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

FORM 6-K

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

For the Month of January 2023

Commission File Number: 001-38097

ARGENX SE
(Translation of registrant's name into English)

**Laarderhoogtweg 25
1101 EB Amsterdam, the Netherlands**
(Address of principal executive offices)

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): ☐

argenx SE

On January 9, 2023, argenx SE (the “Company”) issued a press release and a presentation the Company intends to use at the 41st Annual J.P. Morgan Healthcare Conference being held from January 9-12, 2023, copies of which are filed hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated by reference herein.

The information contained in this Current Report on Form 6-K, including the Exhibits, is incorporated by reference into the Company’s Registration Statements on [F-3 \(File No. 333-258251\)](#) and S-8 (File Nos. [333-225375](#) and [333-258253](#)).

EXHIBITS

Exhibit	Description
99.1	Press Release dated January 9, 2023
99.2	Investor Presentation, January 9, 2023

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: January 9, 2023

By: /s/ Hemamalini (Malini) Moorthy
Hemamalini (Malini) Moorthy
General Counsel

argenx Highlights 2023 Strategic Priorities Across Immunology Pipeline

Reported \$402 million in preliminary full-year 2022 global net VYVGART sales*

ADHERE topline results now expected in second quarter of 2023; Stage B enrollment has surpassed projected target of 130 patients

Registrational trial of efgartigimod in thyroid eye disease (TED) to start in 2023; additional proof-of-concept trials to start in ANCA-associated vasculitis and antibody mediated rejection (AMR)

Submission for marketing approval in Japan of VYVGART for immune thrombocytopenia (ITP) expected in mid-2023

Amsterdam, the Netherlands – January 9, 2022 – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced its strategic priorities for 2023 and provided preliminary financial results for the full year 2022, including global net product sales of VYVGART® (efgartigimod alfa-fcab).

“We had a landmark year in 2022, marking our first as a fully integrated immunology company transforming the treatment paradigm of generalized myasthenia gravis, and one which will stand as only the very beginning of what we expect to achieve as an organization,” said Tim Van Hauwermeiren, Chief Executive Officer, argenx. “Looking forward, we will be expanding our patient reach both geographically and through the anticipated U.S. approval and launch of subcutaneous efgartigimod in March. By the end of 2023, we will be active in 15 IgG- and complement-mediated autoimmune diseases as we work to uncover the full breadth of our differentiated pipeline with key data readouts from additional indications of efgartigimod, as well as ARGX-117 and ARGX-119.”

2023 Strategic Priorities

argenx will focus on four strategic priorities in 2023 to drive sustained growth and value creation as part of its ‘argenx 2025’ vision and a path to profitability.

Reach More Patients with VYVGART

argenx is planning for multi-dimensional expansion to reach more patients with VYVGART, its first-in-class neonatal Fc receptor blocker. This includes generalized myasthenia gravis (gMG) patients through regulatory approvals in new regions and the launch of its subcutaneous (SC) product offering, as well as a new autoimmune indication with the VYVGART regulatory submission for ITP in Japan.

- Prescription Drug User Fee Act (PDUFA) target action date of March 20, 2023, for U.S. Food and Drug Administration approval decision on SC efgartigimod for gMG
 - Regulatory approval decision on SC efgartigimod for gMG expected in EU in fourth quarter of 2023
-

- Submission for marketing approval of SC efgartigimod for gMG expected in Japan in first quarter of 2023
- Regulatory approval decisions of VYVGART for gMG expected in Canada in third quarter of 2023 and in China and Israel by end of 2023
- gMG launch in France, United Kingdom and Italy expected by year-end 2023 following review of respective reimbursement dossiers
- Submission for Japan marketing approval of VYVGART for ITP expected in mid-2023

Pioneer Development of FcRn Class with New Clinical and Translational Data

argenx aims to solidify its FcRn leadership by expanding the scope of IgG-mediated autoimmune diseases in development and further demonstrating the potential of FcRn blockade with three Phase 3 trial readouts, one proof-of-concept trial readout, and a commitment to a 'bedside-to-bench' translational biology effort. By the end of 2023, efgartigimod is expected to be approved, in regulatory review or in development in 13 severe autoimmune diseases.

