



argenx Reports Half Year 2021 Financial Results and Provides Second Quarter Business Update

- Completion of enrollment expected by year-end for ADAPT-SC and ADVANCE (IV) trials of efgartigimod; topline data for both trials expected in first half of 2022
- Introduced “argenx 2025” vision during R&D Day to highlight commitment to patients and science and outline path to becoming global, integrated immunology leader
- Management to host conference call today at 2:30 pm CEST (8:30 am ET) -

July 29, 2021

Breda, the Netherlands – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced its half year 2021 financial results and provided a second quarter business update and outlook for the remainder of the year.

“The first half of 2021 has been marked by clinical, financial and regulatory achievements for argenx. As we look toward 2022, we believe we are well-positioned to build on the impressive progress we have made with our first-in-class FcRn antagonist, efgartigimod. We are expanding our commercial organization to reach patients living with generalized myasthenia gravis this year and expect that these investments will benefit us in the future and support our growing, differentiated pipeline,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

“Beyond myasthenia gravis, we are expanding the breadth of efgartigimod into our fifth and sixth indications, myositis and bullous pemphigoid, and simultaneously investing in potential scientific breakthroughs through our Immunology Innovation Program (IIP). Our first-in-class C2 inhibitor, ARGX-117, emerged from the IIP and has the potential to be our next pipeline-in-a-product opportunity. Collectively, the demonstrated execution this year supports our ‘argenx 2025’ vision and brings us closer than ever to becoming a global, integrated, immunology company,” concluded Mr. Van Hauwermeiren.

SECOND QUARTER 2021 AND RECENT BUSINESS UPDATE

During its July 20th R&D Day, argenx introduced its long-term vision to becoming a global, integrated immunology organization. The ‘argenx 2025’ vision includes the following goals:

- Efgartigimod being globally available to patients across its three expanding commercial franchises in neuromuscular diseases, hematology and dermatology
- Efgartigimod either being commercially available or in clinical development in 15 active indications
- Progress across broader immunology pipeline with ARGX-117 in multiple late-stage trials and ARGX-119 demonstrating proof-of-concept
- Investment in continued expansion of differentiated pipeline through its Immunology Innovation Program (IIP), generating one new asset into pipeline each year



On track with buildout of global commercial organization in anticipation of potential approval of efgartigimod for treatment of generalized myasthenia gravis (gMG)

- Biologics License Application (BLA) under review with U.S. Food and Drug Administration (FDA) with target action date of December 17, 2021 under Prescription Drug User Fee Act (PDUFA)
- Marketing Authorization Application (J-MAA) under review with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) with anticipated approval in first half of 2022
- MAA on track and expected to be filed with European Medicines Agency (EMA) in second half of 2021
- Zai Lab on track with expected regulatory discussions with National Medical Products Administration (NMPA) for approval in China
- ADAPT Phase 3 trial results of efgartigimod for treatment of gMG published in The Lancet Neurology
- Hiring of salesforce expected to be completed in U.S. in third quarter of 2021 and in Japan in fourth quarter of 2021
- Ongoing engagement with gMG patient community through awareness and advocacy efforts, including award-winning docuseries "A Mystery to Me", and continued enrollment into real-world evidence study, MyRealWorld®MG

Efgartigimod is currently being evaluated in five ongoing registrational trials across four indications, including ADAPT-SC (gMG), ADHERE (chronic inflammatory demyelinating polyneuropathy or CIDP), ADVANCE (IV) and ADVANCE-SC (primary immune thrombocytopenia or ITP), and ADDRESS (pemphigus)

- Completion of enrollment expected by end of 2021 in ADAPT-SC and ADVANCE (IV); topline data for both trials expected in first half of 2022
- Broadened efgartigimod opportunity with announcement of new indications, idiopathic inflammatory myopathies (myositis) within neuromuscular franchise and bullous pemphigoid within dermatology franchise
 - o Phase 2/3 trial of efgartigimod for treatment of myositis to start by end of 2021, pending interactions with FDA
 - o Phase 3 registrational trial of efgartigimod for treatment of bullous pemphigoid to start by end of 2021
- Phase 2 proof-of-concept trials of efgartigimod in additional indications to be evaluated as part of collaboration with Zai Lab

