argenx reports half year 2019 financial results and second quarter business update

- Enrollment on track for Phase 3 ADAPT trial of efgartigimod (ARGX-113) in generalized myasthenia gravis (gMG) patients with topline results expected in 2H20
- First of two registration trials from Phase 3 program of efgartigimod in primary immune thrombocytopenia (ITP) patients expected to start in 2H19
- First patient dosed in Phase 1 healthy volunteer (HV) trial evaluating ENHANZE® subcutaneous (SC) formulation of efgartigimod
- Management to host conference call today at 3:00 pm CEST (9:00 am ET); details provided below

August 1, 2019

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced its financial results for the first half of 2019 and provided its second quarter business update and the outlook for the remainder of the year.

"We continue to execute on accelerating and expanding our robust, late-stage innovative clinical development programs, as we invest in forward integration across our organization to maximize value. Efgartigimod is the most advanced and also the broadest FcRn antagonist program with four indications and both intravenous and subcutaneous formulations. Enrollment for the Phase 3 ADAPT trial in generalized myasthenia gravis is progressing as planned, and we are on track to initiate before the end of the year the first of two pivotal Phase 3 trials, ADVANCE, for our global primary immune thrombocytopenia program, as well as a Phase 2 trial in chronic inflammatory demyelinating polyneuropathy. Our Phase 2 trial of efgartigimod in pemphigus vulgaris remains a priority, and we expect to report topline data in the first half of 2020," commented Tim Van Hauwermeiren, CEO of argenx. "As we move towards becoming a fully-integrated biotechnology company, we continue to invest in commercial infrastructure with the build-out of our neuromuscular and hematology franchises and the expansion of our global supply chain through our longstanding collaboration with Lonza, which is expected to support the commercial launch of efgartigimod in generalized myasthenia gravis in 2021."

SECOND QUARTER 2019 AND RECENT HIGHLIGHTS
During its 2019 R&D Day in May, argenx announced its plan to become a fully integrated, global immunology company in accordance with its “argenx 2021” vision, which includes building two successful commercial franchises in neuromuscular and hematological disorders.

Efgartigimod (ARGX-113): Potential to be best-in-class with broad applicability
Efgartigimod is a human IgG1 Fc fragment engineered to increase affinity for FcRn versus endogenous IgG, whilst preserving characteristic pH-dependent binding, which may contribute to efgartigimod’s relatively long serum half-life and pharmacodynamic effect, and may promote tissue penetration. Treatment with efgartigimod results in a targeted reduction of IgG autoantibodies and is a rational approach to diseases where IgGs are directly pathogenic. argenx is evaluating efgartigimod as a potential treatment for four high-value indications, including:

- Generalized Myasthenia Gravis (gMG)
  - Global, multi-center Phase 3 ADAPT clinical trial, including ADAPT+ one-year open-label extension study, currently ongoing
  - With current enrollment on track, topline data are expected in second half of 2020
  - Results from completed Phase 2 clinical trial were published in *Neurology*
- Primary Immune Thrombocytopenia (ITP)
  - Global Phase 3 program to include two registration trials that will be run concurrently
    - First trial (ADVANCE) to evaluate 10 mg/kg intravenous (IV) efgartigimod on top of standard of care medication, with enrollment up to 158 patients; primary endpoint includes achieving sustained platelet count response of at least 50×10^9/L
    - Second trial to evaluate 10 mg/kg IV induction period followed by subcutaneous (SC) injections, all on top of standard of care medication, to evaluate potential of SC product to maintain clinical benefit
    - Phase 3 program was developed following consultation with key regulatory agencies
  - ADVANCE Phase 3 clinical trial expected to start in second half of 2019
- Pemphigus Vulgaris (PV)
  - Phase 2 proof-of-concept clinical trial ongoing and currently enrolling patients in third cohort with extended dosing of efgartigimod
  - Data from Phase 2 clinical trial expected in first half of 2020
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
  - Phase 2 clinical trial on track to start in second half of 2019
  - Key opinion leader (KOL) event planned for fourth quarter 2019 to discuss Phase 2 trial design and unmet needs in CIDP

argenx entered into a global collaboration with Halozyme in February 2019 to develop a SC formulation of efgartigimod using Halozyme’s proprietary ENHANZE® drug delivery technology, gaining exclusive rights to the technology for the FcRn target.