- ADHERE: Topline data in chronic inflammatory demyelinating polyneuropathy (CIDP) now expected in second quarter of 2023; Stage B enrollment has surpassed the initial projected target of 130 patients
- ADDRESS: Topline data in pemphigus expected in second half of 2023
- ADVANCE-SC: Topline data from SC trial in ITP expected in second half of 2023
- Proof-of-concept data in post-COVID-19 postural orthostatic tachycardia syndrome (PC-POTS) expected in fourth quarter of 2023
- Registrational trial to start in TED in fourth quarter of 2023
- Proof-of-concept trials to start in ANCA-associated vasculitis and AMR in kidney transplant in fourth quarter of 2023; AAV trial to be run through IQVIA collaboration
- Externally sponsored research studies to launch in IgG-mediated neuromuscular autoimmune diseases in 2023
- Translational work ongoing to understand potential disease-modifying effect of FcRn mechanism

Drive Earlier-Stage Immunology Opportunities Towards Clinical Proof-of-Concept

Beyond efgartigimod, argenx is advancing a robust portfolio of innovative clinical programs, including ARGX-117 (C2 inhibitor) and ARGX-119 (muscle-specific kinase (MuSK) agonist). Both programs have the potential to be first-in-class opportunities for multiple severe autoimmune indications.

- ARDA: Interim data from proof-of-concept trial of ARGX-117 in multifocal motor neuropathy expected mid-2023
 - Proof-of-concept trial of ARGX-117 expected to start following regulatory discussions for prevention of delayed graft function after kidney transplantation
 - Dermatomyositis selected as third autoimmune indication for development of ARGX-117
 - Phase 1 dose-escalation trial of ARGX-119 in healthy volunteers to start in first quarter of 2023 with subsequent Phase 1b trial to assess early signal detection in patients
-

Build Immunology Innovation Ecosystem to Drive Long-Term Pipeline Growth

argenx continues to invest in its discovery engine, the Immunology Innovation Program, to foster a robust innovation ecosystem and drive early-stage pipeline growth. argenx expects to nominate one new development candidate in 2023.

Preliminary* Fourth Quarter and Full Year 2022 Financial Results

argenx also announced today preliminary* global net VYVGART revenues for the fourth quarter and full-year 2022 of approximately \$175 million and \$402 million, respectively.

As of December 31, 2022, argenx had approximately \$2.2 billion in cash, cash equivalents and current financial assets*. Based on its current operating plans and a projected 2023 cash burn of approximately \$500 million, argenx expects its existing cash, cash equivalents and current financial assets, together with anticipated future product revenues, to fund the company to profitability.

* - The preliminary selected financial results are unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in March 2023.

41st Annual J.P. Morgan Healthcare Conference Presentation and Webcast

Mr. Van Hauwermeiren will highlight these updates in a corporate presentation at the 41st Annual J.P. Morgan Healthcare Conference today, Monday, January 9, 2023, at 9:00 a.m. PT. The live webcast of the presentation may be accessed under Investors on the argenx website. A replay will be available for 30 days following the presentation.

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. 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 developed and is commercializing the first-and- only approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan and the EU. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

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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,” “hope,” “estimates,” “anticipates,” “expects,” “intends,” “may,” “will,” or “should” and include statements argenx makes concerning its preliminary financial results for the full year 2022; its expectations of future profitability; its plans for geographic expansion; the anticipated launch of its subcutaneous (SC) product in the U.S.; the initiation, timing, progress and results of its anticipated clinical development, data readouts and regulatory milestones and plans; its strategic priorities, including the timing and outcome of regulatory filings and regulatory approvals, and anticipated expansions in generalized myasthenia gravis (gMG) and IgG-mediated autoimmune diseases; the potential of its innovative clinical programs; and the nomination of new development candidates. 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. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.



Together We Discover

J.P. Morgan Healthcare Conference
January 2023



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. Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates and research.

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 preliminary financial results for the full year 2022; expectations of future profitability; plans for geographic expansion; the anticipated launch of argenx’s subcutaneous (“SC”) product in the U.S.; the initiation, timing, progress and results of our anticipated clinical development, data readouts and regulatory milestones and plans; strategic priorities, including the timing and outcome of regulatory filings and regulatory approvals, and anticipated expansion in generalized myasthenia gravis (gMG) and IgG-mediated autoimmune diseases; the potential of argenx’s innovative clinical programs; and the nomination of new development 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 presentation. 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.

