argenx Reports Half Year 2024 Financial Results and Provides Second Quarter Business Update

$478 million in second quarter global net product sales

First CIDP patients treated with VYVGART® Hytrulo following June 21st FDA approval

On track to begin four additional registrational studies across efgartigimod and empasiprubart by end of 2024

Management to host conference call today at 2:30 PM CET (8:30 AM ET)

Regulated Information – Inside Information

July 25, 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 announced its half year 2024 results and provided a second quarter business update.

"We were excited to unveil our ambition for the future of argenx – Vision 2030 – last week, outlining our plan to develop and deliver continued and sustainable innovation for patients," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We are already delivering on this promise with impressive commercial execution throughout the first half of the year, expanding our patient reach in MG, and launching in CIDP with our broad FDA label. Our development pipeline is stronger than ever, driven by our unique innovation engine. And we are well-positioned to capture the sizeable growth opportunity before us as we seek to reach earlier-line MG patients over the next 12-18 months with potential label expansions and a pre-filled syringe."

Vision 2030

During its R&D Day on July 16, 2024, argenx unveiled its 'Vision 2030' as part of its long-term commitment to transform the treatment of autoimmune diseases by strengthening its leadership in neonatal Fc receptor (FcRn) biology, investing in its continuous pipeline of differentiated antibody candidates, and scaling in a disciplined way to ensure innovation remains core to the argenx mission. 'Vision 2030' includes the following goals:

- 50,000 patients globally on treatment with an argenx medicine
- 10 labeled indications across all approved assets, including VYVGART and potentially empasiprubart and ARGX-119
- Five new molecules in Phase 3 development indicating ongoing investment in internal discovery engine, the Immunology Innovation Program

Reaching 50,000 Patients Globally

VYVGART (efgartigimod alfa-fcab) is a first-in-class antibody fragment targeting FcRn and is now approved for both intravenous use and subcutaneous injection (SC) (efgartigimod alfa and hyaluronidase-qvfc) 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.

- Generated global net product sales (inclusive of both VYVGART and VYVGART SC) of $478 million in second quarter of 2024
- National Medical Products Administration (NMPA) approved VYVGART SC for treatment of gMG in China through Zai Lab on July 16, 2024
- Additional VYVGART regulatory decisions on approval expected for gMG in 2024, including in Switzerland, Australia, and Saudi Arabia
- Launched VYVGART Hytrulo in CIDP in U.S. with first patients injected in July
- Multiple VYVGART SC regulatory submissions under review or planned for CIDP, including:
  - Regulatory submissions completed in China, Japan, and Europe with decisions on approval expected in 2025
  - Regulatory submission filing in Canada by end of 2024
- Announced plan to evaluate VYVGART in ocular MG with registrational study (ADAPT OCULUS) to start by end of year; OCULUS to support label-expansion strategy into broader MG populations along with ongoing ADAPT SERON study in seronegative MG
- Regulatory submission filed and under review for VYVGART SC pre-filled syringe (PFS) for gMG and CIDP

Advancing Pipeline to Achieve 10 Labeled Indications by 2030

argenx continues to demonstrate breadth and depth within its immunology pipeline, advancing multiple pipeline-in-a-product candidates. argenx is solidifying its leadership in FcRn biology, with efgartigimod currently in development in 15 indications. argenx is also advancing its first-in-class C2 inhibitor, empasiprubart, which is being evaluated in multifocal motor neuropathy (MMN), delayed graft function (DGF), dermatomyositis (DM), and CIDP. In addition, argenx is evaluating ARGX-119, a muscle-specific kinase (MuSK) agonist in both congenital myasthenic syndrome (CMS) and amyotrophic lateral sclerosis (ALS).

