



argenx Reports Full Year 2021 Financial Results and Provides Fourth Quarter Business Update

- VYVGART® (efgartigimod alfa-fcab) approved in the U.S. and Japan as the first-and-only neonatal Fc receptor (FcRn) blocker; U.S. commercial launch underway
- Topline results from Phase 3 bridging study of subcutaneous (SC) efgartigimod in generalized myasthenia gravis (gMG) on track for first quarter 2022
 - Malini Moorthy appointed as General Counsel
- Management to host conference call today at 2:30 pm CET (8:30 am ET)

March 3, 2022

Breda, the Netherlands – argenx (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 2021 and provided a fourth quarter business update.

“2021 was a transformational year for argenx, culminating with the FDA approval of VYVGART, our first-in-class FcRn blocker, in December. We carried this momentum into 2022 with the official U.S. launch of VYVGART and the Japan approval. We were well-prepared to launch VYVGART at the time of approval and are encouraged by the early response of the medical community, the engagement from patients, and the coverage decisions that have been made by payers. We continue to expect steady launch progress in 2022 as we aim to deliver this new therapy to patients living with generalized myasthenia gravis,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

“In addition to executing the global commercial launch of VYVGART, we are primed to deliver several upcoming catalysts through our development pipeline in high-value autoimmune indications. We expect multiple registrational trial readouts for efgartigimod in the next four quarters, the first of which is the SC bridging study in gMG this month. We are expanding the scope of development for efgartigimod to 10 indications and ARGX-117 to two indications by the end of this year, and will also advance ARGX-119 into first-in-human studies. We remain focused on all components of our integrated business so that we can continue to redefine immunology on behalf of patients and deliver shareholder value,” continued Mr. Van Hauwermeiren.

FOURTH QUARTER 2021 AND RECENT BUSINESS UPDATE

U.S. commercial launch ongoing for VYVGART, the first FDA-approved FcRn blocker for adult gMG patients who are anti-acetylcholine receptor (AChR) antibody positive

- VYVGART U.S. salesforce launched in early January; team interacted with over 60% of the 1,000 top priority neurologist targets as of end of February
- VYVGART-specific payer policies have been published in plans covering approximately 25% of U.S. commercial lives; expected to have broad coverage in place by end of second quarter 2022
- Commercial launch preparedness enabled immediate activation of key launch activities



- My VYVGART Path, a personalized patient support system, was active at time of approval; approximately 90% of enrollment forms have come in through this program
- Distribution channels stocked within one week following FDA approval

On track with global launch strategy to make VYVGART available in Japan, Europe, China and Canada, as well as additional regions through license and distribution agreements

- VYVGART approved for adult patients with gMG on January 20, 2022 by Japan's Ministry of Health, Labour and Welfare with expected launch to occur in second quarter 2022
- Decision from European Medicines Agency on Marketing Authorization Application expected in second half of 2022
- argenx Canada established in preparation for potential Health Canada approval and commercial launch
- Medison to file for approval in Israel in second quarter of 2022
- Zai Lab to file for approval in China in mid-2022
- Entered into commercial and distribution agreement with GenPharm for VYVGART commercialization in the Middle East
- Additional license and distribution agreements expected in 2022 to expand global patient reach

Topline data expected from five ongoing efgartigimod registrational trials by end of first quarter of 2023

- **Neuromuscular franchise**
 - ADAPT-SC: Topline data from bridging study of SC efgartigimod for gMG expected in first quarter of 2022
 - ADHERE: Topline data of SC efgartigimod for chronic inflammatory demyelinating polyneuropathy expected in first quarter of 2023
- **Hematology franchise**
 - ADVANCE: Topline data of intravenous efgartigimod for primary immune thrombocytopenia (ITP) expected in second quarter of 2022
 - ADVANCE-SC: Topline data of SC efgartigimod for primary ITP expected in first quarter of 2023
- **Dermatology franchise**
 - ADDRESS: Timing of topline data of SC efgartigimod for pemphigus foliaceus and vulgaris is currently under review given geopolitical events in Ukraine

argenx's leadership position in FcRn blockade to be solidified through expansion of efgartigimod development portfolio into ten total autoimmune conditions by end of 2022

- **BALLAD:** Registrational trial ongoing of SC efgartigimod for bullous pemphigoid with interim analysis planned of first 40 patients
- **ALKIVIA:** Registrational trial on track to start in first quarter of 2022 for idiopathic inflammatory myopathy (myositis); interim analysis planned of first 30 patients of each subtype (immune-mediated necrotizing myopathy, anti-synthetase syndrome and dermatomyositis)



