argenx reports half year 2020 financial results and provides second quarter business update

- Biologics License Application for efgartigimod in generalized myasthenia gravis on track to be submitted to U.S. Food and Drug Administration by end of year
- Full data from ADAPT trial to be presented at upcoming medical meeting in 2020
- Cusatuzumab development strategy aligned with evolving AML treatment landscape to focus on combination with venetoclax and azacitidine
- €1.9 billion in cash and cash equivalents and current financial assets strongly support commercial launch preparation of efgartigimod
- Management to host conference call today at 2:30 pm CEST (8:30 am ET)

July 30, 2020

Breda, the Netherlands / Ghent, Belgium – 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 2020 financial results and provided a second quarter business update and outlook for the remainder of the year.

“We are proud of the progress we have made during the first half of 2020 to advance our immunology pipeline and validate our first-in-class FcRn antagonist, efgartigimod. We announced positive topline results from the Phase 3 ADAPT trial, furthering our conviction that efgartigimod has the potential to significantly improve the standard of care for people with gMG as well as several other autoantibody-driven diseases. We are focused on our planned 2021 U.S. commercial launch of efgartigimod to bring this therapy to patients as quickly as possible and to advance on our ‘argenx 2021’ vision,” said Tim Van Hauwermeiren, CEO of argenx.

"We also remain committed to advancing our robust pipeline, including our late-stage efgartigimod trials in additional autoimmune indications and our early-stage candidates from our Immunology Innovation Program. Regarding cusatuzumab, which we are currently developing in a global collaboration with Janssen, as clinical trial sites re-open, we are taking the opportunity to evaluate the most appropriate development strategy given the rapidly evolving treatment landscape, ” continued Mr. Van Hauwermeiren.

SECOND QUARTER 2020 AND RECENT BUSINESS UPDATE

argenx continues to execute on its “argenx 2021” vision to become a fully integrated, global immunology company. The company continues to implement measures across the organization and in the operations of globally run clinical trials to minimize the impact of COVID-19 on employees, patients and their communities, physicians and ongoing business priorities.

Commercial preparations underway to support potential approval and launch of argenx’s first-in-class FcRn antagonist, efgartigimod, in its first indication, generalized myasthenia gravis (gMG).

- Biologics License Application (BLA) on track to be filed with the U.S. Food and Drug Administration (FDA) by the end of 2020 with an expected U.S. commercial launch in 2021
- Japanese Marketing Authorization Application (J-MAA) expected to be filed with the Pharmaceuticals and Medical Devices Agency (PMDA) in the first half of 2021 with an expected efgartigimod launch in gMG in Japan following the U.S. commercial launch
- Commercial infrastructure readiness activities, including with global supply chain, are on track for launch timeline in the U.S. and Japan

In May, argenx reported positive topline data from the Phase 3 ADAPT trial showing efgartigimod was well-tolerated and able to drive responses that support plans to offer individualized dosing to gMG patients.

- ADAPT met its primary endpoint showing 67.7% of acetylcholine receptor-antibody positive (AChR-Ab+) gMG patients were responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score compared with 29.7% on placebo ($p<0.0001$)
- 63.1% of AChR-Ab+ gMG patients responded to efgartigimod compared with 14.1% on placebo on the Quantitative Myasthenia Gravis (QMG) score ($p<0.0001$)
- 40.0% of efgartigimod-treated AChR-Ab+ patients achieved minimal symptom expression defined as MG-ADL scores of 0 (symptom free) or 1, compared to 11.1% treated with placebo
- In AChR-Ab+ patients who met the primary endpoint, the majority showed a sustained response, including 88.6% who achieved a response for at least six weeks, 56.8% for at least eight weeks and 34.1% for at least 12 weeks
- Safety profile of efgartigimod was comparable to placebo
- Detailed data set to be presented at upcoming medical meeting in 2020
- argenx plans to meet with FDA in fourth quarter of 2020 to discuss bridging strategy for subcutaneous (SC) efgartigimod

Positive ADAPT data support continued progress of efgartigimod in additional severe autoimmune indications within key commercial franchises.