- Registrational studies ongoing of efgartigimod in thyroid eye disease (TED)
- Advancing development of efgartigimod in primary Sjogren's disease (SjD) with Phase 3 study to begin by end of 2024
- Following alignment meeting with FDA, confirmatory study of VYVGART (IV) in primary ITP to start by end of 2024 to enable

registration in U.S.
- 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 fourth quarter of 2024
- Update on BALLAD study development plan evaluating efgartigimod in bullous pemphigoid (BP) expected by end of 2024
- Proof-of-concept studies ongoing with efgartigimod in membranous nephropathy (MN) and lupus nephritis (LN) with studies expected to initiate this year in antibody mediated rejection (AMR) and systemic sclerosis (SSc)
- Phase 3 study of empasiprubart for MMN to initiate in fourth quarter of 2024
- CIDP nominated as fourth empasiprubart indication, recognizing opportunity to bring multiple innovative treatments to patients
- Phase 1b/2a studies of ARGX-119 to assess early signal detection in patients with CMS and ALS to start by end of 2024

Investing in Immunology Innovation Program to Support Five New Molecules in Phase 3 by 2030

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.

- Phase 1 studies of ARGX-213 and ARGX-121 expected to start in second half of 2025
- Investigational new drug (IND) applications for ARGX-220 and ARGX-109 on track to be filed by end of 2025

SECOND QUARTER 2024 FINANCIAL RESULTS

argenx SE
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands of $ except for shares and EPS)	**2024**	**2023**	**2024**	**2023**
Product net sales	$ 477,635	$ 269,313	$ 875,918	$ 487,335
Collaboration revenue	-	1,237	2,718	2,355
Other operating income	11,793	10,485	23,305	21,225
Total operating income	**$ 489,428**	**$ 281,035**	$ **901,941**	$ **510,915**
Cost of sales	**$** (52,383)	$ (24,024)	$ (95,561)	$ (42,359)
Research and development expenses	(225,286)	(195,509)	(450,255)	(361,364)
Selling, general and administrative expenses	(255,699)	(161,977)	(491,694)	(311,149)
Loss from investment in joint venture	(1,521)	(1,619)	(3,313)	(1,880)
Total operating expenses	**$ (534,889)**	**$ (383,129)**	**$ (1,040,823)**	**(716,752)**
Operating loss	**$ (45,461)**	$ **(102,094)**	$ **(138,882)**	$ **(205,837)**
Financial income	$ 38,933	$ 20,441	$ 77,828	$ 37,029
Financial expense	(572)	(207)	(1,084)	(395)
Exchange gains/(losses)	(7,903)	(2,001)	(27,215)	9,164
Loss for the period before taxes	**$ (15,003)**	**$ (83,861)**	$ **(89,353)**	$ **(160,039)**
Income tax benefit/(expense)	$ 44,069	$ (10,507)	$ 56,822	$ 36,800
Profit/(loss) for the period	**$ 29,066**	**$ (94,368)**	$ **(32,531)**	$ **(123,239)**
Profit/(loss) for the period attributable to:				
Owners of the parent	$ 29,066	$ (94,368)	$ (32,531)	$ (123,239)
Weighted average number of shares outstanding	59,490,437	55,828,239	59,400,217	55,690,873
Basic profit/(loss) per share (in $)	0.49	(1.69)	(0.55)	(2.21)
Diluted profit/(loss) per share (in $)	0.45	(1.69)	(0.55)	(2.21)
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2022 and 2023			(77,497)	$ (195,580)
Cash and cash equivalents and current financial assets at the end of the period			3,102,347	$ 1,996,968

DETAILS OF THE FINANCIAL RESULTS

Total operating income for the three and six months ended June 30, 2024 was $489 million and $902 million compared to $281 million and $511 million for the same periods in 2023, and mainly consists of:

- **Product net sales** of VYVGART and VYVGART SC for the three and six months ended June 30, 2024 were $478 million and $876 million compared to $269 million and $487 million for the same periods in 2023.
- **Other operating income** for the three and six months ended June 30, 2024 was $12 million and $23 million compared to $10 million and $21 million for the same periods in 2023. The other operating income for the three and six months ended June 30, 2024 and 2023, primarily relates to research and development tax incentives.

