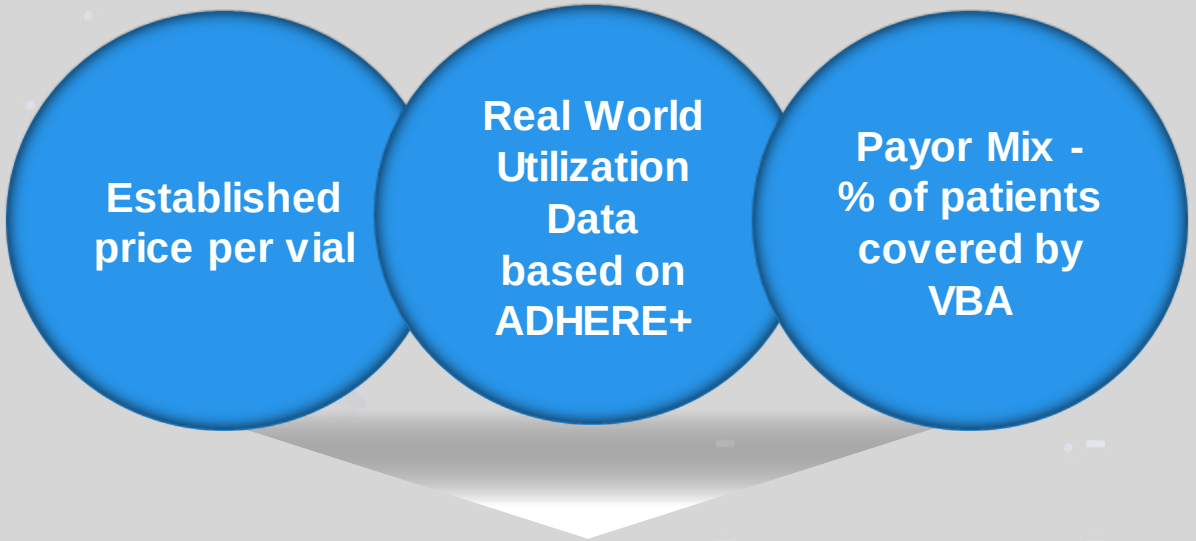
Source: Komodo claims data; argenx market research

Securing Broad Access

Establishing Value Based Agreements

- Ability to leverage existing established relationships with payors
- CIDP VBA designed to cap the exposure of payors based on number of vials per year
- Designed to enable access for eligible patients and provide predictability to payors

Net Revenue Per Patient



Average annual out-of-pocket cost to the patient similar to MG

Expected annual net revenue per patient of ~$450,000*

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*Revenue per patient to vary based on individualized dosing and specific insurance coverage, and mandatory government discounts and rebates

Multidimensional Expansion in CIDP

VYVGART® Hytrulo Approved June 21, 2024

Pre-filled syringe (PFS) filed June 2024

Expected Decisions on Approval 2025

- Filing submitted (VYVDURA) April 2024
- Zai Lab announced acceptance of sBLA in China May 2024
- Submission filed with EMA June 2024

Looking Ahead

TIM VAN HAUWERMEIREN

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Where Innovation Meets Critical Unmet Need