argenx reports first quarter 2020 financial results and provides business update

- Topline data readout from Phase 3 ADAPT trial of efgartigimod in generalized myasthenia gravis on track for mid-2020 and Biologics License Application filing by end of year -

- Enrollment paused in ongoing trials under Janssen and LEO Pharma collaborations -

- ARGX-117 being evaluated in COVID-19 patients with acute respiratory distress syndrome in collaboration with UZ Gent –

- Management to host conference call today at 3:00 pm CEST (9:00 am ET) -

May 14, 2020

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 quarter ended March 31, 2020 and provided a business update.

“We are very excited to be approaching our first pivotal Phase 3 data readout with topline data from the ADAPT trial still on track for mid-year. This is an important milestone as it will precipitate our transition from a late-stage development company towards an integrated commercial organization. We have been investing in the expansion of our commercial infrastructure and are preparing for a 2021 launch of efgartigimod in gMG in the U.S., if approved,” stated Tim Van Hauwermeiren, CEO of argenx.

“Over the last several months, the COVID-19 global pandemic has presented an unprecedented challenge, and as we face uncertainty in the coming months, we are grateful to have strong fundamentals across our business and the ability to fund our deep antibody pipeline. I am most grateful, however, for the continued support of our employees who have demonstrated exceptional focus and an unwavering dedication to our mission of developing therapies for the treatment of severe autoimmune diseases and cancer. This commitment is underscored by our decision to evaluate the potential of ARGX-117 to attenuate complement activation in severe respiratory illness associated with COVID-19 while obtaining key metrics of our drug candidate in this first-in-human trial.”

FIRST QUARTER 2020 AND RECENT HIGHLIGHTS

argenx commitment to its people, patients and business

Despite the challenges of the COVID-19 pandemic, argenx remains focused on executing on its “argenx 2021” vision to become a fully integrated, global immunology company. In order to minimize impact on employees, patients and their communities, physicians and ongoing business priorities, argenx has implemented measures across its organization and in the operation of its globally run clinical trials.

- A work-from-home mandate continues for all employees in the U.S., Belgium and Japan, excluding those providing essential services such as laboratory staff; additionally, all work-related global and domestic travel are suspended.
- In order to enable patients in its clinical trials to receive study drug with continuity, argenx is implementing telehealth, remote monitoring activities and more flexible dosing schedules in its protocols where possible.
- argenx conducts clinical trials globally, including in areas impacted by COVID-19 in North America, Europe and Japan. Enrollment is expected to be delayed in ongoing trials conducted by argenx, but the extent of the full impact is not quantifiable until the trajectory of the pandemic is better understood. The Company will continue to monitor the impact of COVID-19 on all ongoing clinical trials and will implement changes as necessary.

Efgartigimod trials remain open with additional registrational trials expected to launch this year

Efgartigimod is currently being evaluated in four targeted indications where IgG autoantibodies are directly pathogenic. A fifth indication is expected to be announced this year.

- Generalized Myasthenia Gravis (gMG)
  - Topline results from the pivotal Phase 3 ADAPT clinical trial expected by mid-2020
  - All patients have completed primary 26-week trial; patients continue to be dosed in the ADAPT+ one-year, open-label extension study
  - If ADAPT data are positive, a Biologics License Application (BLA) submission is expected to be filed by end of 2020, with commercial launch planned in the U.S. in 2021
  - Plans remain on track to engage with the U.S. Food and Drug Administration (FDA) in 2020 on potential bridging strategy for subcutaneous (SC) ENHANZE®-efgartigimod

·Well-established alliance with Lonza supports robust and flexible manufacturing capabilities and supply chain remains on track to be commercial-ready by end of 2020

- Primary Immune Thrombocytopenia (ITP)
  - Phase 3 ADVANCE trial ongoing and expected to enroll approximately 150 primary ITP patients dosed with 10mg/kg IV

efgartigimod
    - Confirmatory trial of IV efgartigimod expected to initiate in the first half of 2020
    - ADVANCE SC trial expected to initiate in the second half of 2020 evaluating 10mg/kg IV efgartigimod for induction of platelet response and 2mL fixed dose of SC efgartigimod for maintenance
- Pemphigus Vulgaris (PV)
    - Phase 3 registrational trial expected to start in second half of 2020
    - Detailed proof-of-concept data from adaptive Phase 2 trial presented at Society for Investigative Dermatology (SID) Virtual Annual Meeting; presentation currently available on SID and argenx websites.
    - Presentation includes updated data from 31 evaluable patients treated with 10mg/kg or 25mg/kg of IV efgartigimod (data as of cutoff date of March 25, 2020)
        - 90% (28/31) achieved rapid disease control; median time to disease control for monotherapy and combination therapy is 15 and 22 days
        - Complete clinical remission observed in 70% (7/10) of patients receiving optimized dosing regimen determined to be efgartigimod dosed at least every two weeks in combination with oral prednisone (0.25-0.5mg/kg)
        - 73% (11/15) of patients receiving 25mg/kg efgartigimod achieved end of consolidation, including patients who preferred to taper steroid dose
        - 11 patients currently still on study
        - Tolerability profile shown to be favorable and consistent with data from previous efgartigimod studies
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
    - Phase 2 ADHERE trial ongoing with SC ENHANZE®-efgartigimod

