#### argenx Highlights 2024 Strategic Priorities

Reported \$1.2 billion in preliminary\* full-year 2023 global net product sales

Submitted sBLA to FDA for VYVGART<sup>®</sup> Hytrulo for CIDP with priority review voucher (PRV); if approved, launch expected mid-2024

Reported positive data from Phase 2 ARDA study establishing proof-of-concept for empasiprubart in MMN

Data from six Phase 2 proof-of-concept trials expected by end of 2024

Nominated four new pipeline candidates with IND filings expected by end of 2025

January 8, 2024, 7:00 AM CET

**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 2023, including global net product sales (inclusive of both VYVGART<sup>®</sup> and VYVGART Hytrulo), and announced its strategic priorities for 2024.

"In 2023, we reached more than 6,000 patients globally, making VYVGART available to gMG patients around the world," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We continued to invest in and demonstrate the sustainability of our business by successfully launching our subcutaneous VYVGART product, and are poised for continued expansion in gMG and beyond in 2024. argenx is delivering on its promise to transform how the world understands autoimmunity. It is with this commitment in mind that we submitted our sBLA for VYVGART Hytrulo in CIDP and, if approved, expect to launch in the U.S. in mid-2024. We will continue to be aggressive in advancing our pipeline this year and expect to report efgartigimod data from six Phase 2 studies in 2024, and to further develop empasiprubart in MMN. Through sustained investment in our IIP, we expect to see repeat value creation, and plan to submit four new INDs by the end of 2025."

"Two years ago, argenx's key goal was to launch efgartigimod in the U.S. Today, we have built a formidable global commercial organization with product approvals in over 30 countries worldwide and a vibrant pipeline of promising new therapeutics to address immune-mediated diseases. We have forged important partnerships that support our mission to advance the human understanding of immunology to best benefit patients. argenx is well positioned for sustained growth throughout 2024 and well into the future."

#### **2024 Strategic Priorities**

argenx will focus on three strategic priorities in 2024 to drive sustainable long-term growth, including:

- **Reach more patients with VYVGART** by building upon its strong commercial foundation to address ongoing unmet patient need, broaden the MG opportunity, and expand into CIDP
- Advance its extensive pipeline through new data readouts, creating multiple opportunities to demonstrate transformative clinical benefit
- Leverage its repeatable innovation engine, driving pipeline growth through its Immunology Innovation Program

# **Reach More Patients with VYVGART**

VYVGART (efgartigimod alfa fcab) is a first-in-class antibody fragment targeting the neonatal Fc receptor (FcRn) and is now approved in more than 30 countries globally. VYVGART subcutaneous (SC) (efgartigimod alfa and hyaluronidase-qvfc) is approved in the U.S. (as VYVGART Hytrulo) and Europe, making VYVGART the only gMG treatment available as both an IV and simple SC injection. argenx is planning to reach more patients commercially in 2024 through its multi-dimensional expansion efforts. argenx will work to reach patients earlier in the MG treatment paradigm and improve the lives of new MG patient populations through additional global regulatory approvals, and the expansion of uses to treat additional autoimmune indications.

- Regulatory approval decisions of VYVGART for gMG expected in Switzerland, Australia, Saudi Arabia and South Korea by end of 2024
- Through strategic collaboration with Zai Lab, VYVGART to be included on China's 2023 National Reimbursement Drug List (NRDL), starting in January 2024
- Decision on approval of VYVGART SC for gMG in Japan expected in first quarter of 2024 and in China through Zai Lab by end of 2024
- Decision on approval of VYVGART for primary immune thrombocytopenia (ITP) in Japan expected in first quarter of 2024
- Supplemental Biologics License Application (sBLA) submitted to FDA for VYVGART Hytrulo for CIDP with priority review voucher (PRV); if approved, launch expected mid-2024
- Regulatory submissions of VYVGART SC for CIDP in Japan, Europe, China and Canada expected in 2024
- Registrational studies to expand VYVGART label into broader MG populations, including in seronegative patients, to start in 2024
- Update on pre-filled syringe development expected in first half of 2024; ongoing studies to support potential approval in gMG and CIDP in 2024

#### Advance Current Pipeline through Upcoming Data Readouts

argenx continues to demonstrate breadth and depth within its immunology pipeline and is advancing multiple pipeline-in-a-product candidates. With efgartigimod, argenx is solidifying its leadership in FcRn and is on track to be approved or in development in 15 autoimmune indications by 2025. Beyond efgartigimod, argenx is advancing its earlier stage pipeline programs, including empasiprubart (C2 inhibitor) with Phase 2 studies ongoing in multifocal motor neuropathy (MMN), delayed graft function and dermatomyositis (DM). In addition, ARGX-119, a muscle-specific kinase (MuSK) agonist, will initiate Phase 1b/2a studies in congenital myasthenic syndrome and amyotrophic lateral sclerosis in 2024.

Today, argenx reported positive clinical data from the first cohort of the Phase 2 ARDA study of empasiprubart, establishing proof-of-concept in MMN. After confirming IVIg dependence, 27 patients were withdrawn from IVIg treatment and randomized 2:1 to either empasiprubart or placebo for 16 weeks. Patients were monitored for clinical deterioration that required IVIg retreatment, which was the main efficacy endpoint of the study.

