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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of February 2021**

**Commission File Number: 001-38097**

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**ARGENX SE**

(Translation of registrant's name into English)

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**Willemstraat 5**

**4811 AH, Breda, the Netherlands**

(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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#### **EXPLANATORY NOTE**

On February 1, 2021, argenx SE (the “Company”) issued a press release, a copy of which is furnished hereto as Exhibit 99.1, and an investor presentation, a copy of which is filed hereto as Exhibit 99.2.

*The information contained in Exhibit 99.2 to this Current Report on Form 6-K is incorporated by reference into the Company’s Registration Statements on Forms F-3 (File No. 333-225370) and S-8 (File No. 333-225375). The information contained in Exhibit 99.1 to this Current Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), and shall not be incorporated by reference into any filing under the Securities Act or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.*

<b>Exhibit</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release, dated February 1, 2021</u></a>
<a href="#"><u>99.2</u></a>	<a href="#"><u>Investor Presentation, dated February 1, 2021</u></a>

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### ARGENX SE

Date: February 1, 2021

By: /s/ Dirk Beeusaert  
Dirk Beeusaert  
General Counsel

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### Regulated Information/Inside Information

#### argenx Announces “GO” Decision in ADHERE Trial of Efgartigimod in Chronic Inflammatory Demyelinating Polyneuropathy Following Interim Analysis

- Independent data monitoring committee confirmed go-forward decision based on evaluation of interim safety as well as efficacy assessments that surpassed pre-defined “GO” threshold
  - 130 patients targeted for enrollment to support registrational program in CIDP
  - Management to host conference call today at 2:30 p.m. CET (8:30 a.m. ET)

**February 1, 2021**

**Breda, the Netherlands** – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced its plan to continue enrollment in the ADHERE trial evaluating subcutaneous (SC) efgartigimod (co-formulated with Halozyme's ENHANZE<sup>®</sup> drug-delivery technology) in chronic inflammatory demyelinating polyneuropathy (CIDP). The ADHERE trial is expected to enroll approximately 130 patients to support potential registration of SC efgartigimod for the treatment of CIDP.

“Following our review of the interim ADHERE data and confirmation from the data monitoring committee, we are confident in our decision to continue with enrollment. We relied on key learnings from precedent CIDP trials in defining our go-forward thresholds and are excited to have cleared this first hurdle on the path to registration of efgartigimod in CIDP,” commented Wim Parys, M.D., Chief Medical Officer of argenx. “CIDP is now the fourth autoimmune disease that we selected based on its solid biological rationale where we have demonstrated clinical proof-of-concept, further emphasizing the broad applicability of efgartigimod. We hope to be able to offer a new potential treatment to CIDP patients who have limited therapeutic options for this severe, progressive disease.”

The “GO” decision was based on a planned efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE trial. The interim analysis achieved the pre-defined threshold for continuation, which was based on response rates seen in precedent clinical trials of current standard of care in CIDP. The decision to continue enrollment was confirmed by an independent data monitoring committee. In addition, the tolerability profile observed to date is consistent with that of efgartigimod in other clinical trials.

The company will host a conference call today at 2:30 p.m. CET (8:30 a.m. ET) to discuss the decision to continue enrollment in ADHERE.

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**Dial-in numbers:**

*Pease dial in 15 minutes prior to the live call.*

Belgium	0800 389 13
France	0805 102 319
Netherlands	0800 949 4506
United Kingdom	0800 279 9489
United States	1 844 808 7140
International	1 412 902 0128

A live webcast of the presentation will be available on the Company’s website at [www.argenx.com](http://www.argenx.com). A replay of the webcast will be available for approximately 1 year following the presentation.

