# argenx Reports Full Year 2023 Financial Results and Provides Fourth Quarter Business Update

*$374 million in fourth quarter and $1.2 billion in full year global net product sales*

*sBLA for VYVGART® Hytrulo for CIDP accepted for priority review by FDA with PDUFA target action date of June 21, 2024*

*On track to report data from six Phase 2 proof-of-concept trials by end of 2024*

*Management to host conference call today at 2:30 pm CET (8:30 am ET)*

**February 29, 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 financial results for the full year 2023 and provided a fourth quarter business update.

“argenx reached thousands of new patients and their families in 2023 by delivering on our commitment to make VYVGART available to the global MG community,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “This expansion demonstrates that VYVGART has the potential to address the high unmet need for innovation in patients suffering from MG, and moves us closer to sustainability as we build an integrated immunology company. Clinically, we generated significant data through multiple study readouts, achieving key milestones for both the CIDP and MMN patient communities and importantly advancing our second molecule, empasiprubart. Looking forward to 2024, we will act with a continued sense of purpose to expand our patient reach. We will use the learnings and momentum from our gMG launch to strategically lay the groundwork for a potential CIDP approval, leveraging our current infrastructure and deep relationships in the neurology community to position VYVGART SC for success. CIDP patients have been waiting for innovation, and we are eager to translate the transformative ADHERE data into potential benefit for patients as quickly as possible.”

## FOURTH QUARTER 2023 AND RECENT BUSINESS UPDATE

### Reaching 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 for the treatment of generalized myasthenia gravis (gMG). VYVGART subcutaneous (SC) (efgartigimod alfa and hyaluronidase-qvfc) is approved in the U.S. (as VYVGART Hytrulo), Japan (as VYVDURA®) 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 through its multi-dimensional expansion efforts, including patients earlier in the MG treatment paradigm and new patient populations through global regulatory approvals for MG and the expansion of use to treat additional autoimmune indications.

- Generated global net product revenues (inclusive of both VYVGART and VYVGART SC) of $374 million in the fourth quarter and $1.2 billion in the full year of 2023
- Medicines and Healthcare products Regulatory Agency (MHRA) approved VYVGART SC in the United Kingdom for the treatment of adult patients with gMG on February 6, 2024, with self-administration
- Ministry of Health, Labour and Welfare (MHLW) approved VYVDURA in Japan for the treatment of adult patients with gMG, inclusive of seronegative patients, on January 18, 2024, with self-administration
- Decisions on regulatory approvals of VYVGART for gMG expected in Switzerland, Australia, Saudi Arabia and South Korea by end of 2024
- Decision on approval of VYVGART SC for gMG in China through Zai Lab expected 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) for VYVGART Hytrulo accepted for priority review by FDA for chronic inflammatory demyelinating polyneuropathy (CIDP); Prescription Drug User Fee Act (PDUFA) target action date of June 21, 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, expected to start in 2024
- Update on pre-filled syringe development expected in first half of 2024; ongoing clinical studies expected to support potential approval in gMG and CIDP in 2024

### Advancing Current Pipeline

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 (DGF) and dermatomyositis (DM). In addition, argenx is evaluating ARGX-119, a muscle-specific kinase (MuSK) agonist in both congenital myasthenic syndrome (CMS) and amyotrophic lateral sclerosis (ALS).

- Evaluation ongoing to determine path forward in BALLAD study evaluating efgartigimod in bullous pemphigoid (BP), with an update expected in 2024
- Topline data from Phase 2 RHO study evaluating efgartigimod in primary Sjogren’s syndrome expected in first half of 2024

- Topline data from Phase 2 ALPHA study evaluating efgartigimod in post-COVID-19 postural orthostatic tachycardia syndrome (PC-POTS) expected in first half of 2024
- Topline data from seamless Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and DM) expected in second half of 2024
- Full Phase 2 topline data from ARDA study evaluating empasiprubart in MMN expected to be shared in 2024; cohort 2 is ongoing to determine dose response ahead of Phase 3 study start
- Phase 1 study of ARGX-119 ongoing in healthy volunteers; subsequent Phase 1b/2a trials planned to assess early signal detection in patients with CMS and ALS in 2024

**Leveraging Repeatable Innovation Playbook to Drive Long-Term Pipeline Growth**

argenx continues to invest in its discovery engine, the 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 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.