Total operating expenses for the three and six months ended June 30, 2024 were $535 million and $1,041 million compared to $383 million and $717 million for the same periods in 2023, and mainly consists of:

- **Cost of sales** for the three and six months ended June 30, 2024 was $52 million and $96 million compared to $24 million and $42 million for the same periods in 2023. The cost of sales was recognized with respect to the sale of VYVGART and VYVGART SC.
- **Research and development expenses** for the three and six months ended June 30, 2024 were $225 million and $450 million compared to $196 million and $361 million for the same periods in 2023. 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.
- **Selling, general and administrative expenses** for the three and six months ended June 30, 2024 were $256 million and $492 million compared to $162 million and $311 million for the same periods in 2023. 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 three and six months ended June 30, 2024 was $39 million and $78 million compared to $20 million and $37 million for the same periods in 2023. The increase in financial income is mainly due to an increase in interest income coming from an increase of cash, cash equivalents and current financial assets as a result of the July 2023 financing round.

Exchange losses for the three and six months ended June 30, 2024 were $8 million and $27 million compared to $2 million exchange losses and $9 million of exchange gains for the same periods in 2023. 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 three and six months ended June 30, 2024 was $44 million and $57 million of income tax benefit, respectively, compared to $11 million of income tax expense and $37 million of income tax benefit for the same periods in 2023.

Net Result for the three and six months ended June 30, 2024 was $29 million profit and $33 million loss compared to $94 million and $123 million loss for the same periods in 2023. On a per weighted average share basis, the basic profit was $0.49 and diluted profit was $0.45 for the three months ended June 30, 2024, compared to a basic and diluted loss of $1.69 for the same period in 2023. On a per weighted average share basis, the basic and diluted loss was $0.55 for the six months ended June 30, 2024, compared to a basic and diluted loss of $2.21 for the same period in 2023.

Cash, cash equivalents and current financial assets totalled $3.1 billion as of June 30, 2024, compared to $3.2 billion as of December 31, 2023. The decrease in cash and cash equivalents and current financial assets result from a 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 updated its cash burn guidance and now expects to utilize less than $500 million of net cash[1] in 2024 on anticipated operating expenses as well as working capital and capital expenditures.

EXPECTED 2024 FINANCIAL CALENDAR

- October 31, 2024: 3Q 2024 financial results and business update
- February 27, 2025: Full-year 2024 financial results and 4Q 2024 business update

CONFERENCE CALL DETAILS
The half-year 2024 financial results and second 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 and replay may be accessed on the Investors section of the argenx website at argenx.com/investors.

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, X/Twitter, Instagram, Facebook, and YouTube.

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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 "advance," "aim," "anticipates," "continue," "expect," "expand," "plan," or "seek" and include statements argenx makes regarding its Vision 2030 plan to develop and deliver continued and sustainable innovation for patients; its long-term commitments; its Vision 2030 goals, including having 50,000 patients globally on treatment with an argenx medicine, 10 labeled indications across all approved assets, including VYVGART franchise and potentially empasiprubart and ARGX-119, and five new molecules in Phase 3 development indicating ongoing investment in the immunology innovation program; its growth opportunity; its plans to reach earlier-line MG patients over the next 12-18 months with potential label expansions and a pre-filled syringe; the advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the anticipated timing of four additional Phase 3 registrational studies across efgartigimod and empasiprubart, the expected timing of additional VYVGART regulatory decisions on approval for gMG, including in Switzerland, Australia, and Saudi Arabia, the expected timing of additional VYVGART SC regulatory submissions under review or planned for CIDP, including decisions on approval in China, Japan, and Europe and a regulatory submission filing in Canada, the anticipated timing of the initiation of a Phase 3 study for efgartigimod in primary Sjogren's disease (SjD), the anticipated timing of a confirmatory study of VYVGART (IV) in primary ITP, the anticipated timing of topline data from Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets, the anticipated timing of an update on BALLAD study development plan evaluating efgartigimod in BP, the anticipated timing of proof-of-concept studies for efgartigimod in AMR and SSc, the anticipated timing of the initiation of a Phase 3 study of empasiprubart for MMN, the anticipated timing of the initiation of Phase 1b/2a studies of ARGX-119 to assess early signal detection in patients with CMS and ALS, the anticipated timing of the initiation of Phase 1 studies of ARGX-213 and ARGX-121; its investigational new drug applications for ARGX-2220 and ARGX-109 expected to be filed by the end of 2025; its 2024 research and development and selling, general and administrative expenses and operating expenses; its 2024 cash burn; and its 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 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 parties suppliers, service provides 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.

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[1] *reflects cash, cash equivalents and current financial assets*