This presentation contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

We are on a **bold mission**

Transforming the lives of patients with
severe autoimmune disease through
immunology innovation

argenx 

Redefining Autoimmune Diseases With Precision Medicine Approach



Autoimmunity
is Prime for
REVOLUTION

A pipeline of **precision tools**

Redefine our pipeline of autoimmune diseases as
IgG-mediated or complement-driven

Offer **new targeted treatment** modality in diseases
where **innovation** is most needed

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



argenx 

...and gMG
is just the
beginning

Pioneer with
Our Science

Lead with
Compassion for
our Patients

argenx 2025: A Leading, Sustainable
Immunology Company

Drive Impact
Through
Innovation

Build the
Company We
Want to Work
For

argenx 

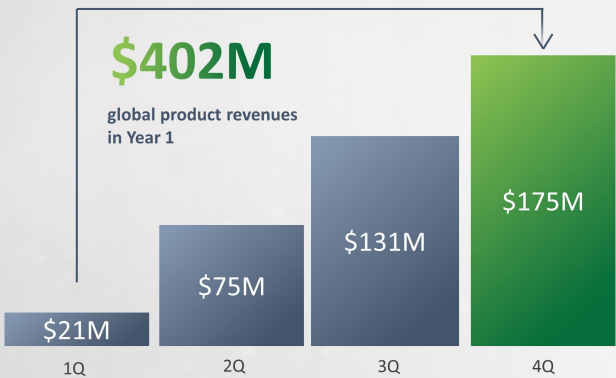
2022: Transformed into an Integrated Immunology Company

VYVGART launched in
U.S., Japan &
Germany

SUBMISSIONS IN
10+ COUNTRIES

Built scalable
global supply chain

LARGE SCALE CAPACITY TO
HANDLE DEMAND



More than 3,000 patients on VYVGART®

Rapid HCP adoption

90% of KEY TARGETS
REACHED in 2022

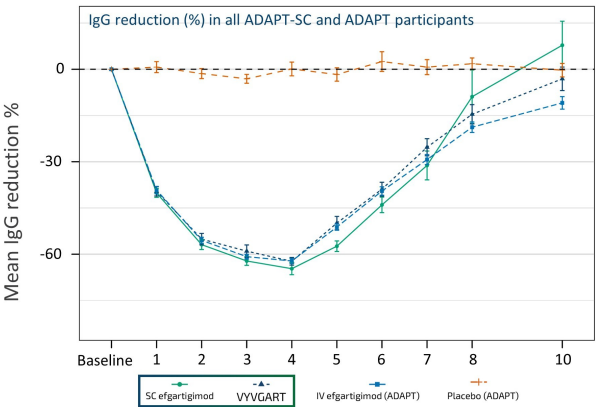
Enabled appropriate
access through value-
based agreements

90% US POLICIES
FAVORABLE

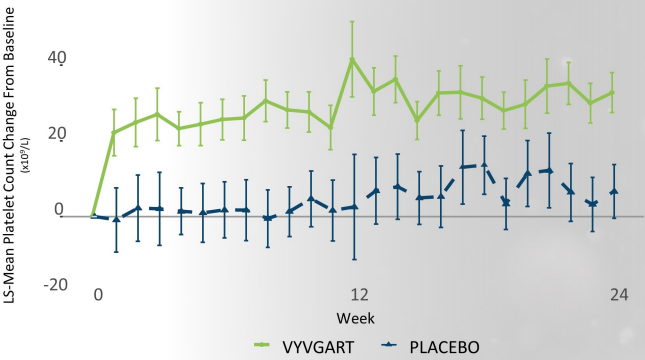


2022: Strengthened Efgartigimod Data Story

SC Noninferiority to IV



Clear Clinical Benefit in ITP



Disease-Modifying Potential of FcRn Blockade



2022: Broadened Scope of Efgartigimod Safety Database

Scope of Safety Database

- >1,300 clinical study subjects
- Cumulative exposure of >1,000 patient years
- Different dosing regimens (up to 19 cycles of 4 weekly doses; up to 2 years of weekly dosing)
- TEAEs consistent across >4 indications; typically mild to moderate
- Low discontinuation rates due to side effects in clinical studies to date

Molecular design yields unique interaction with FcRn and differentiated safety profile