**ADHERE Trial Design**

The ADHERE trial is a randomized, withdrawal study evaluating 1000mg weekly subcutaneous (SC) efgartigimod for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). The trial consists of an open-label Stage A followed by a randomized, placebo-controlled Stage B with a planned interim responder analysis after the first 30 patients enroll in Stage A. In order to enter Stage A and receive efgartigimod, both patients who were treatment-naïve or on therapy must first receive a confirmed diagnosis of CIDP by an independent panel of experts and demonstrate active disease. To show active disease, patients who are on current CIDP therapy have to demonstrate a minimal clinically meaningful worsening after treatment withdrawal based on at least one CIDP clinical assessment tool, including INCAT, iRODS, or mean grip strength. To advance to Stage B, patients need to demonstrate a minimal clinically meaningful response to efgartigimod equivalent with the loss observed on the same efficacy scale on which worsening is observed during the withdrawal period. In Stage B, patients are randomized to either SC efgartigimod or placebo for up to 48 weeks. The primary endpoint is event-driven and based on the adjusted INCAT efficacy score in Stage B.

**About Efgartigimod**

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation. Blocking FcRn reduces IgG antibody levels representing a logical potential therapeutic approach for several autoimmune diseases known to be driven by disease-causing IgG antibodies, including: myasthenia gravis (MG), a chronic disease that causes muscle weakness; pemphigus vulgaris (PV), a chronic disease characterized by severe blistering of the skin; immune thrombocytopenia (ITP), a chronic bruising and bleeding disease; and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disease leading to impaired motor function. The subcutaneous formulation of efgartigimod is co-formulated with Halozyme’s ENHANZE<sup>®</sup> drug delivery technology and is administered as a 1000mg weekly single injection.

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#### **About CIDP**

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare and serious autoimmune disease of the peripheral nervous system. Although confirmation of disease pathophysiology is still emerging, there is increasing evidence that IgG antibodies play a key role in the damage to the peripheral nerves. People with CIDP experience fatigue, muscle weakness and a loss of feeling in their arms and legs that can get worse over time or may come and go. These symptoms can significantly impair a person's ability to function in their daily lives. Without treatment, one-third of people living with CIDP will need a wheelchair.

#### **About argenx**

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx is evaluating efgartigimod in multiple serious autoimmune diseases, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. For more information, visit [www.argenx.com](http://www.argenx.com) and follow us on LinkedIn.

#### **For further information, please contact:**

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#### **Forward-looking Statements**

*The contents of this announcement include statements that are, or may be deemed to be, forward-looking statements. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, intends, may, will, or should, and include statements argenx makes concerning the preliminary analysis of the ADHERE trial and its plans to continue enrollment of the ADHERE trial; the therapeutic potential of its product candidates; the intended results of its strategy; including the timing, design and outcome of the ADHERE clinical trial. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including the effects of the COVID-19 pandemic, the inherent uncertainties associated with preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.*

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# Together We Discover

Reaching Patients Through  
Immunology Innovation



"GO" Decision: ADHERE Trial in CIDP

FEBRUARY 2021

argenx 



# Forward Looking Statements

This presentation has been prepared by argenx se ("argenx" or the "company") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or the company or any director, employee, agent, or adviser of the company. This presentation does not purport to be all-inclusive or to contain all of the information you may desire. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.



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 our business and financial outlook and related plans; the therapeutic and commercial potential of our product candidates; the intended results of our strategy; the expected benefits of our collaborations, including with respect to our collaboration with Zai Lab; our and our collaboration partners' clinical development and regulatory plans, including the timing, design and outcome of ongoing and planned clinical trials and preclinical activities and 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 our product candidates. When used in this presentation, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "will," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements.