Phase 1 healthy volunteer data of C2-inhibitor, ARGX-117, support path forward into multifocal motor neuropathy (MMN)

- Favorable safety profile demonstrated across single and multiple ascending doses and both IV and SC formulations
- Pharmacokinetic/pharmacodynamic profiles demonstrate potential for infrequent dosing schedules
- Phase 2 trial of MMN patients on track to start by end of 2021



Immunology Innovation Program (IIP) continues to bring value to argenx through internal pipeline programs, partnerships and licensing agreements

- ARGX-119, a SIMPLE Antibody™ aimed at boosting the neuromuscular junction in disease, emerging from IIP to be next pipeline candidate within neuromuscular franchise
- Regained worldwide rights to anti-CD70 antibody cusatuzumab from Janssen; argenx to evaluate potential alternatives to advance cusatuzumab through partnership
- 15-20 discovery programs under evaluation at any point in time that have emerged from IIP

HALF YEAR 2021 FINANCIAL RESULTS (CONSOLIDATED)

(in thousands of \$ except for shares and EPS)	Six Months Ended June 30,		
	2021	2020	Variance
Revenue	\$ 470.398	\$ 24.683	\$ 445.715
Other operating income	17.079	9.619	7.460
Total operating income	487.477	34.302	453.175
Research and development expenses	-273.907	-189.251	-84.656
Selling, general and administrative expenses	-129.599	-67.926	-61.673
Total operating expenses	-403.506	-257.177	146.329
Change in fair value on non-current financial assets	11.152	934	10.218
Operating income / (loss)	\$ 95.123	\$ -221.941	\$ 317.064
Financial income/(expenses)	-745	-2.403	1.658
Exchange gain/(losses)	-18.375	245	-18.620
Profit / (Loss) before taxes	\$ 76.003	\$ -224.099	\$ 300.102
Income taxes	-12.835	-2.491	-10.345
Profit / (Loss) for the period	\$ 63.167	\$ -226.590	\$ 289.757
Weighted average number of shares outstanding	50.638.702	43.476.103	
Basic profit / (loss) per share (in \$)	1,25	-5,21	
Diluted profit / (loss) per share (in \$)	1,17	-5,21	
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2020 and 2019	734.545	663.686	
Cash, cash equivalents and current financial assets at the end of the period	2.730.997	2.164.347	

DETAILS OF THE FINANCIAL RESULTS

As of January 1, 2021, the Company changed its functional and presentation currency from euro to U.S. dollars, which results in reporting financial highlights in U.S. dollar as compared to euro in prior periods. Historical financials have been converted at the average exchange rate of the related period.

Cash, cash equivalents and current financial assets totaled \$2,731.0 million as of June 30, 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 (i) the closing of a global offering, which resulted in the receipt of \$1,092.1 million in net proceeds in February 2021, (ii) the net receipt of a \$73.1 million



non-creditable, non-refundable development cost-sharing payment received from Zai Lab as part of the strategic collaboration for efgartigimod in Greater China, (iii) 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.

Total operating income increased by \$453.2 million for the six months ended June 30, 2021 to \$487.5 million, compared to \$34.3 million for the six months ended June 30, 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 recognition of \$315.1 million and the closing of the strategic collaboration for efgartigimod with Zai Lab, resulting in the recognition of \$151.9 million in collaboration revenue.

Research and development expenses increased by \$84.7 million for the six months ended June 30, 2021 to \$273.9 million, compared to \$189.3 million for the six months ended June 30, 2020. The increase in the first six months of 2021 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 \$129.6 million for the six months ended June 30, 2021, compared to \$67.9 million for the six months ended June 30, 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 of a possible future commercialization of argenx's lead product candidate efgartigimod.