- On track to file four investigational new drug (IND) applications by end of 2025
- Received $30M milestone from AbbVie for advancement of ABBV-151 (ARGX-115) to Phase 2

**FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL RESULTS**

**argenx SE**

**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS**

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| **(in thousands of $ except for shares and EPS)** | **2023** | **2022** | **2023** | **2022** |
| Product net sales | $ 374,351 | $ 173,396 | $ 1,190,783 | $ 400,720 |
| Collaboration revenue | 32,486 | 764 | 35,533 | 10,026 |
| Other operating income | 11,003 | 7,956 | 42,278 | 34,520 |
| **Total operating income** | **$ 417,840** | **$ 182,116** | **$ 1,268,594** | **$ 445,267** |
| Cost of sales | $ (39,477) | $ (12,786) | $ (117,835) | $ (29,431) |
| Research and development expenses | (306,373) | (147,798) | (859,492) | (663,366) |
| Selling, general and administrative expenses | (208,826) | (135,287) | (711,905) | (472,132) |
| Loss from investment in joint venture | (1,788) | (677) | (4,411) | (677) |
| **Total operating expenses** | **(556,464)** | **(296,548)** | **(1,693,643)** | **(1,165,607)** |
| **Operating loss** | **$ (138,624)** | **$ (114,432)** | **$ (425,049)** | **$ (720,341)** |
| Financial income | $ 40,308 | $ 13,925 | $ 107,386 | $ 27,665 |
| Financial expense | (280) | (990) | (906) | (3,906) |
| Exchange gains/(losses) | 37,418 | 60,259 | 14,073 | (32,732) |
| **Loss for the period before taxes** | **$ (61,178)** | **$ (41,238)** | **$ (304,496)** | **$ (729,314)** |
| Income tax benefit / (expense) | $ (37,994) | $ 2,625 | $ 9,443 | $ 19,720 |
| **Loss for the period** | **$ (99,172)** | **$ (38,613)** | **$ (295,053)** | **$ (709,594)** |
| **Loss for the year attributable to:** | | | | |
| Owners of the parent | $ (99,172) | $ (38,613) | $ (295,053) | $ (709,594) |
| Weighted average number of shares outstanding | 59,118,827 | 55,364,124 | 57,169,253 | 54,381,371 |
| Basis and diluted (loss) per share (in $) | (1.68) | (0.70) | (5.16) | (13.05) |
| Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2022 and 2021 | | | $ 987,296 | $ (144,180) |
| Cash and cash equivalents and current financial assets at the end of the period | | | $ 3,179,844 | $ 2,192,548 |

**DETAILS OF THE FINANCIAL RESULTS**

**Total operating income** for the fourth quarter and full year in 2023 was $418 million and $1,269 million, respectively, compared to $182 million and $445 million for the same periods in 2022, and mainly consists of:

- **Product net sales** of VYVGART and VYVGART SC for the fourth quarter and full year in 2023, were $374 million and $1,191 million, respectively, compared to $173 million and $401 million for the same periods in 2022.
- **Collaboration revenue** for the fourth quarter and full year in 2023 was $32 million and $36 million, respectively, compared to $1 million and $10 million for the same periods in 2022. The increase is mainly related to the clinical development milestone argenx achieved with AbbVie following the dosing of the first patient in the Phase 2 trial for ABBV-151. Collaboration revenue for full year in 2023 also includes $1 million in royalty revenue from VYVGART sales in China.

- **Other operating income** for the fourth quarter and full year in 2023 was $11 million and $42 million, respectively, compared to $8 million and $35 million for the same periods in 2022. The other operating income for the fourth quarter and full year in 2023, primarily relates to research and development tax incentives and payroll tax rebates.

**Total operating expenses** for the fourth quarter and full year in 2023 were $556 million and $1,694 million, respectively, compared to $297 million and $1,166 million for the same periods in 2022, and mainly consists of:

- **Cost of sales** for the fourth quarter and full year in 2023 was $39 million and $118 million, respectively, compared to $13 million and $29 million for the same periods in 2022. The cost of sales was recognized with respect to the sale of VYVGART and VYVGART SC.
- **Research and development expenses** for the fourth quarter and full year in 2023 were $306 million and $859 million, respectively, compared to $148 million and $663 million for the same periods in 2022. The research and development expenses mainly relate to external research and development expenses and personnel expenses incurred in the clinical development of efgartigimod in various indications and the expansion of other clinical and preclinical pipeline candidates. The research and development expenses for the fourth quarter and the full year in 2023, includes the amortization of the priority review voucher submitted with the sBLA filling for VYVGART Hytrulo for the treatment of CIDP, which resulted in an expense of $102 million.
- **Selling, general and administrative expenses** for the fourth quarter and full year in 2023 were $209 million and $712 million, respectively, compared to $135 million and $472 million for the same periods in 2022. The selling, general and administrative expenses mainly relate to professional and marketing fees linked to the commercialization of VYVGART and VYVGART SC, and personnel expenses.

**Financial income** for the fourth quarter and full year in 2023 was $40 million and $107 million, respectively, compared to $14 million and $28 million for the same periods in 2022. The increase in financial income is mainly due to an increase in interest income which results from higher interest rates and a higher amount of current financial assets, cash and cash equivalents as a result of the financing round in July 2023.