Such statements, based as they are on the current analysis and expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond the Company's control. Such risks include, but are not limited to: the impact of COVID-19 pandemic on our business, the impact of general economic conditions, general conditions in the biopharmaceutical industries, changes in the global and regional regulatory environments in the jurisdictions in which the Company does or plans to do business, market volatility, fluctuations in costs and

changes to the competitive environment. Consequently, actual future results may differ materially from the anticipated results expressed in the forward-looking statements. In the case of forward-looking statements regarding investigational product candidates and continuing further development efforts, specific risks which could cause actual results to differ materially from the Company's current analysis and expectations include: failure to demonstrate the safety, tolerability and efficacy of our product candidates; final and quality controlled verification of data and the related analyses; the expense and uncertainty of obtaining regulatory approval, including from the U.S. Food and Drug Administration and European Medicines Agency; the possibility of having to conduct additional clinical trials; our ability to obtain and maintain intellectual property protection for our product candidates; and our reliance on third parties such as our licensors and collaboration partners regarding our suite of technologies and product candidates. Further, even if regulatory approval is obtained, biopharmaceutical products are generally subject to stringent on-going governmental regulation, challenges in gaining market acceptance and competition. These statements are also subject to a number of material risks and uncertainties that are described in the Company's filings with the U.S. Securities and Exchange Commission ("SEC"), including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. The reader should not place undue reliance on any forward-looking statements included in this presentation. These statements speak only as of the date made and the Company is under no obligation and disavows any obligation to update or revise such statements as a result of any event, circumstances or otherwise, unless required by applicable legislation.

# Efgartigimod: Broad Pipeline Opportunity

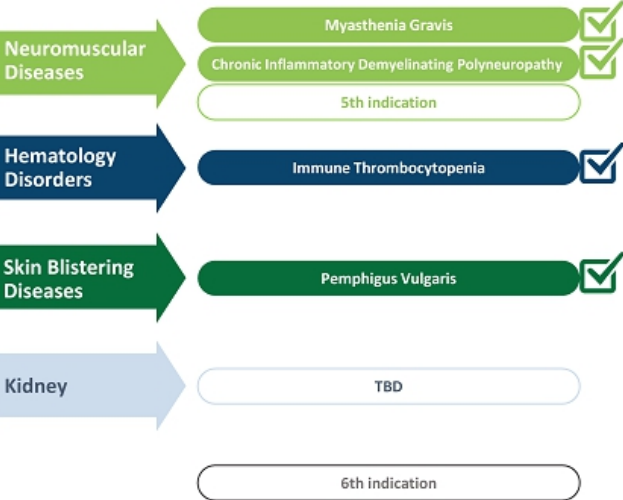
**Landscape of IgG-mediated Severe Autoimmune Diseases**  
(sampling)

- Immune Thrombocytopenia
- Lupus
- Guillain-Barré syndrome
- Myasthenia Gravis
- Scleroderma
- Anca Vasculitis
- Epidermolysis Bullosa Acquisita
- Pemphigus
- Neuromyelitis Optica
- Multiple Sclerosis
- Hemolytic Anemia
- Membranous Nephropathy
- Rheumatoid Arthritis
- Thyroid Eye Disease
- Bullous Pemphigoid

**Solid Biology Rationale:**  
Predominantly mediated by pathogenic IgGs

**Feasible for Biotech:**  
Orphan indication, efficient clinical & regulatory pathway

**argenx Franchises & Indications**  
Efgartigimod to date achieved proof-of-concept in 4/4 indications; 2/2 in neuromuscular franchise



# CIDP: Significant Unmet Need Exists for Patients

## Rare, Chronic, and Progressive

Symmetric proximal and distal weakness with sensory loss and decreased reflexes

Can progress quickly to severe disability (wheelchair)

50% of patients are severely disabled at some stage of illness

Pain and fatigue commonly reported

## Prevalence & Opportunity

~16,000 patients in the US

> \$ 3Bn in IVIG Sales globally

## Diagnosis/Metrics

Commonly misdiagnosed

Diagnosis often confirmed by physicians trying therapy for 3 months and reassessing

