



argenx Highlights 2025 Strategic Priorities

Reported \$2.2 billion in preliminary full-year 2024 global product net sales, inclusive of \$737 million in fourth quarter sales*

Pre-filled syringe FDA PDUFA on track for April 2025 to support reaching patients earlier in treatment paradigm

10 ongoing registrational studies in 2025 across efgartigimod and empasiprubart enable next wave of indications

Empasiprubart to be evaluated in two head-to-head registrational studies against IVIg to position C2 inhibitor for broad, early-line use in MMN and CIDP

Transition to sustainable profitability in 2025 enables continued investment in innovation

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Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today reported preliminary financial results for the full-year 2024, including global product net sales, and announced its strategic priorities for 2025.

“2024 was a transformative year as we significantly expanded our global patient reach with VYVGART and advanced a world-class pipeline of precision therapies,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “The team’s strong execution has positioned argenx to be a profitable company in 2025, providing us flexibility to invest in the next wave of innovation across the company. Today, we are all in on our innovation mission, applying our successful innovation playbook to bring transformational outcomes to even more patients by unleashing the next wave of autoimmune indications and therapies, and securing our future by advancing multiple programs against first-in-class targets. We are positioned for significant expansion in 2025 with the FDA decision on approval of our pre-filled syringe, global CIDP rollout, and label-expansion studies underway for MG. To further support our growth, we are thrilled to have 10 ongoing registrational and 10 proof-of-concept studies in 2025, teeing us up for several data readouts across our pipeline in the next 12-24 months.

“Innovation is the cornerstone of everything we do, from the foundational science all the way to payor negotiations; it is our goal to deliver innovative and disruptive science for the benefit of patients who need better access to transformational safe, effective, and convenient precision therapies. Innovation has no meaning unless it reaches the marketplace, and we will continue to prioritize patient outcomes in all that we do.”

2025 Strategic Priorities

argenx established its ‘Vision 2030’ to outline the next phase of growth as part of its long-term commitment to transform the treatment of autoimmune diseases. Through this vision, argenx aims to treat 50,000 patients globally with its medicines, secure 10 labeled indications across all approved medicines, and advance five pipeline candidates into Phase 3 development by 2030.

To achieve the goals set out in its ‘Vision 2030’, argenx has set the following priorities for 2025:

- ▮ **Expand the global VYVGART opportunity** by reaching more patients broadly across MG, CIDP and ITP through additional regulatory approvals and continuous evidence generation
- ▮ **Launch VYVGART SC as a pre-filled syringe** to innovate on the patient experience and move earlier in the MG and CIDP treatment paradigms
- ▮ **Execute 10 registrational and 10 proof-of-concept studies** to fuel pipeline growth across efgartigimod, empasiprubart and ARGX-119
- ▮ **Advance four new molecules** into Phase 1 development, expanding the next wave of innovation
- ▮ **Generate sustainable value** through continued investment in the Immunology Innovation Program, focused on first-in-class, antibody-based medicines with pipeline-in-a-product potential

Expand the global VYVGART opportunity and launch VYVGART SC as a pre-filled syringe

VYVGART® (IV: efgartigimod alfa-fcab and SC: efgartigimod alfa and hyaluronidase-qvfc) is a first-in-class FcRn blocker approved in three indications, including generalized myasthenia gravis (gMG) globally, primary immune thrombocytopenia (ITP) in Japan, and chronic inflammatory demyelinating polyneuropathy (CIDP) in the U.S., Japan, and China.

- ▮ Regulatory decisions on approval of VYVGART for gMG expected in first half of 2025, including in Israel (SC), South Korea (IV), and Kuwait (IV)
- ▮ Continued innovation around the patient experience for VYVGART SC, including four key regulatory decisions on approval expected in 2025
 - ▮ FDA review ongoing of pre-filled syringe (PFS) for gMG and CIDP with Prescription Drug User Fee Act (PDUFA) target action date of April 10, 2025
 - ▮ PFS decisions on approval for gMG and CIDP expected in Europe in first half of 2025 and Japan and Canada in second half of 2025
 - ▮ Autoinjector development underway with launch planned for 2027
- ▮ Evidence generation through Phase 4 and label-enabling studies in MG, CIDP and ITP
 - ▮ Label-enabling studies ongoing to reach broader MG populations, including ADAPT-SERON (seronegative gMG), ADAPT-JR