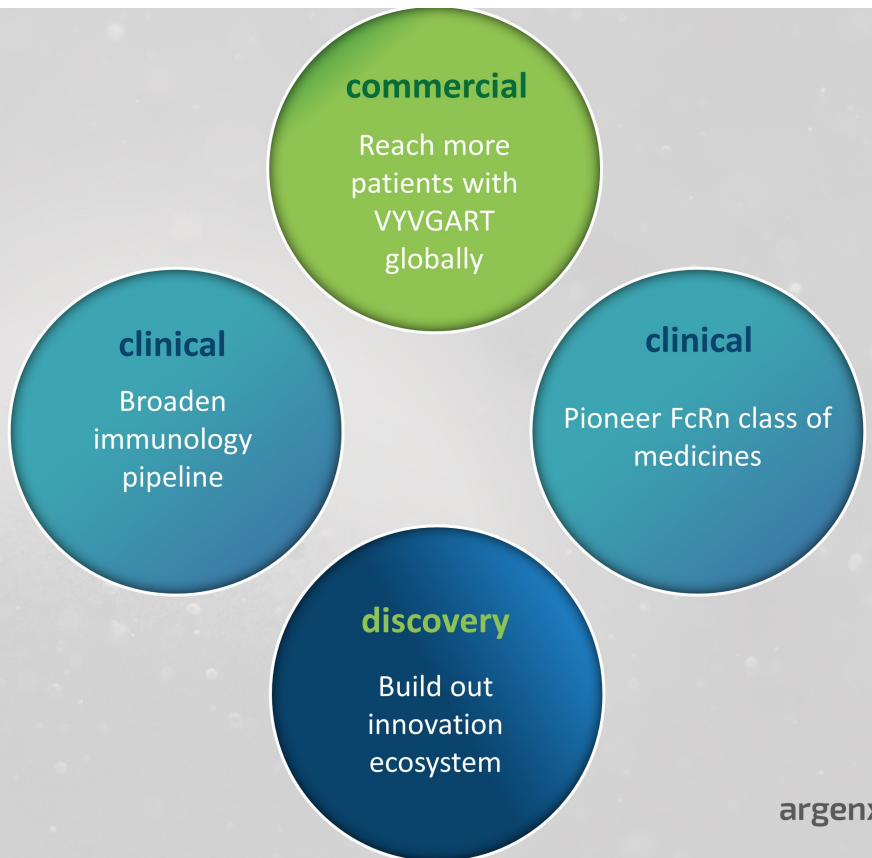
No reduction in albumin levels; no increase in lipid levels



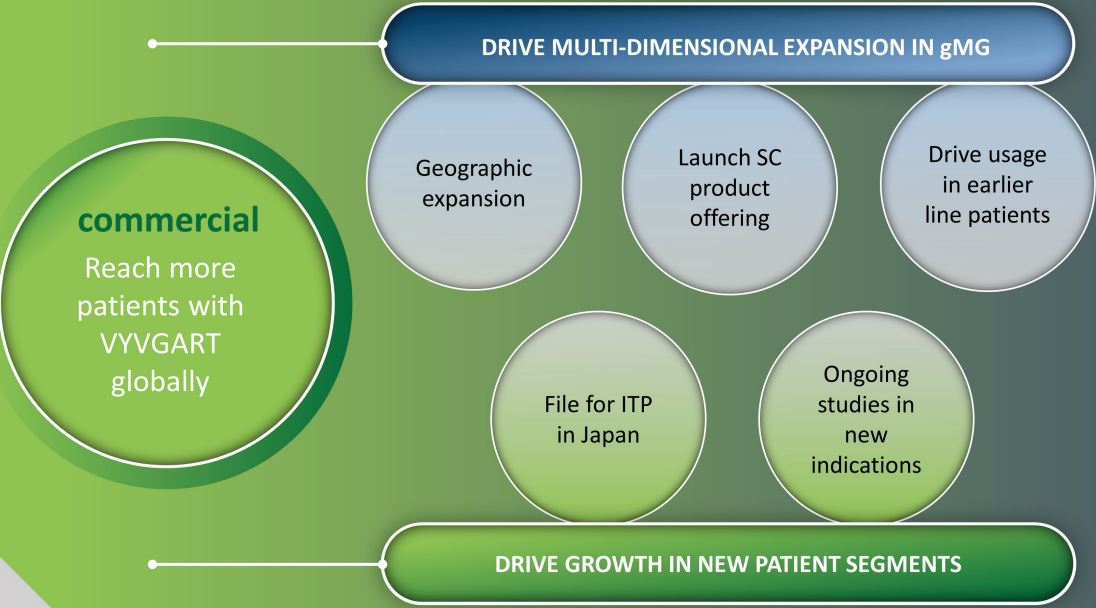
Post-marketing data confirm positive benefit/risk profile as established in clinical trials