- First subject dosed in Phase 1 healthy volunteer (HV) trial evaluating safety, pharmacokinetics, pharmacodynamics and bioavailability of ENHANZE® SC formulation of efgartigimod
- Initiation of study triggered $5 million milestone payment to Halozyme
- Data from Phase 1 HV trial are expected by end of 2019 after which argenx will disclose a path forward in patients for ENHANZE® SC formulation of efgartigimod

Cusatuzumab (ARGX-110): First-in-class opportunity in acute myeloid leukemia (AML)
Cusatuzumab is a first-in-class monoclonal antibody inhibiting CD70, a target that is uniquely present on both leukemic stem cells and AML blasts but not healthy cells. It is being developed under an exclusive global collaboration and license agreement with Janssen for the treatment of AML, high-risk myelodysplastic syndromes and other hematological malignancies.

- Phase 2 and registration-directed clinical trial in AML on track to start in second half of 2019
  - Trial to enroll up to 150 patients with previously untreated AML and who are not eligible for intensive chemotherapy
  - In this two-part trial, patients will first be randomized to receive one of two dose levels of cusatuzumab (10 mg/kg and 20 mg/kg) in combination with azacytidine (75 mg/m^2) followed by an expansion cohort to evaluate efficacy of the selected dose of cusatuzumab

Early Development Programs

argenx announced during its R&D Day the expansion of its product pipeline with the addition of two new proprietary therapeutic candidates, ARGX-117 and ARGX-118. Both emerged from argenx's Innovative Access Program, in which it collaborates closely with disease biology experts, bringing the argenx cutting-edge antibody discovery and engineering technologies to the heart of novel target research.

- ARGX-117 is a complement-targeting antibody against C2, a component of both the classical and lectin pathways in the complement cascade
  - Potential therapeutic applications in multiple autoimmune diseases
  - argenx exercised its second exclusive license to Halozyme's ENHANZE® technology for use with this molecule
  - Expected to file Clinical Trial Application (CTA) by end of 2019 with first-in-human trial expected to start in first quarter of 2020
- ARGX-118 is a highly differentiated antibody against Galectin-10, the protein of Charcot-Leyden crystals (CLCs), which play a major role in severe asthma and the persistence of mucus plugs
  - Immunology breakthrough in airway inflammation
  - SIMPLE Antibody™ observed to have unique crystal-dissolving properties
  - Currently in final stages of lead optimization work
  - Data were published in *Science* by argenx collaborator Dr. Bart Lambrecht from VIB Inflammation Research Center supporting role of CLCs and potential of ARGX-118 in airway inflammation

Corporate Update

- Appointed Wim Parys, M.D. as Chief Medical Officer effective July 1, 2019. Most recently, Dr. Parys served as Head of R&D of the Global Public Health group of Janssen.

HALF YEAR 2019 FINANCIAL RESULTS (CONSOLIDATED)

	Six Months Ended June 30		
(in thousands of €)	**2019**	**2018**	**Variance**
Revenue	€ 43,532	€ 17,910	€ 25,622
Other operating income	7,767	2,588	5,179
Total operating income	**51,299**	**20,498**	**30,801**
Research and development expenses	(78,304)	(34,371)	(43,933)
Selling, general and administrative expenses	(27,462)	(11,514)	(15,948)
Operating loss	**€ (54,467)**	**€ (25,387)**	**€ (29,080)**
Financial income	7,210	1,256	5,954
Exchange gains	2,486	4,024	(1,538)
Loss before taxes	**€ (44,771)**	**€ (20,107)**	**€ (24,664)**
Income tax (expense)/benefit	€ (350)	€ 31	€ (381)
Loss for the period and total comprehensive loss	**€ (45,121)**	**€ (20,076)**	**€ (25,045)**
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2018 and 2017	€ 379,714	€ (20,922)	
Cash, cash equivalents and current financial assets at the end of the period	€ 944,283	€ 338,852	

On June 30, 2019, cash, cash equivalents and current financial assets totaled €944.3 million, compared to €564.6 million on December 31, 2018. The increase in cash, cash equivalents and current financial assets resulted primarily from the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen which resulted in a $300 million upfront payment and a $200 million equity investment in January 2019.

