argenx Reports Half Year 2023 Financial Results and Provides Second Quarter Business Update

- $269 million in second quarter VYVGART® (efgartigimod alfa-fcab) global net product sales

- VYVGART® Hytrulo now available in the U.S. with first vials shipped in July

- Global VYVGART expansion continued with commercial launch in Italy and distribution agreement with Handok in South Korea

- Topline results from ADVANCE-SC and ADDRESS expected in fourth quarter of 2023

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

July 27, 2023

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 2023 financial results and provided a second quarter business update.

"We are thrilled to see the momentum continue across all aspects of our business, with a catalyst-rich first half of the year. For another quarter we saw consistent revenue growth with VYVGART, delivering on our promise to bring transformative change to the treatment of gMG and reaching more patients through global approvals and the launch of our SC offering. Now with the positive ADHERE data, we have strengthened our conviction in the potential of VYVGART for CIDP patients but also more broadly across IgG-mediated autoimmune diseases, motivating us to explore the full extent of the opportunity. Our ambition level is high and we are positioning argenx for long-term growth with VYVGART, empasiprubart, and our pipeline of immunology solutions. It is time to raise the bar for patients on what a treatment can offer and we are more inspired than ever in our pursuit to do so," said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

SECOND QUARTER 2023 AND RECENT BUSINESS UPDATE

VYVGART Expansion

VYVGART is a first-in-class antibody fragment targeting the neonatal Fc receptor (FcRn) and is now approved globally in six countries or regions (U.S., Japan, EU, UK, Israel, China) for generalized myasthenia gravis (gMG). VYVGART Hytrulo was approved by the U.S. Food and Drug Administration (FDA) on June 20, 2023, and is the first subcutaneous (SC) injectable for gMG. argenx is planning for multi-dimensional expansion to reach more patients with VYVGART through additional global regulatory approvals.

- Generated global net VYVGART revenues of $269 million in second quarter of 2023
- Launched VYVGART Hytrulo in U.S. and shipped first vials in July

- Launched VYGART in Italy in July following successful completion of reimbursement negotiations
- VYVGART approval decision in Canada expected in third quarter of 2023
- Approval decisions of SC efgartigimod expected in Europe in fourth quarter of 2023, Japan by first quarter of 2024, and China by end of 2024
- Marketing authorization application (MAA) filed in Japan for VYVGART for primary immune thrombocytopenia (ITP); approval decision expected in first half of 2024
- Entered into VYVGART commercial and distribution agreement with Handok in South Korea

Efgartigimod Research and Development

argenx is solidifying its leadership in immunology innovation by expanding the scope of IgG-mediated autoimmune diseases in development and further demonstrating the potential of FcRn blockade in ongoing clinical trials. By the end of 2023, efgartigimod is expected to be approved, in regulatory review or in development in 13 severe autoimmune diseases.

- Announced positive topline results from ADHERE of VYVGART Hytrulo for chronic inflammatory demyelinating polyneuropathy (CIDP)
    - Primary endpoint met (p=0.000039); VYVGART Hytrulo demonstrated 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in risk of relapse versus placebo
    - 67% of patients in open-label Stage A demonstrated evidence of clinical improvement (ECI), indicating IgG autoantibodies play significant role in underlying biology of CIDP
    - Safety and tolerability profile consistent with confirmed safety profile of VYVGART
    - 91% (226/249) of eligible patients continued to ADHERE+ open-label extension study
- Topline data from ADDRESS (pemphigus) and ADVANCE-SC (primary immune thrombocytopenia) studies expected in fourth quarter of 2023
- GO/NO GO decisions expected from BALLAD (bullous pemphigoid) in first quarter of 2024 and ALKIVIA (myositis) in second half of 2024
- Topline data from ALPHA (post-COVID postural orthostatic tachycardia syndrome (PC-POTS)) expected in first quarter of 2024 and RHO (Sjogren's syndrome) in second half of 2024
- Studies ongoing in membranous nephropathy (MN) and lupus nephritis (LN) through Zai Lab collaboration
- Registrational study in thyroid eye disease (TED) and proof-of-concept studies in ANCA-associated vasculitis (ANCA) and antibody mediated rejection (AMR) in kidney transplant to start in fourth quarter of 2023

Pipeline Progress

argenx is advancing a robust portfolio of innovative clinical programs, including empasiprubart (C2 inhibitor) and ARGX-119 (muscle-specific kinase (MuSK) agonist). Both programs have the potential to be first-in-class opportunities for multiple severe indications.