1. Ulrichts P, et al. *J Clin Invest*. 2018;128(10):4372-4386. doi: 10.1172/JCI97911.

2023: Key Drivers of our Path to Profitability

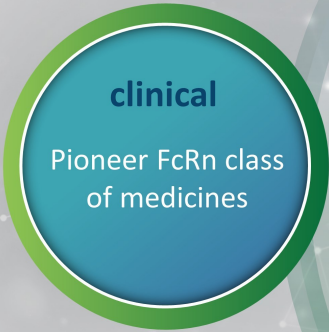


Reach More Patients with VYVGART Globally

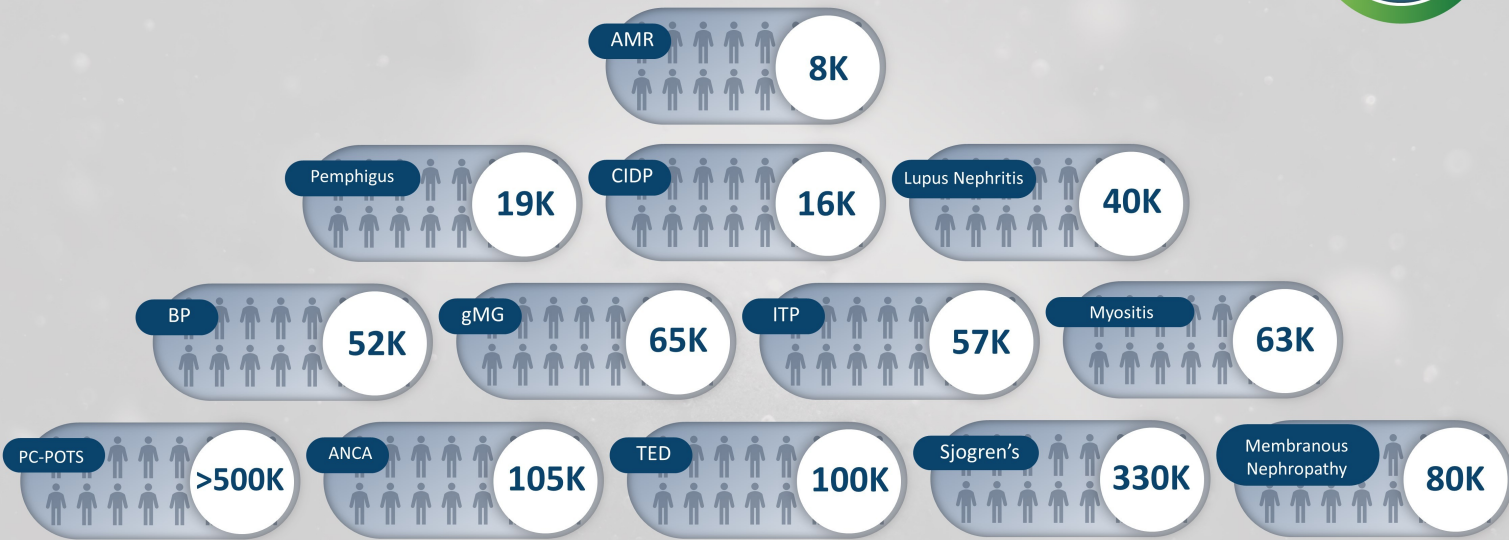


IgG Autoantibodies Serve as Unifying Biology