(pediatric) and ADAPT-OCULUS (ocular MG), with topline results expected in second half of 2025 (SERON) and first half of 2026 (OCULUS and JR)

- Phase 4 switch study ongoing in CIDP to inform treatment decisions when switching a patient on IVIg to VYVGART SC
- ADVANCE-NEXT confirmatory study ongoing of VYVGART IV in primary ITP to support FDA submission with topline results expected in second half of 2026

Execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubart and ARGX-119

argenx continues to demonstrate breadth and depth within its immunology pipeline, advancing multiple first-in-class product candidates with potential across multiple high-need indications. argenx is solidifying its leadership in FcRn biology with efgartigimod, complement inhibition with empasiprubart and in the role of MuSK at the neuromuscular junction with ARGX-119. In 2025, argenx plans to execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubart and ARGX-119 to advance its next wave of launches.

Efgartigimod Development

Efgartigimod is being evaluated in more than 15 severe autoimmune diseases (including MG, CIDP and ITP), exploring the significance of FcRn biology across neurology and rheumatology indications, as well as new therapeutic areas. To prioritize those indications that can drive transformative benefit, argenx has made the decision to discontinue development of efgartigimod in bullous pemphigoid (BP).

- Registrational ALKIVIA study ongoing evaluating three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and dermatomyositis (DM); topline results expected in second half of 2026
- Two registrational UplightTED studies ongoing in thyroid eye disease (TED); topline results expected in second half of 2026
- Registrational UNITY study ongoing in primary Sjögren's disease; topline results expected in 2027
- Decision made to discontinue development in BP based on results from 98 patients in the Phase 2 BALLAD study
- Proof of concept studies ongoing in lupus nephritis (LN), systemic sclerosis (SSc) and antibody mediated rejection (AMR); topline results expected in LN in fourth quarter of 2025, SSc in second half of 2026, and AMR in 2027
- Two new indications nominated, including autoimmune encephalitis (AIE) and one that will be disclosed later in 2025
- Externally sponsored research studies ongoing in early MG, MG crisis, Guillain-Barré syndrome (GBS), stiff person syndrome (SPS), and neuromyelitis optica spectrum disorder (NMO-SD)

Empasiprubart Development

argenx is evaluating empasiprubart in registrational studies in multifocal motor neuropathy (MMN) and CIDP, and proof-of-concept studies in delayed graft function (DGF) and DM.

- Registrational EMPASSION study ongoing in MMN evaluating empasiprubart head-to-head versus IVIg; topline results expected in second half of 2026
- Registrational EMVIGORATE study in CIDP evaluating empasiprubart head-to-head versus IVIg to start in first half of 2025
- Proof of concept studies ongoing in DGF and DM; topline results expected in DGF in second half of 2025 and in DM in first half of 2026

ARGX-119 Development

argenx is evaluating ARGX-119 in congenital myasthenic syndromes (CMS), amyotrophic lateral sclerosis (ALS), and spinal muscular atrophy (SMA).

- Phase 1b proof-of-concept study ongoing in CMS; topline results expected in second half of 2025
- Phase 2a proof-of-concept study ongoing in ALS; topline results expected in first half of 2026
- SMA nominated as third indication with proof-of-concept study to start in 2025

Advance four new pipeline molecules and generate sustainable value through continued investment in Immunology Innovation Program

argenx continues to invest in its Immunology Innovation Program (IIP) to drive long-term sustainable pipeline growth. Through the IIP, four new pipeline candidates have been nominated, including: ARGX- 213, targeting FcRn and further solidifying argenx's leadership in this new class of medicine; ARGX- 121, a first-in-class molecule targeting IgA; ARGX-109, targeting IL-6, which plays an important role in inflammation, and ARGX-220, a first-in-class sweeping antibody for which the target has not yet been disclosed.

- Investigational new drug (IND) applications to be filed in 2025 for ARGX-213, ARGX-121, ARGX-109 and ARGX-220; Phase 1 results expected for ARGX-109 in second half of 2025 and for ARGX-213 and ARGX-121 in first half of 2026

Preliminary* Fourth Quarter and Full-Year 2024 Financial Results

Today, argenx also announced preliminary* global product net sales for the fourth quarter and full-year 2024 of approximately \$737 million and \$2.2 billion, respectively.