- Initiated second dose cohort in Phase 2 ARDA study of empasiprubart in multifocal motor neuropathy (MMN)
    - Independent Data Monitoring Committee recommended study continuation based on favorable safety profile observed in first dose cohort

- Early efficacy signals support proof-of-concept in MMN
- Second cohort to evaluate next dose of empasiprubart based on efficacy signals observed in first cohort
- Topline results from both first and second cohorts expected in 2024

- Phase 2 studies of empasiprubart in delayed graft function (DGF) on track to start by end of year and dermatomyositis in first quarter of 2024
- Phase 1 study of ARGX-119 ongoing in healthy volunteers; subsequent Phase 1b trial to assess early signal detection in patients with congenital myasthenic syndrome and amyotrophic lateral sclerosis (ALS)

Immunology Innovation Program

argenx continues to invest in its discovery engine, the Immunology Innovation Program, to foster a robust innovation ecosystem and drive early-stage pipeline growth. argenx expects to nominate one new pipeline candidate in 2023.

SECOND QUARTER 2023 FINANCIAL RESULTS

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands of $ except for shares and EPS)	**2023**	**2022**	**2023**	**2022**
Product net sales	$ 269,313	$ 74,833	$ 487,335	$ 95,996
Collaboration revenue	1,237	361	2,355	2,610
Other operating income	10,485	9,989	21,225	18,057
Total operating income	**281,035**	**85,183**	**510,915**	**116,663**
Cost of sales	(24,024)	(5,010)	(42,359)	(6,382)
Research and development expenses	(195,509)	(126,919)	(361,364)	(278,887)
Selling, general and administrative expenses	(161,977)	(127,798)	(311,149)	(228,664)
Loss from investment in joint venture	(1,619)	-	(1,880)	-
Total operating expenses	**(383,129)**	**(259,727)**	**(716,752)**	**(513,933)**
Operating loss	$ **(102,094)**	$ **(174,544)**	$ **(205,837)**	$ **(397,270)**
Financial income	20,441	4,912	37,029	5,733
Financial expense	(207)	(1,178)	(395)	(2,131)
Exchange gains/(losses)	(2,001)	(46,169)	9,164	(53,382)
Loss for the period before taxes	$ **(83,861)**	$ **(216,979)**	$ **(160,039)**	$ **(447,050)**
Income tax (expense)/benefit	$ (10,507)	$ 8,229	$ 36,800	$ 11,114
Loss for the period	$ **(94,368)**	$ **(208,750)**	$ **(123,239)**	$ **(435,936)**
Loss for the period attributable to:				
Owners of the parent	$ (94,368)	$ (208,750)	$ (123,239)	$ (435,936)
Weighted average number of shares outstanding	55,828,239	54,802,339	55,690,873	53,449,915
Basis and diluted loss per share (in $)	(1.69)	(3.81)	(2.21)	(8.16)
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2021 and 2022			(195,580)	260,665
Cash and cash equivalents and current financial assets at the end of the period			1,996,968	2,597,393

DETAILS OF THE FINANCIAL RESULTS

Total operating income for the second quarter and year-to-date in 2023 was $281.0 million and $510.9 million, respectively, compared to $85.2 million and $116.7 million for the same periods in 2022, and mainly consists of:

- **Product net sales** of VYVGART for the three months ended and six months ended June 30, 2023, were $269.3 million and $487.3 million, compared to $74.8 million and $96.0 million for the same periods in 2022.
- **Other operating income** for the second quarter and year-to-date in 2023 was $10.5 million and $21.2 million, respectively, compared to $10.0 million, and $18.1 million for the same periods in 2022. The other operating income for the three and six months ended June 30, 2023 primarily relates to research and development tax incentives and payroll tax rebates.