- Zai Lab to launch proof-of-concept trials in lupus nephritis and membranous nephropathy in 2022 with argenx to lead global registrational programs for each potential indication
- Entered strategic collaboration with IQVIA to leverage its global clinical development capabilities and accelerate expansion of efgartigimod into additional potential indications
 - o Proof-of-concept trials in primary Sjogren’s syndrome expected to initiate in second half of 2022 and COVID-19-mediated postural orthostatic tachycardia syndrome (POTS) in mid-2022

ARGX-117, a novel C2 inhibitor, has potential to be second pipeline-in-a-product for multiple autoimmune indications

- Ongoing proof-of-concept trial to evaluate safety, tolerability, and potential dosing regimen in multifocal motor neuropathy (MMN)
- Phase 2 proof-of-concept trial expected to start in 2022 for prevention of delayed graft function and/or allograft failure after kidney transplantation

Continued investment in Immunology Innovation Program (IIP) to broaden autoimmune pipeline for sustained value creation opportunities

- Phase 1 dose-escalation trial of ARGX-119, an agonist SIMPLE Antibody™ to muscle-specific kinase (MuSK), expected to start after Clinical Trial Application filing in fourth quarter of 2022
 - o Trial will evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers, and also early signal detection in patients

Strengthened leadership team with appointment of Malini Moorthy as General Counsel

- Ms. Moorthy brings to argenx over 20 years of global legal and compliance experience in the pharmaceutical and medical device industries

Yvonne Greenstreet to step down from argenx Board of Directors in order to focus on her transition to Chief Executive Officer at Alnylam

FOURTH QUARTER AND FULL YEAR 2021 FINANCIAL RESULTS

(in thousands of \$ except for shares and EPS)	Year Ended December 31,		
	2021	2020	Variance
Revenue	\$ 497,277	\$ 41,243	\$ 456,034
Other operating income	42,141	23,668	18,473
Total operating income	539,418	64,911	474,507
Research and development expenses	(580,520)	(370,885)	(209,635)
Selling, general and administrative expenses	(307,644)	(171,643)	(136,001)
Total operating expenses	(888,164)	(542,528)	(345,636)
Operating loss	\$ (348,746)	\$ (477,617)	\$ 128,871



Financial income/(expenses)	(944)	(1,501)	557
Exchange gains/(losses)	(50,053)	(126,234)	76,181
Loss before taxes	\$ (399,743)	\$ (605,352)	\$ 205,609
Income tax expense	\$ (8,522)	\$ (3,103)	\$ (5,419)
Loss for the year	\$ (408,265)	\$ (608,455)	\$ 200,190
Loss for the year attributable to:			
Owners of the parent	\$ (408,265)	\$ (608,455)	\$ 200,190
Weighted average number of shares outstanding	51,075,827	45,410,442	5,665,385
Basic and diluted loss per share (in \$)	(7.99)	(13.40)	
Net increase in cash and cash equivalents and current financial assets compared to year-end 2020 and 2019	\$ 340,276	\$ 495,791	
Cash and cash equivalents and current financial assets at the end of the period	\$ 2,336,728	\$ 1,996,452	

DETAILS OF THE FINANCIAL RESULTS

Cash, cash equivalents and current financial assets totaled \$2,336.7 million as of December 31, 2021, compared to \$1,996.5 million on December 31, 2020. The increase in cash and cash equivalents and current financial assets resulted primarily from the closing of a global offering of shares, which resulted in the receipt of \$1,092.1 million in net proceeds in February 2021 and the net receipt of a \$73.1 million non-creditable, non-refundable development cost-sharing payment from Zai Lab as part of the strategic collaboration for efgartigimod in Greater China in part offset by the payment of \$98.0 million related to the purchase of the priority review voucher from Bayer HealthCare Pharmaceuticals, and other net cash flows used in operating activities.

Revenue increased by \$456.0 million for the twelve months ended December 31, 2021 to \$497.3 million, compared to \$41.2 million for the twelve months ended December 31, 2020. The increase was primarily due to the recognition of the transaction price as a consequence of the termination of the collaboration agreement with Janssen resulting in the one-time recognition of \$315.1 million, and the recognition of \$177.5 million in collaboration revenue related to the strategic collaboration with Zai Lab, including the cost-sharing payment and the development milestone, triggered by the FDA approval of VYVGART.