Rationale for POC Indications

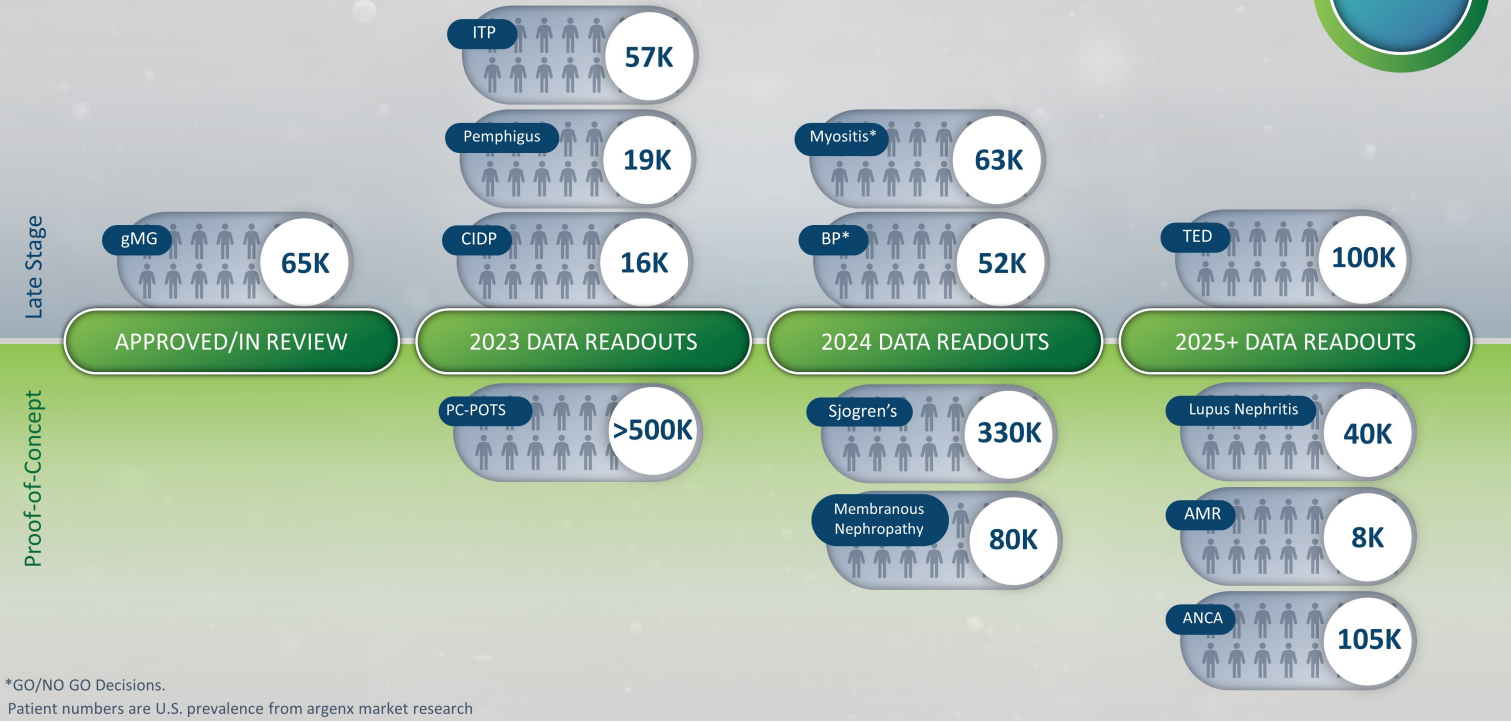


Pipeline-in-a-Product Indicates Significant Market Opportunity



Patient numbers are U.S. prevalence from argenx market research

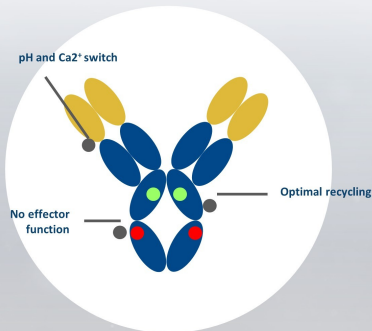
Steady Cadence of Data Readouts Over Next Several Years