The change in fair value on non-current financial assets amounted to \$11.2 million for the six months ended June 30, 2021, which is the result of the closing of a Series B financing round of AgomAb Therapeutics, for which argenx maintains a profit share in exchange for granting the license for the use of HGF-mimetic antibodies from the SIMPLE Antibody™ platform.

Exchange losses totaled \$18.4 million for the six months ended June 30, 2021, compared to an exchange gain of \$0.2 million for the six months ended June 30, 2020. As a result of the change in the Company's functional and presentation currency, the exchange losses for the six months ended June 30, 2021 are reflecting the unfavorable change in euro/U.S. dollar exchange rate, mainly attributable to unrealized exchange rate losses on cash, cash equivalents and current financial asset position in euro.

FINANCIAL GUIDANCE

Based on current plans to fund anticipated operating expenses and capital expenditures, argenx continues to expect its 2021 cash burn to approximately double from 2020. The increased spend will support the Company's transition to an integrated immunology company, including the build-out of global commercial infrastructure and drug product inventory ahead of the expected launch of efgartigimod in gMG in the U.S, the advancement of its clinical-stage pipeline, including expected global trials of efgartigimod in six indications, and the continued investment in its Immunology Innovation Program.



EXPECTED 2021 FINANCIAL CALENDAR

- October 28, 2021: Q3 2021 financial results and business update

CONFERENCE CALL DETAILS

The half year 2021 financial results and second quarter business update will be discussed during a conference call and webcast presentation today at 2:30 pm CEST/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	0800 389 13
France	0805 102 319
Netherlands	0800 949 4506
United Kingdom	0800 279 9489
United States	1 844 808 7140
International	1 412 902 0128

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. 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 is evaluating efgartigimod in multiple serious autoimmune diseases. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, Japan, and Switzerland. For more information, visit www.argenx.com and follow us on LinkedIn at <https://www.linkedin.com/company/argenx/> and Twitter at <https://twitter.com/argenxglobal>.

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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 the argenx 2025 vision; its statement that the submissions in China and the EU are on track and that it is well-positioned for a global launch of its first-in-class FcRn antagonist, including that BLA for IV efgartigimod for treatment of gMG accepted for review by the U.S. Food and Drug Administration (FDA) in March 2021 with target action date of December 17, 2021 under Prescription Drug User Fee Act (PDUFA); J-MAA submitted to Japan’s PMDA and accepted for review with anticipated Japan commercial launch in 2022; MAA expected to be filed with European Medicines Agency (EMA) in second half of 2021 and Zai Lab Limited to discuss potential accelerated regulatory pathway for approval in China with National Medical Products Administration (NMPA); statements regarding its commercial readiness; its statement that enrollment in trials for ADAPT-SC and ADVANCE(IV) to complete by end of 2021 and topline data expected in first half of 2022; its statement that a Phase 2/3 trial of efgartigimod for treatment of myositis to start by end of 2021, pending interactions with FDA, Phase 3 registrational trial of efgartigimod for treatment of bullous pemphigoid to start by end of 2021, and Phase 2 proof-of-concept trials to be evaluated with Zai Lab Limited; its plan to evaluate alternatives; its expectation of a U.S. launch of efgartigimod; that Phase 2 trial of MMN on track to start by end of 2021; its expectation that its 2021 cash burn will approximately double from 2020; its hope to reach patients this year; its statements regarding the therapeutic potential of Efgartigimod in patients with gMG; its plans to start enrollment in two additional efgartigimod indications this year ;, the 2021 business and financial outlook and related plans; the therapeutic potential of its product candidates; the intended results of its strategy and argenx’s, and its collaboration partners’, advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts; the design of future clinical trials and the timing and outcome of regulatory filings and regulatory approvals. 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 effects of the COVID-19 pandemic, argenx’s expectations regarding its 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.