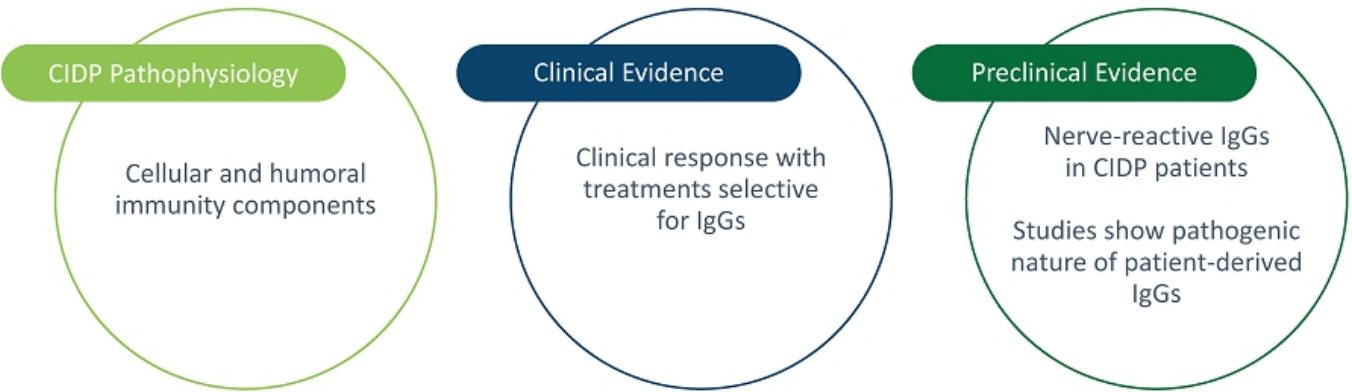
## Treatment

70% of CIDP patients need ongoing treatment

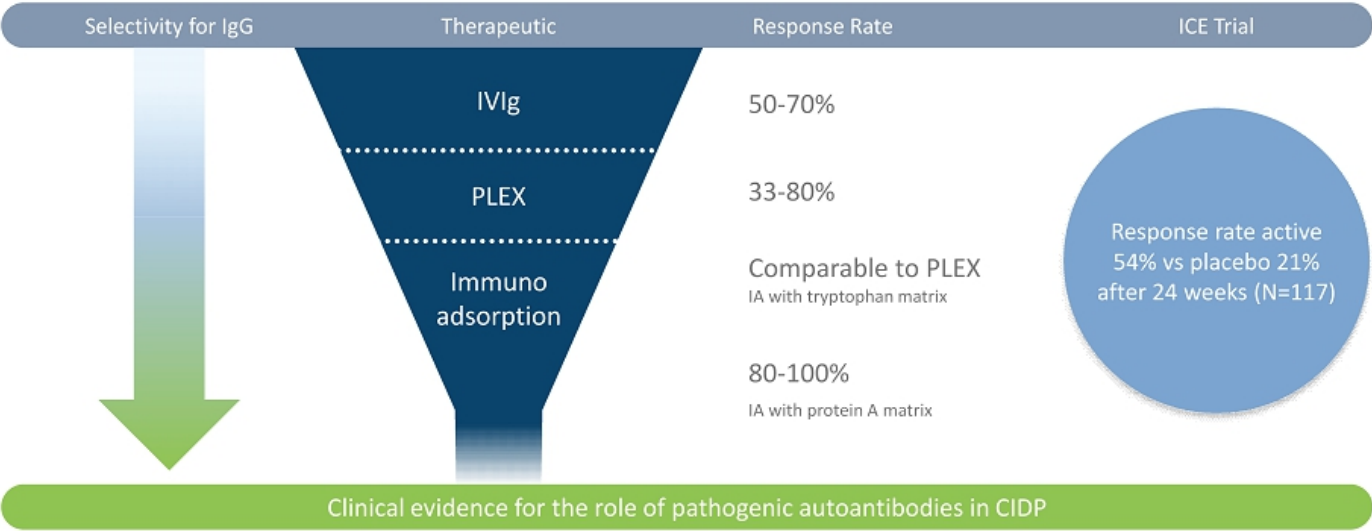
Available treatments come with long infusion times and adverse effects