ARGX-117: Targets C2 at Junction of Classical and Lectin Pathways

clinical
Broaden
immunology
pipeline

ARGX-117: Sweeping Antibody



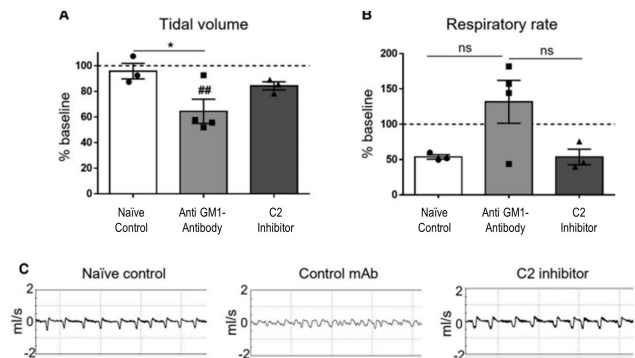
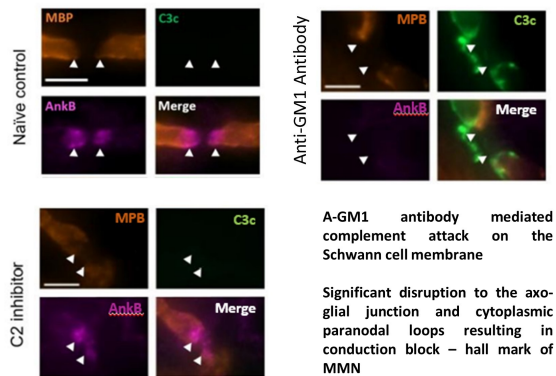
Three Indications Selected Based on Biology Rationale

Indication selection starts with autoimmune diseases driven by classical and/or lectin pathway

Phase 2 proof-of-concept trial underway in multifocal motor neuropathy (MMN) with interim data expected in mid-2023

Phase 2 trials to start in delayed graft function and dermatomyositis

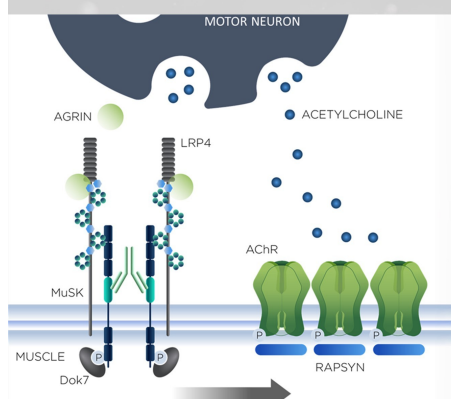
ARGX-117: Strong Translational Biology Rationale for C2 Blockade in MMN



Significant reduction of injury to paranodal proteins at the Nodes of Ranvier improves respiratory function *in vivo*

ARGX-119: MuSK Agonist with Broad Potential in Neuromuscular Disease

clinical
Broaden
immunology
pipeline



First-in-Human Phase 1 Healthy Volunteer Study

Single Ascending Dose
(0.005mg/kg – 15mg/kg)



10 dose cohorts

Multiple Ascending Dose
(0.3mg/kg – 2.5mg/kg)



3 dose cohorts/4 weekly doses

First-in-
Patient

Congenital
Myasthenic
Syndrome (CMS) and
MuSK MG

First-in-patient trial in CMS and MuSK MG to serve as proof of biology

Translational work ongoing in amyotrophic lateral sclerosis

argenx

Positioned for Long-term Franchise Growth

Neurology

gMG, CIDP,
Myositis, TED, MMN, CMS,
Musk MG, ALS

Hematology and Rheumatology

ITP, Sjogren's, POTS, Anca
Vasculitis

Dermatology

Pemphigus, Bullous
Pemphigoid,
Dermatomyositis

Nephrology

Membranous
Nephropathy, Lupus
Nephritis, AMR, DGF

Innovation Ecosystem



Positioned for a Catalyst-Rich 2023

Commercial

VYVGART gMG Approval in China	YE 2023
VYVGART gMG Approval in Canada	3Q 2023
VYVGART gMG Launch in France, UK, Italy	YE 2023
SC efgartigimod gMG Approval in US	March 20, 2023
SC efgartigimod gMG Approval in EU	4Q 2023
SC efgartigimod gMG Submission in Japan	1Q 2023
VYVGART ITP Submission in Japan	Mid-2023

Clinical

Efgartigimod

• ADHERE data in CIDP	2Q 2023
• ADDRESS data in Pemphigus	2H 2023
• ADVANCE (SC) data in ITP	2H 2023
• POC data in Post-COVID POTS	4Q 2023
• Initiate registrational trial in TED	4Q 2023
• Initiate POC studies in AAV and AMR	4Q 2023

Additional pipeline

• ARGX-117: ARDA MMN interim results	Mid-2023
• ARGX-117: Initiate DGF POC study	2H 2023
• ARGX-119: Initiate Phase 1 study	1Q 2023

Our mission continues...



argenx

Breadth and Depth Within Autoimmune Pipeline