- Primary immune thrombocytopenia (ITP) registrational program includes ongoing ADVANCE trial evaluating 10mg/kg IV efgartigimod in up to 156 patients
  - Enrollment delays in the program have been observed due to COVID-19
  - Discussions ongoing with FDA on how to bring forward SC components of program to meet COVID-19 enrollment challenges
- Chronic inflammatory demyelinating polyneuropathy (CIDP) Phase 2 ADHERE trial ongoing evaluating SC efgartigimod
  - Due to COVID-19 enrollment delays, potential decision to expand trial up to 130 patients now expected in 2021
- Pemphigus vulgaris (PV) registrational trial to start in second half of 2020 following proof-of-concept data from adaptive Phase 2 trial that showed fast onset of disease control and deep responses with potential for steroid sparing
- Fifth indication to be announced by end of 2020

Cusatuzumab development strategy aligned with evolving treatment landscape and anticipated global adoption of venetoclax in acute myeloid leukemia (AML) clinical practice.

- Development plan, in collaboration with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, to now focus on cusatuzumab in combination with venetoclax, including in the Phase 1b ELEVATE combination trial of cusatuzumab with venetoclax and azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy
  - Trial enrolling again after pause due to COVID-19
- Maturing data from Phase 2 CULMINATE trial of cusatuzumab in combination with azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy suggest that complete response rates are not likely to exceed those from the VIALE-A trial of venetoclax in combination with azacitidine presented at the European Hematology Association (EHA) Annual Congress in June 2020
  - Based on enrollment to date, dose selected to be 20mg/kg
  - CULMINATE trial will continue to evaluate responses and durability for existing patients but will not enroll new patients
  - Topline data to be reported in early 2021
  - Registration strategy to be determined following evaluation of maturing data across cusatuzumab program and AML treatment landscape
- Phase 1 trial of cusatuzumab in combination with azacitidine trial in Japan evaluating newly diagnosed, elderly AML patients who are ineligible for intensive chemotherapy remains ongoing
- Phase 2 BEACON trial of cusatuzumab in combination with azacitidine versus azacitidine alone in higher-risk patients with myelodysplastic syndromes (MDS) who are ineligible for intensive chemotherapy remains paused for enrollment
- Part 1 dose escalation of Phase 1 study of cusatuzumab in combination with azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy, published in *Nature Medicine*

argenx continues to advance its early-stage pipeline of first-in-class antibodies against immunologic targets.

- ARGX-117 targeting complement C2 to be evaluated in Phase 1 healthy volunteer trial starting in third quarter of 2020
  - Following analysis of Phase 1 data, argenx plans to launch Phase 2 proof-of-concept trials in severe autoimmune diseases, including multifocal motor neuropathy (MMN)
  - Single-center Phase 1 trial remains open for enrollment to evaluate ARGX-117 as a potential treatment for acute respiratory distress syndrome (ARDS), a frequent and serious complication associated with COVID-19
- ARGX-118 targeting Galectin-10 is undergoing lead optimization work as a potential treatment for airway inflammation
- ARGX-119 on track to be announced in 2020

Partnered antibody candidates that emerged from argenx's Immunology Innovation Program continue to have the potential to bring non-dilutive capital in the form of milestone payments and future royalties

- AbbVie's ongoing Phase 1 trial of ABBV-151 (formerly ARGX-115) in solid tumors remains open for enrollment
- LEO Pharma plans to reopen sites in late August for enrollment in ongoing Phase 1 trial of LP0145 (formerly ARGX-112) for the treatment of atopic dermatitis
- Staten initiated dosing in first-in-human clinical trial of STT-5058 (formerly ARGX-116) targeting apoC3 for the potential treatment of dyslipidemia

HALF YEAR 2020 FINANCIAL RESULTS (CONSOLIDATED)

	Six Months Ended June 30,		
(in thousands of € except for shares and EPS)	**2020**	**2019**	**Variance**
Revenue	€ 22,388	€ 43,532	€ (21,143)
Other operating income	8,729	7,767	961
Total operating income	**31,117**	**51,299**	**(20,182)**
Research and development expenses	(171,718)	(78,304)	(93,414)
Selling, general and administrative expenses	(61,644)	(27,462)	(34,181)
Total operating expenses	**(233,362)**	**(105,767)**	**(127,595)**
Change in fair value on non-current financial assets	848	—	848