# Solid Biology Rationale for FcRn Approach in CIDP



# CIDP: Therapeutic Activity Shown With Increasing Selectivity For IgG Reductions

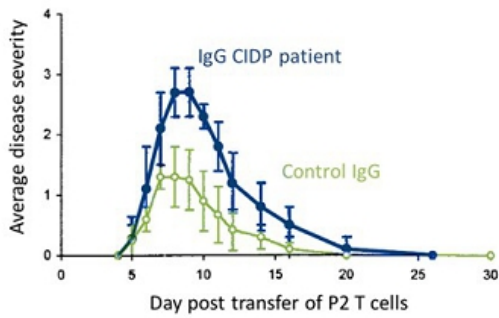


Oaklander et al (2017), Cochrane Database Syst Rev    Lieker et al (2017), J Clin Apher, 32(6):486-493    Zinman et al (2005) Transfus Apher Sci. 2005 Nov;33(3):317-24.

# Passive Transfer Studies Show Pathogenic Nature of Patient IgGs

Purified IgG from CIDP patients with immunoreactivity towards myelinated nerves

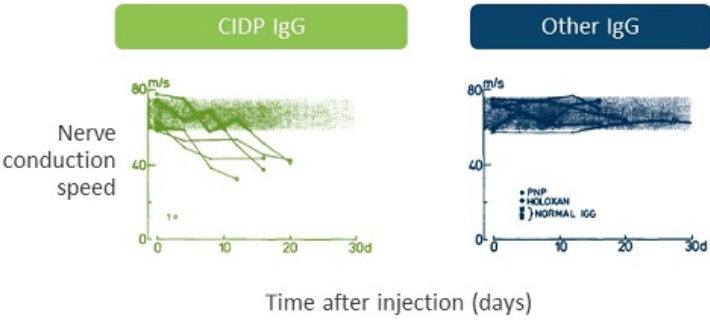
Exacerbation of EAN disease model by injection of CIDP IgG



Yan et al (2000), Ann Neurol, 47(6): 765-775

Purified IgG from PLEX-responsive CIDP patients

CIDP-specific reduction in nerve conduction speed in non-human primates



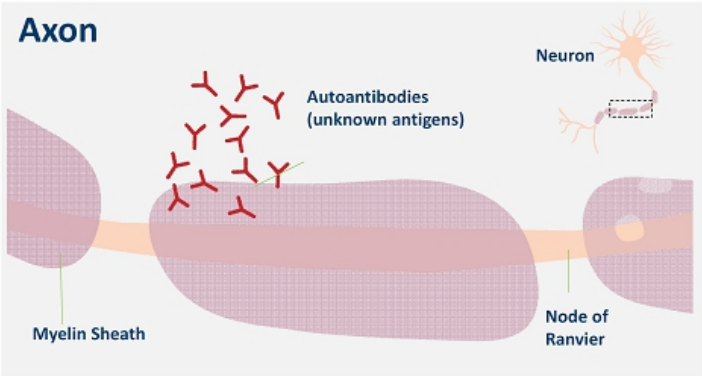
Heiniger et al (1984), J Neurol Sci 66:1-14