Total operating income increased by €30.8 million for the six months ended June 30, 2019 to reach €51.3 million, compared to €20.5 million for the six months ended June 30, 2018. The increase is primarily related to (i) a €16.0 million increase in the recognition of milestone payments following the initiation of a first-in-human clinical trial with ABBV-151 (formerly named ARGX-115) under the AbbVie collaboration, which triggered a $30 million milestone payment, (ii) an increase of €7.8 million related to the recognition of research and development service fees under the Janssen collaboration and (iii) an increase of €5.2 million, mainly driven by higher payroll tax rebates for employing

certain research and development personnel.

Research and development expenses totaled €78.3 million and €34.4 million for the six months ended June 30, 2019 and 2018, respectively. The increase in the first six months of 2019 resulted primarily from higher external research and development expenses and personnel expenses, reflecting higher clinical trials costs and manufacturing expenses related to the development of argenx's product candidate portfolio and the recruitment of additional employees to support research and development activities.

Selling, general and administrative expenses totaled €27.5 million and €11.5 million for the six months ended June 30, 2019 and 2018, respectively. The increase of €16.0 million in selling, general and administrative expenses for the six months ended June 30, 2019 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 six months ended June 30, 2019, financial income amounted to €7.2 million, compared to €1.3 million for the six months ended June 30, 2018. The increase of €5.9 million in the first six months of 2019 related primarily to an increase in the interest received on cash, cash equivalents and current financial assets.
Exchange gains totaled €2.5 million for the six months ended June 30, 2019, compared to the €4.0 million for the six months ended June 30, 2018 and were mainly attributable to unrealized exchange rate gains on argenx's cash and current financial assets position in U.S. Dollars due to the favorable fluctuation of the EUR/USD exchange rate in the first six months of 2019.

The total comprehensive loss for the six months ended June 30, 2019 was €45.1 million, compared to €20.1 million for the six months ended June 30, 2018.

The 90 day average number of shares outstanding per June 30, 2019 was 38,026,040.

Financial Outlook
Based on the current objectives of the Company's business plan, argenx expects that its existing cash, cash equivalents and investments will fund planned operating and capital expense requirements into 2021. With the launch of a second global Phase 3 trial for efgartigimod, the execution of the development plan for cusatuzumab, the build-out of the commercial organization, and the expansion of the Company's ambition level within its growing business plan, argenx expects operating and capital expense requirements to continue to increase year-over-year.

U.S. SEC and Statutory Financial Reporting
argenx's primary accounting framework is International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). Unaudited condensed half yearly interim financial statements prepared in accordance with International Accounting Standards IAS 34 Interim Financial Reporting 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 European Union (EU) for statutory purposes. The unaudited condensed consolidated statement of financial position, the unaudited condensed consolidated statements of profit and loss and other comprehensive income, the unaudited condensed consolidated statements of cashflow, and the unaudited condensed consolidated statement 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 condensed consolidated statement of profit and loss and other comprehensive income for the six months ended June 30, 2019 presented in this press release is unaudited.

2019 FINANCIAL CALENDAR

- October 24, 2019: Q3 2019 business update and financial results

CONFERENCE CALL DETAILS
The half year results will be discussed during a conference call and webcast presentation today at
3:00 pm CEST/9:00 am ET. To participate in the conference call and Q&A session, please select your phone number provided below and use the confirmation code **7539308**. The live webcast may be accessed on the homepage of the argenx website at www.argenx.com or by clicking here.

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About argenx
argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. The company is focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. argenx's ability to execute on this focus is enabled by its suite of differentiated technologies. The SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows argenx to exploit novel and complex targets, and its three complementary Fc engineering technologies are designed to expand the therapeutic index of its product candidates.
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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 financial condition, results of operation and business outlook; the sufficiency of its cash, cash equivalents and current financial assets; its 2019 business and financial calendar and related plans; the clinical data of its product candidates; the intended results of its strategy; the momentum of its product candidate pipeline as well as 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; and interaction with regulators, including the potential approval of its current or future drug candidates. 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 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.