argenx Reports Full Year 2020 Financial Results and Provides Fourth Quarter Business Update

- Biologics License Application (BLA) for IV efgartigimod accepted for review by U.S. Food and Drug Administration (FDA) for generalized myasthenia gravis (gMG)

- Pre-approval access program opened in U.S. and Europe for eligible gMG patients

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

March 4, 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 reported financial results for the full year 2020 and provided a fourth quarter business update.

"2020 was an exceptional year for argenx, marked by execution across the organization and highlighted by the positive results of our pivotal Phase 3 ADAPT trial. We have started 2021 on strong footing with the FDA's acceptance for review of the BLA for efgartigimod, bringing us one step closer to offering a new therapy option to people living with gMG. In preparation for our first commercial launch, we remain committed to a series of educational and engagement efforts with patients, physicians and payors on FcRn as a target and the unmet disease burden that gMG patients face," said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

"With proof-of-concept established for efgartigimod in four indications and enrollment on track to begin in the fifth and sixth indications this year, we are building out a broad development plan with our FcRn antagonist. In addition, we expect Phase 1 healthy volunteer data mid-year from our C2 antagonist ARGX-117, our second program in severe autoimmunity, solidifying our commitment to continued pipeline expansion with antibody-based medicines that have potential in multiple autoimmune indications," concluded Mr. Van Hauwermeiren.

FOURTH QUARTER 2020 AND RECENT BUSINESS UPDATE

BLA for efgartigimod accepted for review by FDA; on track with commercial and regulatory preparations in the U.S., Japan, the EU and China.

- BLA for IV efgartigimod for treatment of gMG accepted for review by FDA with action date set for December 17, 2021 under Prescription Drug User Fee Act (PDUFA)
- Japanese Marketing Authorization Application (J-MAA) expected to be filed with Pharmaceuticals and Medical Devices Agency (PMDA) in first half of 2021 with anticipated Japan commercial launch in 2022
- MAA expected to be filed with European Medicines Agency (EMA) in second half of 2021
- Zai Lab Limited to discuss potential accelerated regulatory pathway for approval in China with National Medical Products Administration (NMPA)
- Commercial readiness activities on track, including:

- Build-out of supply chain to ensure ample commercial product available at launch to meet early demand
- Hiring of experienced, neurology-focused sales team with aim to have approximately 70 sales representatives in place for launch
- Ongoing education efforts with key stakeholder groups, including patients, physicians and payors

- Launched pre-approval access program (PAA) in the U.S. and Europe to open availability of efgartigimod to people living with gMG who have a high degree of unmet clinical need and are not able to participate in a clinical trial

Seven global trials to be ongoing in 2021 of efgartigimod across IV and subcutaneous (SC) formulations; proof-of-concept now demonstrated in four indications, which strategically fit within growing commercial franchises.

- **ADAPT-SC**: Enrollment ongoing in registrational trial evaluating non-inferiority based on pharmacodynamic effect of SC efgartigimod compared to IV efgartigimod for treatment of gMG; trial expected to enroll approximately 50 patients
- **ADHERE**: Enrollment ongoing in registrational trial evaluating SC efgartigimod for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) following interim analysis of safety data as well as efficacy assessments that surpassed pre-defined "GO" threshold; trial expected to enroll approximately 130 patients
- **ADVANCE and ADVANCE-SC**: Registrational trials ongoing of IV and SC efgartigimod for treatment of primary immune thrombocytopenia (ITP); trials expected to each enroll approximately 156 patients
- **ADDRESS**: Registrational trial ongoing of SC efgartigimod for treatment of pemphigus (vulgaris and foliaceus); trial expected to enroll approximately 150 patients
- Enrollment in fifth and sixth indications to begin in 2021
- Agreement with Zai Lab Limited expected to expand and accelerate global development of efgartigimod, including into additional autoimmune indications

Data expected mid-2021 from Phase 1 healthy volunteer trial of ARGX-117, a potential first-in-class C2 antagonist and second program with broad applicability in severe autoimmunity.

- Trial to evaluate safety and tolerability of single and multiple ascending doses of IV and SC ARGX-117, and to identify dose to take forward into potential Phase 2 proof-of-concept trials, including for multifocal motor neuropathy (MMN)

Combination trials of cusatuzumab remain ongoing for treatment of acute myeloid leukemia (AML) as part of global collaboration and licensing agreement with Cilag GmbH International, an affiliate of Janssen.

- Data update from Phase 2 CULMINATE trial evaluating cusatuzumab in combination with azacitidine for treatment of newly diagnosed AML to be presented in peer-reviewed forum
- Decision to initiate additional cusatuzumab studies under collaboration will be determined following review of all available data including ongoing Phase 1b ELEVATE trial (NCT04150887), which is evaluating cusatuzumab in combination with venetoclax and azacitidine for treatment of newly diagnosed AML

Immunology Innovation Program (IIP) continues to drive pipeline expansion by identifying potential value-creation opportunities through collaboration with leading disease biologists.