Other operating income increased by \$18.5 million to \$42.1 million for the year ended December 31, 2021, compared to \$23.7 million for the year ended December 31, 2020. The increase was primarily driven by (i) the increase in research and development incentives, as a result of the increased research and development costs incurred, (ii) the increase in payroll tax rebates, as a direct result of the increase in the employment of highly qualified research and development personnel eligible for



specific payroll tax rebates, and (iii) the increase in fair value of argenx's profit share in AgomAb Therapeutics NV.

Research and development expenses increased by \$209.6 million for the twelve months ended December 31, 2021 to \$580.5 million, compared to \$370.9 million for the twelve months ended December 31, 2020. The increase resulted primarily from higher external research and development expenses, mainly related to the efgartigimod program in various indications and other clinical and preclinical programs. Furthermore, the research and development personnel expenses increased due to a planned increase in headcount and the increased costs of the share-based payment compensation plans related to the grant of stock options.

Selling, general and administrative expenses totaled \$307.6 million for the twelve months ended December 31, 2021, compared to \$171.6 million for the twelve months ended December 31, 2020. The increase resulted primarily from higher personnel expenses, including the costs of the share-based payment compensation plans related to the grant of stock options, and consulting fees linked to the preparation for a commercialization of VYVGART.

Exchange losses totaled \$50.1 million for the twelve months ended December 31, 2021, compared to \$126.2 million for the twelve months ended December 31, 2020 and are mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in Euro.

FINANCIAL GUIDANCE

Based on current plans to fund anticipated operating expenses and capital expenditures, argenx expects to utilize up to half of its available cash, cash equivalents and current financial assets in 2022. The increased spend will support the global VYVGART launches, clinical development of efgartigimod in 10 indications and ARGX-117 in two indications, investment in the global supply chain, and continued focus on pipeline expansion through the Immunology Innovation Program.

US SEC AND STATUTORY FINANCIAL REPORTING

argenx's primary accounting standard for quarterly earnings releases and annual reports is International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). Quarterly summarized statements of profit or loss based on IFRS as issued by the IASB are available on www.argenx.com.

In addition to reporting financial figures in accordance with IFRS as issued by the IASB, argenx also reports financial figures in accordance with IFRS as adopted by the EU for statutory purposes. The consolidated statements of financial position, the consolidated statements of profit or loss, the consolidated statements of comprehensive income / loss, the consolidated statements of cash flows, and the consolidated statements of changes in equity are not affected by any differences between IFRS as issued by the IASB and IFRS as adopted by the EU.

The consolidated statements of profit or loss of argenx SE for the year ended December 31, 2021, as presented in this press release are unaudited.



EXPECTED 2022 FINANCIAL CALENDAR:

- May 5, 2022: Q1 2022 financial results and business update
- July 28, 2022: HY 2022 financial results and business update
- October 27, 2022: Q3 2022 financial results and business update

CONFERENCE CALL DETAILS

The full year 2021 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 9752
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-and-only approved neonatal Fc receptor (FcRn) blocker in the U.S. and Japan. 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 concerning execution of its global launch strategy and expected therapy delivery to patients in Japan, Europe, China and Canada; its expectation concerning its development pipeline and ability to deliver shareholder value as a result thereof; expected registrational trial readouts in 2022; development of efgartigimod in up to ten indications and ARGX-117 in up to two indications by end of 2022; expected advancement of ARGX-119 into first-in-human studies; expected broad U.S. policy coverage of VYVGART by the end of second quarter 2022; the estimated number of covered patients in the U.S.; anticipated pathway for approval in Japan and launch in the second quarter of 2022; expected approval by European Medicines Agency of MAA in the second half of 2022; establishment of argenx Canada in the first quarter of 2022 and preparation for potential Health Canada approval and commercial launch; plans for Medison to file for approval in Israel in second quarter of 2022; expected partnership with GenPharm for commercialization in the Middle East; partnership agreements expected to be announced in 2022; the timing and its expectations with respect to reporting data from registrational trials; expectations with respect to leadership potential through expansion of efgartigimod portfolio into ten indications by end of 2022; expected launch and timing of proof of concept trials, including by Zai Labs and IQVIA, and dose escalation trials in 2022; and its expectations with respect to its use of available cash and liquidity needs for 2022. 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.