argenx Reports Third Quarter 2021 Financial Results and Provides Business Update

– U.S. and Japan commercial teams fully staffed ahead of potential launches of efgartigimod in generalized myasthenia gravis (gMG) –

– Signed partnership agreement with Medison for distribution of efgartigimod in Israel –

– Wim Parys, M.D. to retire as Chief Medical Officer in March 2022 –

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

October 28, 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 third quarter 2021 financial results and provided a business update and outlook for the remainder of the year.

“With three parallel regulatory reviews in our key priority territories of the U.S., Japan and the EU and the simultaneous build-out of our respective commercial organizations, we are well-positioned for the planned global launch of efgartigimod for the treatment of generalized myasthenia gravis. In order to optimize our strategy to make efgartigimod available to patients in need across the world, we are pursuing innovative partnerships, such as the strategic partnership with Zai Lab in China and the agreement with Medison in Israel which we are excited to announce today,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

“As part of our commitment to becoming a fully-integrated, global immunology company, we are expanding our efgartigimod development plan to be in at least 15 indications by 2025 while also advancing a series of additional high-potential programs emerging from our Immunology Innovation Program. This includes a first-in-class C2 inhibitor, ARGX-117, which is on track to begin the first Phase 2 trial in multifocal motor neuropathy patients by the end of this year. Our growing commercial infrastructure along with our expanding pipeline ambitions provide considerable opportunity for argenx to deliver long-term, sustainable growth,” concluded Mr. Van Hauwermeiren.

THIRD QUARTER 2021 AND RECENT BUSINESS UPDATE

Three global regulatory reviews ongoing for FcRn antagonist efgartigimod for the treatment of 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 quarter of 2022
- MAA under review with European Medicines Agency (EMA) with anticipated approval in second half of 2022
- Zai Lab on track with expected regulatory discussions with National Medical Products Administration (NMPA) for approval in China
- Signed exclusive partnership agreement with Medison to commercialize efgartigimod for gMG in Israel; under agreement, Medison will also be responsible for seeking requisite regulatory approvals
- Field teams onboard in U.S. and Japan, including 70 U.S. and 24 Japan sales representatives

New data from Phase 3 ADAPT trial of efgartigimod for the treatment of gMG presented during American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting. Additional data to be presented at upcoming Myasthenia Gravis Foundation of America (MGFA) Scientific Session. Highlights of the new data points include:

- Among acetylcholine receptor-antibody positive (AChR-Ab+) patients, minimal symptom expression or MSE (MG-ADL of 0 or 1) was achieved by 59.1% (26/44) of MG-ADL responders following efgartigimod treatment during first cycle and 44.4% (16/36) during second cycle, compared to 36.8% (7/19) and 0% (0/11), respectively, for placebo patients
- Among acetylcholine receptor-antibody negative (AChR-Ab-) patients, MSE was achieved in 31.6% (6/19) of MG-ADL responders following efgartigimod treatment during first cycle compared to 15.8% (3/19) for placebo patients
- gMG and pemphigus patients who were vaccinated for influenza and pneumococcus during and prior to efgartigimod treatment in recent clinical trials showed that the ability to mount an immune antibody response was not impacted
- Consistent and statistically significant disease score improvements were demonstrated following efgartigimod treatment across ADAPT patient subtypes, regardless of concomitant medication or affected muscle domain (bulbar, ocular, respiratory, limb/gross motor)
- Initial patient-reported data from MyRealWorld® MG real-world evidence study (N = 144) showed that despite taking an average of 2.3 treatments to control symptoms, people living with gMG experience substantial negative physical, mental, social, and emotional impacts of the disease
    - 92% of responders agreed there is a significant need for new gMG treatments and are hopeful for ones with fewer side effects (96%)
- In a separate argenx-sponsored patient burden survey (N = 150), 51% of gMG patients stopped working entirely as a consequence of their disease

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)

- Enrollment complete in ADAPT-SC and ADVANCE (IV); topline data for both trials expected in first half of 2022
- Full Phase 2 trial results of efgartigimod for treatment of pemphigus published in British Journal of Dermatology
- Protocol finalized for registrational trial of efgartigimod for treatment of idiopathic inflammatory myopathy (myositis), following FDA consultation; trial on track to start in first quarter of 2022
- Registrational trial of efgartigimod for treatment of bullous pemphigoid on track to start by end of 2021

ARGX-117, a first-in-class C2-inhibitor, has potential to be the next pipeline-in-a-product opportunity across multiple severe autoimmune indications