# Nerve-reactive IgGs in CIDP patients

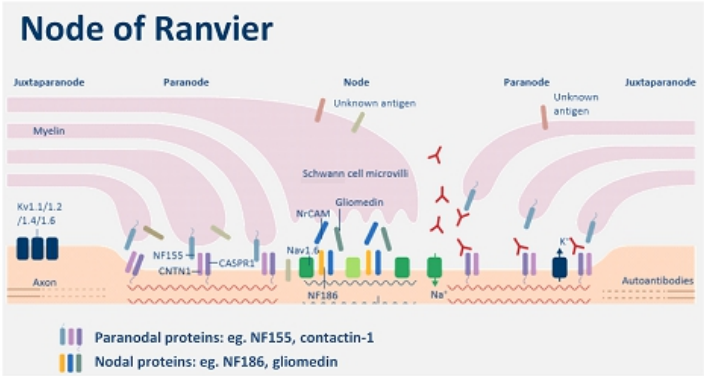
## Anti-myelin sheath IgG

30-40% of patients



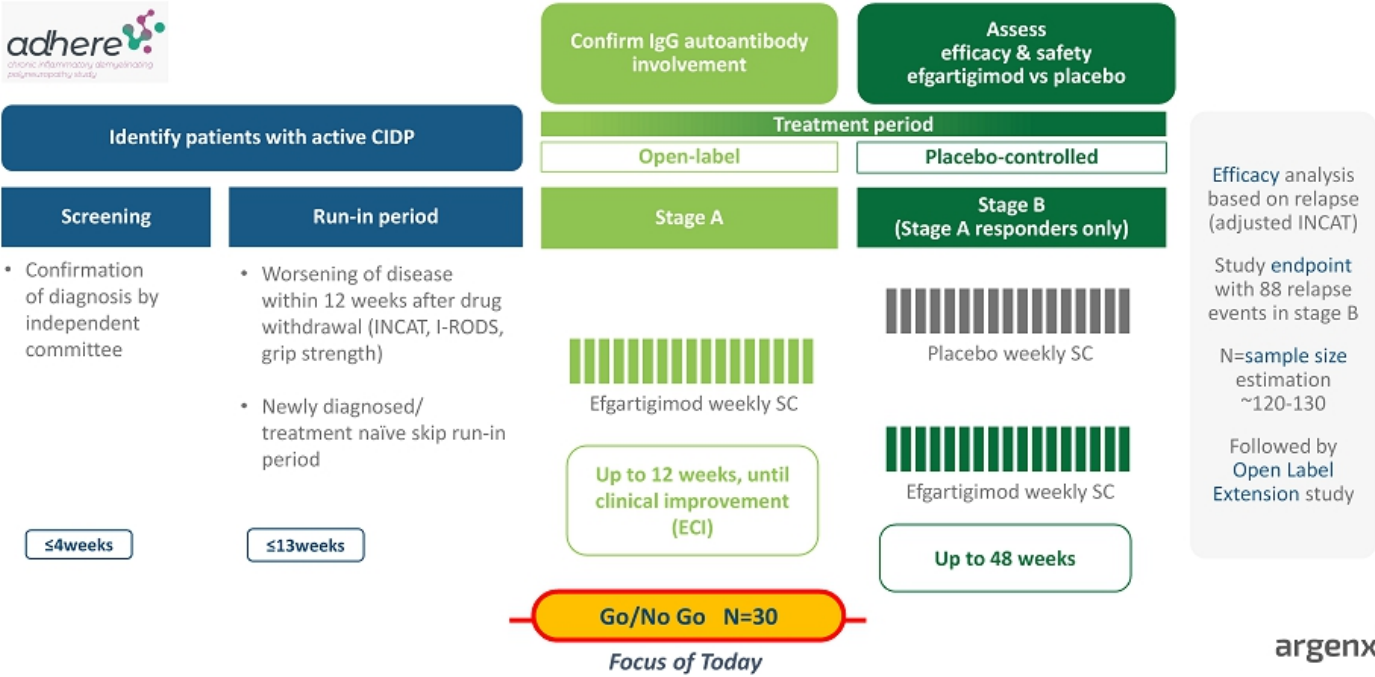