As of December 31, 2024, argenx had approximately \$3.4 billion in cash, cash equivalents and current financial assets*.

* - The preliminary selected financial information is unaudited, subject to adjustment, and provided as an approximation in advance of the company's announcement of complete financial results in February 2025. Refer to the Preliminary Financial Results note in this document.

2025 Financial Guidance

Based on its current operating plans, argenx expects its combined R&D and SG&A expenses in 2025 to be approximately \$2.5 billion.

Tim Van Hauwermeiren will highlight these updates in a corporate presentation at the 43rd Annual J.P. Morgan Healthcare Conference today, Monday, January 13, 2025, at 9:45 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 VYVGART and VYVGART SC

VYVGART[®] is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker for the treatment of generalized myasthenia gravis (gMG), chronic inflammatory demyelinating polyneuropathy (CIDP), and primary immune thrombocytopenia (ITP). VYVGART SC is a subcutaneous combination of efgartigimod alfa and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE[®] drug delivery technology to facilitate subcutaneous injection delivery of biologics. It is marketed as VYVGART[®] Hytrulo in the U.S., VYVGART SC in Europe, VYVDURA[®] in Japan, and may be marketed under different proprietary names following approval in other regions.

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 approved neonatal Fc receptor (FcRn) blocker, globally in the U.S., Japan, Israel, the EU, the UK, China and Canada. 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](#), [X](#) (formerly known as Twitter), and [Instagram](#).

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Preliminary Financial Results

The financial information presented in this press release is preliminary, estimated, and unaudited. They are subject to the completion and finalization of argenx's financial and accounting closing procedures. They reflect management's estimates based solely upon information available to management as of the date of this press release. Further information learned during that completion and finalization may alter the final results. In addition, the preliminary estimates should not be viewed as a substitute for full quarterly and annual financial statements prepared in accordance with IFRS. There is a possibility that argenx's financial results for the quarter ended December 31, 2024, and full year financial results for 2024 could vary materially from these preliminary estimates. In addition to the completion of the financial closing procedures, factors that could cause actual results to differ from those described above are set forth below. Accordingly, you should not place undue reliance upon this preliminary information.

Additional information regarding the company's fourth quarter 2024 financial results and full year financial results for 2024 will be available in the company's annual report and Form 20-F, which will be filed with the Netherlands Authority for the Financial Markets and U.S. Securities and Exchange Commission (the "SEC"), respectively.

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 "aim," "can," "continue," "expect," "goal," "may," "ongoing," "plan," "possible," "target," and "will," and include statements argenx makes regarding its expected profitability in 2025; its 2025 strategic priorities, including its launch of pre-filled syringes, 10 Phase 3 studies and 10 Phase 2 studies across efgartigimod, empasiprubart and ARGX-119, the advancement of four molecules in Phase 1 studies and the continued investment in the Immunology Innovation Program; its significant expansion in 2025; the continued growth of VYVGART, including its expected autoinjector launch in 2027 and four global decisions in 2025; its expectations regarding the continued growth in CIDP, including its plan to launch multiple CIDP products in 2025 and the expected timing of the EMVIGORATE study; its expectations regarding the growth of the MMN market opportunity, including the expected timing of the EMPASSION study; the anticipated timing of data readouts and regulatory milestones and plans, including the timing of planned clinical trials and regulatory filings and approvals; its vision for 2030, including having 5 new molecules in Phase 3, 10 labeled indications and having 50,000 patients on treatment; the anticipated timing of pending regulatory decisions in Israel, South Korea, Kuwait, the U.S., Europe, Japan and Canada; the expected timing of Phase 4 and label-enabling studies in MG, CIDP and ITP; and its expected 2025 research and development and selling, general and administrative expenses. 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 results of argenx's clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements in products and product candidates; the acceptance of argenx's products and product candidates by patients as safe, effective and cost-effective; the impact of governmental laws and regulations on our business; disruptions caused on our reliance of third party suppliers, service providers and manufacturing; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. 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.