**Exchange gains** for the fourth quarter and full year in 2023 were $37 million and $14 million respectively, compared to $60 million of exchange gains and $33 million of exchange losses for the same periods in 2022. Exchange gains/losses are mainly attributable to unrealized exchange rate gains or losses on the cash, cash equivalents and current financial assets denominated in Euro.

**Income tax** for the fourth quarter and full year in 2023 was $38 million of tax expense and $9 million of tax benefit, respectively, compared to $3 million and $20 million of tax benefit for the same periods in 2022. Tax expense for the fourth quarter in 2023, consists of $12 million of income tax benefit and $50 million of deferred tax expense, compared to $12 million of income tax expense and $15 million of deferred tax benefit for the comparable prior period.

**Net loss** for the fourth quarter and full year in 2023, was $99 million and $295 million, respectively, compared to $39 million and $710 million over the prior year periods. On a per weighted average share basis, the net loss was $5.16 and $13.05 for the twelve months ended December 31, 2023 and 2022, respectively.

**Cash, cash equivalents and current financial assets** totalled $3.2 billion as of December 31, 2023, compared to $2.2 billion as of December 31, 2022. The increase in cash and cash equivalents and current financial assets resulted primarily from the closing of a global offering of shares, including a U.S. offering, which resulted in the receipt of $1.2 billion in net proceeds in July 2023, partially offset by net cash flows used in operating activities.

**FINANCIAL GUIDANCE**

Based on its current operating plans, argenx expects its combined Research and development and Selling, general and administrative expenses in 2024 to be less than $2 billion. argenx expects to utilize up to $500 million of net cash in 2024 on these anticipated operating expenses as well as working capital and capital expenditures.

**EXPECTED 2024 FINANCIAL CALENDAR**

- May 9, 2024: Q1 2024 financial results and business update
- July 25, 2024: Q2 2024 financial results and business update
- October 31, 2024: Q3 2024 financial results and business update

**CONFERENCE CALL DETAILS**
The full year 2023 financial results and fourth quarter business update will be discussed during a conference call and webcast presentation today at 2:30 pm CET/8:30 am ET. A webcast of the live call may be accessed on the Investors section of the argenx website at argenx.com/investors. A replay of the webcast will be available on the argenx website.

**Dial-in numbers:**
*Please dial in 15 minutes prior to the live call.*

| | |
|---|---|
| Belgium | 32 800 50 201 |
| France | 33 800 943355 |
| Netherlands | 31 20 795 1090 |
| United Kingdom | 44 800 358 0970 |
| United States | 1 888 415 4250 |
| Japan | 81 3 4578 9081 |
| Switzerland | 41 43 210 11 32 |

**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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**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 "plans," "aims," "continues," "anticipates," "expects," "will," or "commitment" and include statements argenx makes concerning its utilization of its learnings and momentum from its gMG launch for a potential CIDP approval and to position VYVGART SC for success; its plans to expand its patient reach, including through its multidimensional expansion efforts aimed at including patients earlier in the MG treatment paradigm and pursuing global regulatory approvals for MG as well as additional autoimmune indications; our goal to translate the ADHERE data into potential benefit for patients; the advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including: (1) expected decisions on regulatory approvals of VYVGART for gMG in Switzerland, Australia, Saudi Arabia and South Korea by end of 2024, (2) expected decisions on approval of VYVGART SC for gMG in China through Zai Lab by end of 2024, (3) expected decisions on approval of VYVGART for ITP in Japan in the first quarter of 2024, (4) expected regulatory submissions of VYVGART SC of CIDP in Japan, Europe, China and Canada in 2024, (5) the expansion of our VYVGART registrational studies into broader MG populations, including in seronegative patients, expected to start in 2024, (6) the update on pre-filled syringe development expected in the first half of 2024, (7) clinical studies expected to support potential approval in gMG and CIDP in 2024, (8) expected update on the path forward for BALLAD study in 2024, (9) expected topline data from Phase 2 RHO in the first half of 2024, (10) expected topline data from Phase 2 ALPHA study in the first half of 2024, (11) expected topline data from Phase 2/3 ALKIVIA in the second half of 2024, (12) the full Phase 2 topline data from ARDA study expected in 2024, (13) planned Phase 1b/2a clinical trials of ARGX-119 in 2024, (14) four IND applications expected to be filed by end of 2025, (15) expected data from six Phase 2 proof-of-concept trials by the end of 2024, and (16) the expected approval or development in 15 autoimmune indications by 2025; the potential of its continued investment in its IIP to drive long-term sustainable pipeline growth; its future financial and operating performance, including its anticipated operating expenses and utilization of net cash for 2024; and our goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. 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, the results of argenx's clinical trials, expectations regarding 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, 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 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.