## Anti-paranodal IgG4

~10% of patients



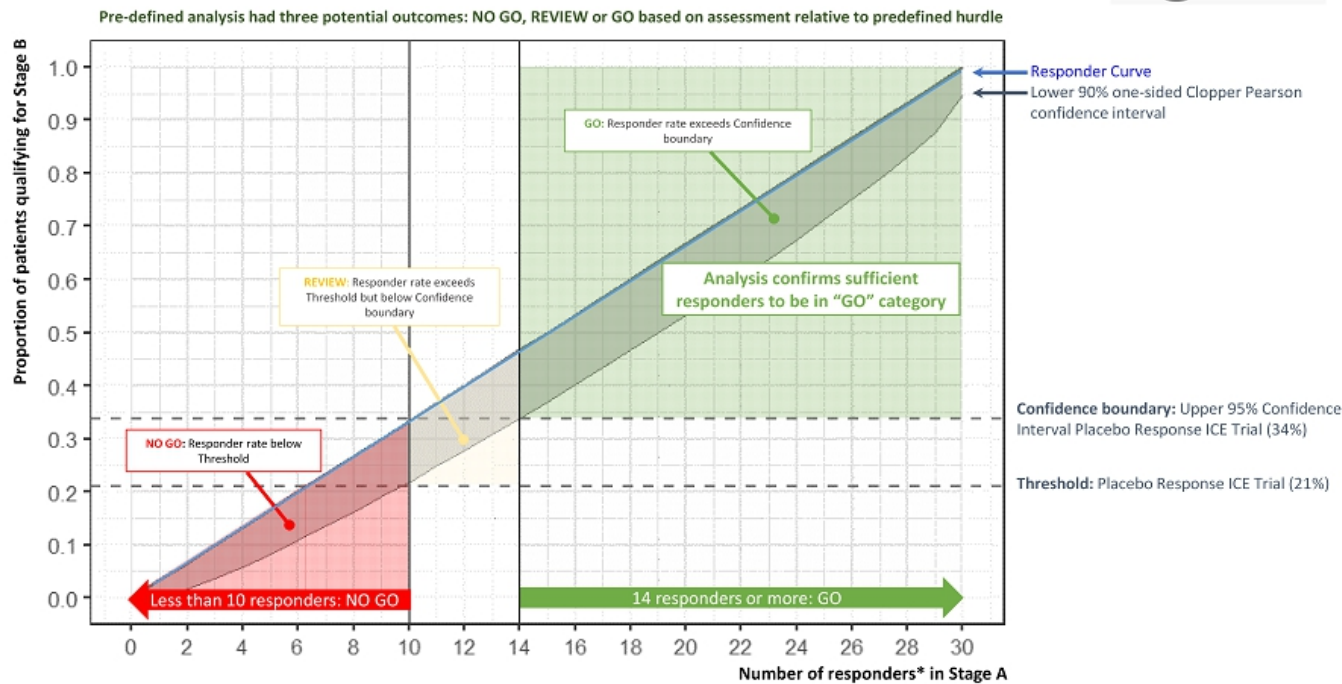
Querol et al (2017) Nature Rev Neurol 13:533-547