- Preclinical work ongoing in early-stage pipeline, including ARGX-118, ARGX-119 and ARGX-120
- 17 discovery programs under evaluation that emerged from IIP

argenx continues its transition to a global, integrated, immunology organization.

- Geneva office opened to support commercial infrastructure ahead of expected EU launch of efgartigimod
- Planned transition agreement in place for Chief Financial Officer Eric Castaldi as part of evolution to commercial-stage company; recruitment efforts ongoing for U.S.-based successor
- Yvonne Greenstreet, President and Chief Operating Officer of Alnylam, has been nominated to Board of Directors to fill position of Dr. David Lacey, who intends to transition to an advisory role for the Company
- Completed public offering of 3,593,750 ordinary shares in February 2021 with gross proceeds of $1.15 billion

Q4 AND FY2020 FINANCIAL RESULTS

(in thousands of € except for shares and EPS)	Year Ended December 31, 2020	2019	Variance
Revenue	€ 36,425	€ 69,783	€ (33,358)
Other operating income	18,109	12,801	5,308
Total operating income	**54,534**	**82,584**	**(28,050)**
Research and development expenses	(325,479)	(197,665)	(127,814)
Selling, general and administrative expenses	(149,367)	(64,569)	(84,798)
Total operating expenses	**(474,846)**	**(262,234)**	**(212,612)**
Change in fair value on non-current financial assets	2,544	1,096	1,448
Operating loss	€ **(417,769)**	€ **(178,554)**	€ **(239,215)**
Financial income/(expense)	(1,414)	14,275	(15,689)
Exchange gains/(losses)	(106,956)	6,066	(113,022)
Loss before taxes	€ **(526,139)**	€ **(158,213)**	€ **(367,926)**
Income tax expense	€ (2,784)	€ (4,752)	€ 1,968
Loss for the year and total comprehensive loss	€ **(528,923)**	€ **(162,965)**	€ **(365,958)**
Loss for the year and total comprehensive loss attributable to:			
Owners of the parent	€ **(528,923)**	€ **(162,965)**	€ **(365,958)**

Weighted average number of shares outstanding	45,410,442	38,619,121
Basic and diluted loss per share (in €)	(11.65)	(4.22)
Net increase in cash and cash equivalents and current financial assets compared to year-end 2019 and 2018	291,147	771,252
Cash and cash equivalents and current financial assets at the end of the period	1,626,968	1,335,821

DETAILS OF FINANCIAL RESULTS

Cash and cash equivalents and current financial assets totaled €1,627.0 million on December 31, 2020, compared to €1,335.8 million on December 31, 2019. The increase in cash and cash equivalents and current financial assets resulted primarily from the closing of a global offering in May 2020, including a U.S. offering and a European private placement, which resulted in the receipt of €778.1 million in gross proceeds, decreased by €47.4 million of underwriter discounts and commissions, and offering expenses, partially offset by net cash flows used in operating activities.

Revenue decreased by €33.4 million for the year ended December 31, 2020 to €36.4 million, compared to €69.8 million for the year ended December 31, 2019. The decrease was due to the milestone payments following the first-in-human clinical trial with ABBV-151 under the AbbVie collaboration which was achieved in the year ended December 31, 2019, partly offset by revenue recognition of the transaction price related to the Janssen collaboration. The increase in other income is primarily driven by increased research and development incentives and higher payroll tax rebates for employing certain highly qualified research and development personnel.

Research and development expenses increased by €127.8 million for the year ended December 31, 2020 to €325.5 million, compared to €197.7 million for the year ended December 31, 2019. The increase resulted primarily from higher external research and development expenses, primarily related to the efgartigimod program in various indications, cusatuzumab program and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

Selling, general and administrative expenses totaled €149.4 million for the year ended December 31, 2020, compared to €64.6 million for the year ended December 31, 2019. The increase primarily resulted from higher personnel expenses and consulting fees related to the preparation of a possible future commercialization of argenx's lead product candidate efgartigimod.

For the year ended December 31, 2020, financial expenses, which is the net of primarily interest received and changes in fair value of invested funds, amounted to €1.4 million, compared to a financial income of €14.3 million for the year ended December 31, 2020. Financial expenses correspond mainly to the decrease in net asset value of money invested funds following the impact of the COVID-19 outbreak on the financial markets.

Exchange losses totaled €107.0 million for the year ended December 31, 2020, compared to an exchange gain of €6.1 million for the year ended December 31, 2019. The unfavorable change is mainly attributable to unrealized exchange rate losses on cash and cash equivalents and current financial asset position in U.S. dollars.

FINANCIAL GUIDANCE

Based on current plans to fund anticipated operating expenses and capital expenditures, argenx expects its cash burn to increase significantly in 2021, approximately doubling compared to 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 seven expected global trials of efgartigimod, and the continued investment in its Immunology Innovation Program.

EXPECTED 2021 FINANCIAL CALENDAR

- May 14, 2021: Q1 2021 financial results and business update
- July 29, 2021: HY 2021 financial results and business update
- October 28, 2021: Q3 2021 financial results and business update

CONFERENCE CALL DETAILS

The full year 2020 results and fourth 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, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. 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," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning its 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.