
**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 December 2022

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): ☐

EXPLANATORY NOTE

On December 10, 2022, argenx SE (the “Company”) issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Current Report on Form 6-K, including Exhibit 99.1, is incorporated by reference into the Company’s Registration Statements on [Forms F-3 \(File No. 333-258251\)](#), and S-8 (File Nos. [333-225375](#) and [333-258253](#)).

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated December 10, 2022

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: December 12, 2022

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



argenx to Present Pivotal ADVANCE Trial Data During ASH Plenary Session Highlighting VYVGART® (efgartigimod alfa-fcab) as Potential New Treatment Modality for Immune Thrombocytopenia

First immune thrombocytopenia (ITP) plenary selection in 15 years underscores significant unmet need in this rare, serious autoimmune bleeding disease

VYVGART showed rapid, clinically and statistically significant improvements in platelet counts compared with placebo; safety profile consistent with previous trials

Topline data from ADVANCE-SC trial of subcutaneously (SC) administered VYVGART for ITP expected in second half of 2023

Amsterdam, the Netherlands – December 10, 2022 – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that data from its Phase 3 ADVANCE trial will be presented during the plenary session at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition in New Orleans, LA (Sunday, December 11, 2022, 2-4pm CT). The ADVANCE study is the first of two registrational trials evaluating the efficacy, safety and tolerability of VYVGART® (efgartigimod alfa-fcab) for the treatment of adult patients with primary ITP.

“We are very excited to present our ITP data during the plenary session at ASH, giving us the opportunity to highlight the potential of a new approach to treating this rare, complex disease. People living with ITP need more treatment options with new mechanisms of action that target the underlying biology of the disease, and we look forward to sharing our findings in helping to address this gap with the broader ITP community,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “ADVANCE is the second Phase 3 clinical trial in which VYVGART has demonstrated a strong clinical benefit, underscoring our belief in the breadth of potential for this asset in a range of high-need IgG-mediated autoimmune diseases.”

Topline data from ADVANCE were reported in May 2022. The trial met its primary endpoint demonstrating a significantly higher proportion ($p=0.0316$) of VYVGART-treated chronic ITP patients achieved a sustained platelet response (17/78; 21.8%) compared to placebo (2/40; 5%). Sustained platelet response was defined as having platelet counts greater than or equal to $50 \times 10^9/L$ on at least four of the last six scheduled visits between weeks 19 and 24 of treatment. Key platelet-derived secondary endpoints (first two secondary endpoints) were also met. VYVGART was well-tolerated in this 24-week chronic dosing study and the observed safety and tolerability profile was consistent with previous clinical trials.



Highlights From ASH Plenary Session

- **Early, sustained platelet count increase:** 38% of VYVGART-treated participants reached a platelet count of $30 \times 10^9/L$ platelets at week 1 compared to 11.1% placebo
- **Sustained response across all subgroups:** subgroup analyses (including on prior ITP therapy, time since diagnosis, baseline platelet count and age/region demographics) of patients who achieved the primary endpoint all favored VYVGART over placebo
- **International Working Group (IWG) responder status:** VYVGART resulted in higher responses than placebo on analysis of IWG response criteria
 - 51.2% (44/86) of VYVGART-treated patients achieved an IWG response compared to 20% placebo
 - IWG responders were defined as having a platelet count of at least $30 \times 10^9/L$, a two-fold increase in platelet count from baseline, and the absence of bleeding for two separate, consecutive weekly visits
- **Extent of disease control:** VYVGART-treated patients experienced substantially more weeks with disease control, with 44% sustaining response for at least 5-9 weeks (12% placebo), 28% for at least 10-14 weeks (0% placebo), and 17% for at least 15-19 weeks (0% placebo)
 - Sustained platelet count response was achieved in 90% (9/10) of VYVGART responders who switched from weekly to every other week dosing (after surpassing platelet counts of $100 \times 10^9/L$ for three out of four consecutive visits); one placebo patient switched to biweekly dosing but did not achieve a sustained platelet count response
- **Key pharmacodynamic parameters:** total IgG levels were reduced in VYVGART-treated patients throughout observation period, supporting proposed mechanism of action
 - Mean IgG levels decreased steadily over the first 4 weeks of treatment; baseline remained $>60\%$ throughout the trial
- **Consistent safety profile:** continuous weekly or biweekly dosing was well-tolerated and did not result in any new safety signals from those reported from previous trials

“I am honored to deliver this oral presentation on behalf of my co-investigators at ASH, one of the most prestigious hematology meetings, to provide my peers with additional details on the promising results from the ADVANCE study,” stated Catherine Broome, M.D., Associate Professor of Medicine at Georgetown University Lombardi Comprehensive Cancer Center, and Principal Investigator in the ADVANCE trial. “Along with the previously reported positive efficacy, safety and tolerability data from the trial, further analyses show efgartigimod demonstrated rapid and sustained reduction in IgG autoantibodies, which correlated with platelet count response, as well as consistent improvement over placebo across each evaluated weekly timepoint. The data generated to date give us optimism that this therapy could provide a new tool in the treatment of ITP, and we look forward to seeing results from the subcutaneous study in 2023.”