- Phase 1 data showed favorable safety profile and potential for infrequent dosing schedules
- Phase 2 trial for treatment of multifocal motor neuropathy (MMN) on track to start by end of 2021

Wim Parys, M.D. to retire as Chief Medical Officer (CMO) on March 31, 2022 and transition to member of Research and Development Committee of argenx Board of Directors

- Succession plans underway for Luc Truyen, M.D., Ph.D., Vice President, Research & Development Operations at argenx, to assume CMO role in April 2022

THIRD QUARTER FINANCIAL RESULTS (CONSOLIDATED)

	Nine Months Ended September 30,		
(in thousands of $ except for shares and EPS)	**2021**	**2020**	**Variance**
Revenue	$ 471,255	$ 33,652	$ 437,603
Other operating income	23,327	14,056	9,271
Total operating income	**494,582**	**47,708**	**446,874**
Research and development expenses	-413,346	-276,412	-136,935
Selling, general and administrative expenses	-210,221	-113,206	-97,015
Total operating expenses	**-623,568**	**-389,618**	**-233,950**
Change in fair value on non-current financial assets	11,152	1,201	9,951
Operating income / (loss)	$ **-117,834**	$ **-340,709**	$ **222,875**
Financial income/(expenses)	-1,040	-1,824	785
Exchange gain/(losses)	-35,990	-65,324	29,335
Profit / (Loss) for the period	$ **-154,864**	$ **-407,857**	$ **252,993**
Income taxes	-15,584	-3,023	-12,561
Profit / (Loss) for the period	$ **-170,447**	$ **-410,880**	$ **240,433**
Weighted average number of shares outstanding	52,774,661	44,717,568	
Basic profit / (loss) per share (in $)	-3.23	-9.19	
Diluted profit / (loss) per share (in $)	-3.23	-9.19	
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2020 and 2019	537,518	611,512	
Cash, cash equivalents and current financial assets at the end of the period	2,533,969	2,112,174	

DETAILS OF THE FINANCIAL RESULTS

As of January 1, 2021, the Company changed its functional and presentation currency from euro to U.S. dollar, 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 $2,534.0 million as of September 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 $446.9 million for the nine months ended September 30, 2021 to $494.6 million, compared to $47.7 million for the nine months ended September 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 $136.9 million for the nine months ended September 30, 2021 to $413.3 million, compared to $276.4 million for the nine months ended September 30, 2020. The increase in the first nine 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 $210.2 million for the nine months ended September 30, 2021, compared to $113.2 million for the nine months ended September 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 nine months ended September 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^{TM} platform.

Exchange losses totaled $36.0 million for the nine months ended September 30, 2021, compared to $65.3 million for the nine months ended September 30, 2020. As a result of the change in the Company's functional and presentation currency, the exchange losses for the nine months ended September 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 full-year 2021 cash burn to approximately double from 2020. The increased spend has supported 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 registrational trials of efgartigimod in six indications, and the continued investment in its Immunology Innovation Program. As argenx further expands its commercial infrastructure and differentiated pipeline of assets, it is expected that the spend associated with these activities will continue to increase.

EXPECTED 2022 FINANCIAL CALENDAR

- March 3, 2022: FY 2021 financial results and business update
- May 12, 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 third quarter 2021 financial results and 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 and Twitter.

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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 regulatory reviews in priority territories and commercial build out; that it is well-positioned for a global launch of efgartigimod; its statement that it is expanding its efgartigimod development plan to be in at least 15 indications by 2025 while also advancing a series of additional high-potential programs emerging from our Immunology Innovation Program including a first-in-class C2 inhibitor, ARGX-117, which is on track to begin the first Phase 2 trial in multifocal motor neuropathy patients by the end of this year 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 approval in 2022; MAA expected approval by European Medicines Agency (EMA) in 2022; and Zai Lab Limited support for mid-2022 submission in China with National Medical Products Administration (NMPA); statements regarding its commercial readiness; its statement that topline data expected in first half of 2022 in trials for ADAPT-SC and ADVANCE(IV) ; its statement that a trial of efgartigimod for treatment of myositis to start in first half of 2022, pending interactions with FDA and Phase 3 registrational trial of efgartigimod for treatment of bullous pemphigoid on track to start by end of 2021; 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 statements regarding the therapeutic potential of Efgartigimod in patients with gMG; the 2021 business and financial outlook and related plans, including its opportunity to deliver long-term, sustainable growth; the therapeutic potential of its product candidates; the intended results of its strategy and argenx’s, and its collaboration partners’, advancement of, anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts; and 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.