Total operating expenses for the second quarter and year-to-date in 2023 were $383.1 million and $716.8 million, respectively, compared to $259.7 million and $513.9 million for the same periods in 2022, and mainly consists of:

- **Cost of sales** for the second quarter and year-to-date in 2023 was $24.0 million and $42.4 million, respectively, compared to $5.0 million and $6.4 million for the same periods in 2022. The cost of sales was recognized with respect to the sale of VYVGART.
- **Research and development expenses** increased by $68.6 million and $82.5 million for the three months and six months ended June 30, 2023, to $195.5 million and $361.4 million, respectively, compared to $126.9 million and $278.9 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.
- **Selling, general and administrative expenses** for the second quarter and year-to-date in 2023 were $162.0 million and $311.1 million, respectively, compared to $127.8 million and $228.7 million for the same periods in 2022. The selling, general and administrative expenses mainly relate to professional and marketing fees linked to commercialization of VYVGART in the U.S., EU and Japan, and personnel expenses.

Financial income for the second quarter and year-to-date in 2023 was $20.4 million and $37.0 million, respectively, compared to $4.9 million and $5.7 million for the same periods in 2022. The increase in financial income is mainly due to an increase in interest income on current financial assets and cash and cash equivalents attributable to higher interest rates.

Exchange gains/losses for the second quarter and year-to-date in 2023 were $2.0 million of exchange losses and $9.2 million of exchange gains, respectively, compared to $46.2 million and $53.4 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 position in Euro.

Income tax for the second quarter and year-to-date in 2023 was $10.5 million of tax expense and $36.8 million of tax benefit, respectively, compared to $8.2 million and $11.1 million of tax benefit for the same periods in 2022.

Net loss for the three and six month periods ended June 30, 2023, was $94.4 million and $123.2 million, respectively, compared to $208.8 million and $435.9 million over the prior year periods. On a per weighted average share basis, the net loss was $2.21 and $8.16 for the six months ended June 30, 2023 and 2022, respectively.

Cash, cash equivalents and current financial assets totalled $2.0 billion as of June 30, 2023, compared to $2.2 billion as of December 31, 2022. Cash and cash equivalents and current financial assets decreased primarily as a result of net cash flows used in operating activities. The cash position as of June 30, 2023, excludes the $1.3 billion in estimated gross proceeds from the global equity offering, which closed on July 24, 2023.

With the closing of this transaction, argenx will review its cash burn expectations and provide an update accordingly.

UPCOMING FINANCIAL CALENDAR

- October 31, 2023: Q3 2023 financial results and business update
- February 29, 2024: FY 2023 financial results and business update

CONFERENCE CALL DETAILS

The second quarter 2023 financial results and 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 in the U.S., Japan, Israel, the EU, the UK and China. 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 regarding its plans for its global commercial expansion of VYVGART to reach more patients; continued investment in its Immunology Innovation Program to foster a robust innovation ecosystem and drive early-stage pipeline growth; the therapeutic potential of its product candidates; the intended results of its strategy and its collaboration partners', including ongoing studies through its collaboration with Zai Lab; advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the (1) expected topline data from registrational ADDRESS and ADVANCE-SC studies in 2023, (2) expected GO/NO GO decisions from its BALLAD and ALKIVIA trials in 2024, (3) expected topline data from its ALPHA and RHO trials in 2024, (4) timeline of registrational and proof-of-concept studies in ANCA-associated vasculitis and antibody mediated rejection in kidney transplant, (5) potential of empasiprubart and ARGX-119 to be first-in-class opportunities for multiple serious indications and timeline of studies and results thereof and (6) planned nomination of a new product development candidate in 2023; the timing and outcome of regulatory filings and regulatory approvals, including the anticipated regulatory approvals of VYVGART in Canada and Japan and approvals of SC efgartigimod in Europe, Japan and China, and the number of autoimmune diseases for which efgartigimod is expected to be approved, in regulatory review or in development by end of 2023; and 2023 business and financial outlook and related plans, including the anticipated release of updated cash burn expectations and the timeline of future releases of financial results and business updates. 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 inflation and deflation and the corresponding fluctuations in interest rate; regional instability and conflicts, such as the conflict between Russia and Ukraine, argenx's expectations regarding the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. 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.