The Phase 3 ADVANCE IV trial is the first of two registrational trials being conducted as part of the ongoing ITP development program. ADVANCE-SC is evaluating SC VYVGART for the treatment of primary ITP. Topline data from the ADVANCE-SC study are expected in the second half of 2023.

Phase 3 ADVANCE Trial Design

The Phase 3 ADVANCE trial was a randomized, double-blind, placebo-controlled, multicenter, global trial evaluating the efficacy and safety of VYVGART in adult patients with chronic or persistent primary ITP. A total of 131 adult patients with primary ITP in North America, Europe and Japan enrolled in the trial and received VYVGART or placebo for a total of 24 weeks as part of the primary trial. Enrolled patients had a confirmed ITP diagnosis and a mean entry platelet count of less than $30 \times 10^9/L$. Patients were on a stable dose of at least one ITP treatment prior to randomization and had received at least one prior therapy. Concomitant medications permitted included corticosteroids, nonsteroidal immunosuppressive drugs, fostamatinib or TPO-RAs. If patients were on 'watch and wait' at baseline, they had to have received at least 2 prior treatments for ITP.

Patients were randomized in a 2:1 ratio to receive VYVGART or placebo for a total of 24 weeks as part of the primary trial. Randomized patients received weekly infusions from weeks 1-4 and were eligible to adjust frequency to bi-weekly depending on platelet count. Administration frequency was fixed from study visits 16-24. The primary endpoint was measured by the proportion of patients with chronic ITP with a sustained platelet count response defined as achieving platelet counts of greater than or equal to $50 \times 10^9/L$ for at least four of the last six scheduled visits between weeks 19 and 24. Patients who received rescue therapy at week 12 or later, or for whom dose and/or frequency of concurrent ITP therapies increased at week 12 or later, were considered non-responders. Key secondary endpoints included extent of disease control over 24-week treatment period, proportion of overall population with sustained platelet count response, incidence and severity of WHO-classified bleeding events and an extended primary endpoint analysis between weeks 17 and 24.

See the full Prescribing Information for VYVGART in the U.S., which includes the below Important Safety Information. For more information related to VYVGART in Japan, visit [argenx.jp](https://www.argenx.jp).

Important Safety Information for VYVGART® (efgartigimod alfa-fcab) intravenous (IV) formulation (U.S. prescribing information)

What is VYVGART® (efgartigimod alfa-fcab)?

VYVGART is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).



What is the most important information I should know about VYVGART?

VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections. More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART. Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- **Undesirable immune reactions (hypersensitivity reactions).** VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Before taking VYVGART, tell your health care provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection.
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your health care provider whether you need to receive age-appropriate immunizations before initiation of a new treatment cycle with VYVGART. The use of vaccines during VYVGART treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the common side effects of VYVGART?

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection.

These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

Please see the full Prescribing Information for VYVGART and talk to your doctor.



About American Society of Hematology (ASH) Annual Meeting and Exposition

The 64th ASH Annual Meeting and Exposition is scheduled to take place December 10-13, 2022 at the Ernest N. Morial Convention Center in New Orleans, Louisiana. This in-person event will be broadcast virtually. The ASH 2022 Annual Meeting abstracts are available at: <https://www.hematology.org/meetings/annual-meeting/abstracts>.

About Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is an autoimmune disorder where immunoglobulin G (IgG) autoantibodies destroy platelets and reduce platelet production, which can lead to an increased risk of excessive bleeding and bruising. In severe cases, frequent bleeding events can cause anemia or even brain hemorrhage in rare cases. ITP is also associated with debilitating fatigue and significant impacts on mental health, including anxiety, fear and depression. Many ITP patients are inadequately controlled on current therapies so there remains a significant unmet need for additional treatment options.

About VYVGART® (efgartigimod alfa-fcab)

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. It is the first and only approved FcRn blocker. VYVGART is approved in the United States and Europe for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs). VYVGART is being studied in adults with primary immune thrombocytopenia (ITP) and other IgG autoantibody-mediated diseases.

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 the potential of VYVGART® (efgartigimod alfa-fcab) for the treatment of adult patients with ITP; the intended results of its strategy and its collaboration partners’, advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts; and the timing and outcome of regulatory filings and regulatory approvals. 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.