Operating loss	**€ (201,397)**	**€ (54,467)**	**€ (146,929)**
Financial income/(expense)	(2,178)	7,210	(9,388)
Exchange gains/(losses)	199	2,486	(2,287)
Loss before taxes	**€ (203,376)**	**€ (44,771)**	**€ (158,605)**
Income tax (expense)/benefit	€ (2,261)	€ (350)	€ (1,911)
Loss for the year and total comprehensive loss	**€ (205,637)**	**€ (45,121)**	**€ (160,516)**
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2019 and 2018	596,977	1,368,229	
Cash, cash equivalents and current financial assets at the end of the period	1,932,798	944,283	

DETAILS OF THE FINANCIAL RESULTS

On June 30, 2020, cash and cash equivalents and current financial assets totaled €1,932.8 million, 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, including a U.S. offering and a European private placement, which resulted in the receipt of €730.7 million net proceeds in June 2020.

Total operating income decreased by €20.2 million for the six months ended June 30, 2020 to €31.1 million, compared to €51.3 million for the six months ended June 30, 2019. This decrease is primarily related to the milestone payments following the first-in-human clinical trial with ABBV-151 under the AbbVie collaboration which was achieved in the first six months of 2019, partly offset by the revenue recognition of the transaction price related to the Janssen collaboration and the increase in other income mainly driven by higher payroll tax rebates for employing certain research and development personnel.

Research and development expenses in the first six months of 2020 amounted to €171.7 million, compared to €78.3 million for the first six months of 2019. The increase resulted primarily from higher external research and development expenses primarily related to the efgartigimod program in various indications, the cusatuzumab program and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to the planned increase in headcount.

Selling, general and administrative expenses totaled €61.6 million in the first six months of 2020, compared to €27.5 million for the first six months of 2019. This 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 six months ended June 30, 2020, financial expenses, which primarily relate to interest received and changes in fair value of current financial assets, amounted to €2.2 million compared to a financial income of €7.2 million for the six months ended June 30, 2019. Financial expenses corresponded mainly to a decrease in net asset value on its current financial assets following the impact of the COVID-19 outbreak on the financial markets.

Exchange gains totaled €0.2 million for the six months ended June 30, 2020, compared to €2.5 million for the six months ended June 30, 2019 and were mainly attributable to unrealized exchange rate gains on cash, cash equivalents and current financial assets.

A net loss of €205.6 million and an operating loss of €201.4 million were realized for the six months ended June 30, 2020, compared to a net loss of €45.1 and operating loss of €54.5 million for the six months ended June 30, 2019.

EXPECTED 2020 FINANCIAL CALENDAR:

- October 22, 2020: Q3 financial results & business update

CONFERENCE CALL DETAILS

The half year 2020 results and second quarter business update will be discussed during a conference call and webcast presentation today at 2:30 pm CET/8:30 am ET. To participate in the conference call, please select your phone number below and use the confirmation code **7470386**. The webcast may be accessed on the Investors section of the argenx website at argenx.com/investors.

Dial-in numbers:

Please dial in 5–10 minutes prior to 2:30 p.m. CET/ 8:30 a.m. ET using the number and conference ID below.

Confirmation Code: **7470386**

Belgium	+32 (0)2 793 3847
Belgium	0800 484 71
France	+33 (0)1 7070 0781
France	0805 101 465
Netherlands	+31 (0)20 0795 6614
Netherlands	0800 023 5015
United Kingdom	+44 (0) 844 481 9752
United Kingdom	0800 279 6619
United States	+1 (646) 741 3167
United States	+1 (877) 870 9135

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 is translating 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/.

For further information, please contact:

Beth DelGiacco, Vice President, Investor Relations (US)
+1 518 424 4980
bdelgiacco@argenx.com

Joke Comijn, Director Corporate Communications & Investor Relations (EU)
+32 (0)477 77 29 44
+32 (0)9 310 34 19
jcomijn@argenx.com

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 2020 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 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 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.