- Empasiprubart demonstrated a 91% reduction in the need for IVIg rescue compared to placebo [HR: 0.09 95% CI (0.02; 0.44)]
- According to the Patient Global Impression of Change scale, 94% (17/18) of empasiprubarttreated patients rated their condition as improved since study start, including 55% (10/18) who were much or very much improved. Of placebo patients, 89% (8/9) worsened or had no change.
- Empasiprubart demonstrated improvement on all six efficacy measurements compared to baseline
- Safety and tolerability profile were consistent with Phase 1 results
- Cohort 2 is ongoing to determine dose response ahead of a Phase 3 study start

argenx is on track to report topline data from five additional proof-of-concept studies in 2024, including:

- Phase 2 RHO study evaluating efgartigimod in primary Sjogren's syndrome expected in first half of 2024
- Phase 2 ALPHA study evaluating efgartigimod in post-COVID-19 postural orthostatic tachycardia syndrome (PC-POTS) expected in first half of 2024
- Seamless Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets (immune-mediated necrotizing myopathy (IMNM), antisynthetase syndrome (ASyS), and DM) expected in the second half of 2024

# Leverage Repeatable Innovation Playbook to Drive Long-Term Pipeline Growth

argenx continues to invest in its discovery engine, the Immunology Innovation Program (IIP), to drive longterm 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 and ARGX-220, which are first-in-class targets broadening argenx's focus across the immune system; and ARGX-109, targeting IL-6, which plays an important role in inflammation. Preclinical work is ongoing in each candidate and argenx is on track to file four investigational new drug (IND) applications by the end of 2025.

#### Preliminary\* Fourth Quarter and Full-Year 2023 Financial Results

Today, argenx also announced preliminary\* global net VYVGART revenues for the fourth quarter and fullyear 2023 of approximately \$374 million and \$1.2 billion, respectively.

As of December 31, 2023, argenx had approximately \$3.2 billion in cash, cash equivalents and current financial assets\*. Based on its current operating plans, argenx expects its combined R&D and SG&A expenses in 2024 to be less than \$2 billion. The projected 2024 cash burn will be 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 February 2024.

### 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference Presentation and Webcast

Mr. Van Hauwermeiren will highlight these updates in a corporate presentation at the 42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference today, Monday, January 8, 2024, 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.

#### Phase 2 ARDA Study Design

The Phase 2 ARDA study is a randomized, double-blinded, placebo-controlled multicenter study to evaluate the safety and tolerability, efficacy, pharmacokinetics, pharmacodynamics, and immunogenicity of two dose regimens of empasiprubart in adults with multifocal motor neuropathy (MMN). The study consists of an IVIg dependency and monitoring period and two 16-week treatment cohorts of 24 MMN patients receiving empasiprubart or placebo in a 2x1 randomization. The dosing for Cohort 2 was established after a planned interim analysis of the first nine patients to complete the 16-week treatment period from Cohort 1. The primary endpoint is safety and tolerability. Additional endpoints include time to IVIg retreatment, biomarker analyses of C2 levels, and changes in measurements on key functional scores (modified medical research council (mMRC)-10 sum score, grip strength, MMN-RODS) as well as several patient-reported quality of life outcome measures (fatigue severity score (FSS), chronic acquired polyneuropathy patient-reported index (CAP-PRI), and values of the patient global impression change (PGIC) scale).

#### About Multifocal Motor Neuropathy

Multifocal motor neuropathy (MMN) is a rare, chronic autoimmune disease of the peripheral nervous system. The disease is characterized by slowly progressive, asymmetric muscle weakness mainly of the hands, forearms and lower legs. MMN is often associated with anti-GM1 IgM autoimmunity, leading to activation of the classical complement pathway, driving subsequent axon damage. High-dose IVIg is the only approved treatment for MMN and patients typically experience disease progression despite therapy, indicating an unmet need for efficacious and better tolerated therapeutic options.

# About Empasiprubart

Empasiprubart (ARGX-117) is a first-in-class humanized sweeping antibody that binds specifically to C2 thereby blocking both the classical and lectin pathways of the complement cascade. By blocking upstream complement activity, empasiprubart has the potential to reduce tissue inflammation representing a broad pipeline opportunity across multiple severe autoimmune indications. In addition to multifocal motor

neuropathy, argenx is evaluating empasiprubart in delayed graft function following kidney transplant and dermatomyositis.

### 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 globally 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 SC is a subcutaneous combination of efgartigimod alfa and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE<sup>®</sup> drug delivery technology to facilitate subcutaneous injection delivery of biologics. It is marketed as VYVGART Hytrulo in the U.S. and VYVGART SC in Europe, 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, Twitter, and Instagram.

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#### **Preliminary Financial Results**

The financial results presented in this press release are 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, 2023, and full year financial results for 2023 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 2023 financial results and full year financial results for 2023 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, "forwardlooking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "plans," "aims," "believes," "continues," "hope," "estimates," "preliminary," "anticipates," "expects," "intends," "may," "will," "should," or "commitment" and include statements argenx makes concerning its preliminary financial results for the full year 2023; its expansion efforts, including reaching more patients with VYVGART within the MG treatment paradigm, through geographic expansion and into new autoimmune indications, expanding into CIDP, and the anticipated development of empasiprubart and ARGX-119; the anticipated timing of its launch of SC efgartigimod for CIDP 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; its expectations of future profitability; 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, including but not limited to argenx's ability to successfully execute its business and growth strategies, the inherent uncertainties associated with development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements, the acceptance of our products and product candidates by our patients as safe, effective and cost-effective, volatile market conditions, and the impact of governmental laws and regulations on our business. 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 forwardlooking 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.