# Chronic Inflammatory Demyelinating Polyneuropathy: Phase 2/3 ADHERE Trial



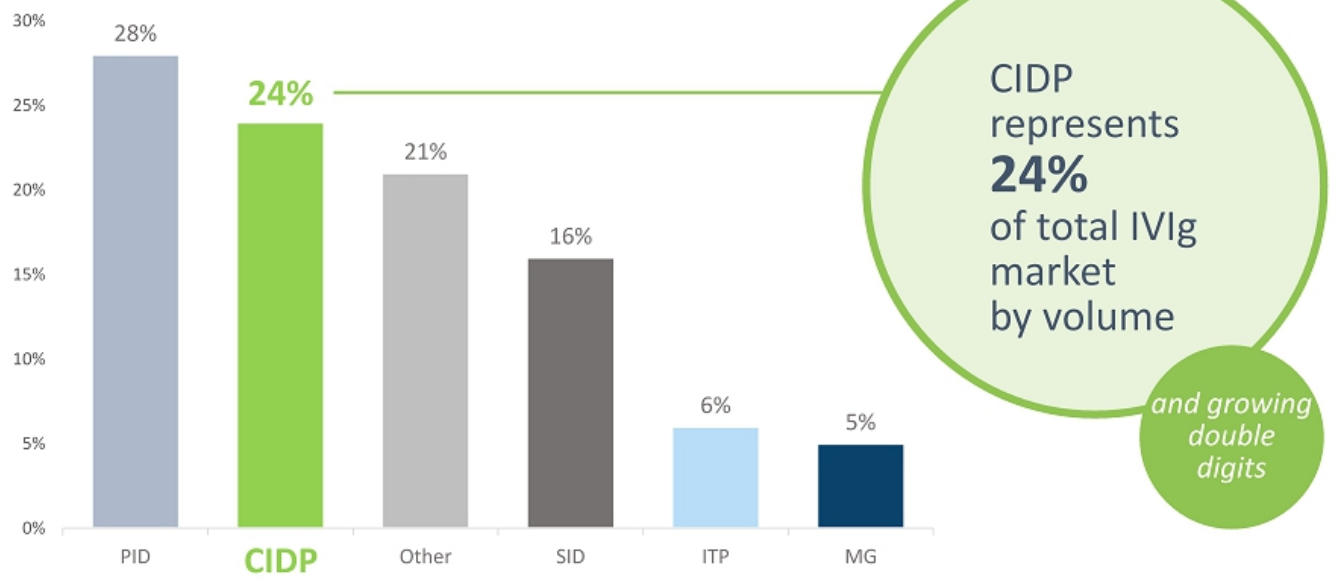


Clear “GO” Based on Observed Activity in CIDP



\*minimal clinically meaningful response, allowing transition to Stage B, equivalent with the loss observed on the same efficacy scale (INCAT, iRODS, or mean grip strength) on which worsening is observed during the withdrawal period

Global Immunoglobulins Market \$12.8Bn

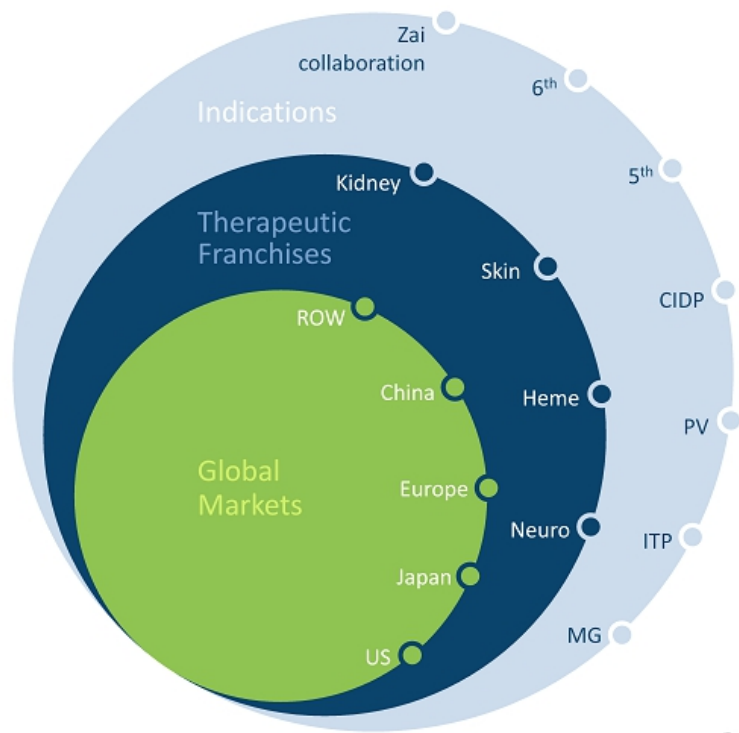


## Key Conclusions

- GO decision to continue ADHERE enrollment in support of potential registration of efgartigimod in CIDP
- Decision supported by independent data monitoring committee
- Safety data consistent with current understanding of efgartigimod safety profile
- First patient trial with 1000mg SC efgartigimod (single injection)
- Efgartigimod achieved 4/4 in proof-of-concept indications; 2/2 in neuromuscular franchise
- Current global IVIg sales exceeds \$3B
- High unmet need exists in CIDP; patients need more options

## Uniquely Positioned For exponential expansion

- efgartigimod indications
- therapeutic franchises
- global markets




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Reaching Patients Through  
Immunology Innovation



"GO" Decision: ADHERE Trial in CIDP

FEBRUARY 2021

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