Janssen and LEO Pharma have paused enrollment of clinical trials of cusatuzumab and LP0145 (ARGX-112)

Enrollment is paused in two ongoing clinical trials initiated under the global cusatuzumab collaboration and licensing agreement with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson. Trials that have paused enrollment under the collaboration include:

- Pivotal Phase 2 CULMINATE study evaluating cusatuzumab in combination with azacitidine for the treatment of newly diagnosed elderly acute myeloid leukemia (AML) patients who are unfit for intensive chemotherapy;
- Phase 1b platform trial evaluating cusatuzumab in combination with venetoclax and azacitidine

Additionally, LEO Pharma has paused enrollment of the ongoing trial of LP0145 for the treatment of atopic dermatitis.

Timing to restart enrollment of all trials will depend on the trajectory of COVID-19 infection rates

ARGX-117 being evaluated as potential treatment for ARDS in COVID-19 patients

ARGX-117 is a potentially first-in-class complement-targeting antibody against C2 with potential therapeutic applications in severe autoimmune diseases.

- argenx is sponsoring a Phase 1 trial in collaboration with Ghent University Hospital to evaluate ARGX-117 as a potential treatment for acute respiratory distress syndrome (ARDS), a frequent and serious complication associated with COVID-19.
    - Both classical and lectin pathways of complement system are active in ARDS; by targeting C2, an important component of both pathways, ARGX-117 could inhibit downstream inflammatory responses associated with ARDS
    - Collaboration leverages longstanding Immunology Innovation Program relationships with Erik Hack, M.D., Ph.D., Professor Emeritus, UMC Utrecht, and Bart Lambrecht, M.D., Ph.D., Director of Inflammation at VIB, UZGent and Belgian National Commissioner on the COVID-19 pandemic
    - Key pharmacokinetic (PK), pharmacodynamic (PD), dose finding and tolerability data to be gained during first-in-human trial
- Phase 1 trial in healthy volunteers to start by end of 2020
    - Following analysis of Phase 1 data, argenx plans to launch Phase 2 proof-of-concept trial in multifocal motor neuropathy (MMN) within its neuromuscular franchise, and to develop in additional indications

argenx continues to expand its early-stage pipeline

- Lead optimization work ongoing for ARGX-118 as treatment for airway inflammation
- New product candidate ARGX-119 expected to be announced in 2020

FIRST QUARTER 2020 FINANCIAL RESULTS (CONSOLIDATED)

	Three Months Ended March 31,		
in thousands of €	**2020**	**2019**	**Variance**
Revenue	€ 19,171	€ 36,453	€ (17,282)
Other operating income	€ 4,237	€ 3,564	€ 673
Total operating income	€ **23,408**	€ **40,017**	€ **(16,609)**
Research and development expenses	€ (94,917)	€ (34,752)	€ (60,165)
Selling, general and administrative expenses	€ (25,038)	€ (11,306)	€ (13,732)

Operating loss	€	**(96,547)**	€	**(6,041)**	€	**(90,506)**
Financial income	€	1,742	€	3,458	€	(1,716)
Financial expense	€	(4,998)	€	—	€	(4,998)
Exchange gain/(losses)	€	20,845	€	9,512	€	11,333
Profit/(Loss) before taxes	€	**(78,958)**	€	**6,929**	€	**(85,887)**
Income tax expense	€	(1,088)	€	(180)	€	(908)
Profit/(Loss) for the period and total comprehensive loss	€	**(80,046)**	€	**6,749**	€	**(86,795)**
Weighted average number of shares outstanding		42,786,194		34,497,705		
Basic profit/(loss) per share (in €)		(1.87)		0.18		
Diluted profit/(loss) per share (in €)		(1.87)		0.17		
Net increase in cash, cash equivalents and current financial assets compared to year-end 2018 and 2017	€	(30,287)	€	397,052		
Cash, cash equivalents and current financial assets at the end of the period	€	1,305,534	€	961,621		

DETAILS OF THE FINANCIAL RESULTS

Cash, cash equivalents and current financial assets totaled €1,305.5 million on March 31, 2020, compared to €1,335.8 million on December 31, 2019 and €961.6 million on March 31, 2019.

Operating income amounted to €23.4 million for the three months ended March 31, 2020, compared to €40.0 million for the three months ended March 31, 2019. The decrease in the first three months of 2020 was primarily explained by the revenue recognized in the first quarter of 2019, following a $30.0 million development milestone payment received under the AbbVie collaboration agreement.

Research and development expenses increased by €60.1 million during the three months ended March 31, 2020 to reach €94.9 million, compared to €34.8 million for the three months ended March 31, 2019. This planned increase was mainly the result of (i) increased external research and development expenses reflecting higher clinical trial costs and manufacturing expenses related to the development of the argenx product candidate portfolio and (ii) higher personnel expenses as a result of increased costs of the share-based payment compensation plans related to the grant of stock options to argenx research and development employees and increased costs associated with additional research and development employees.

Selling, general and administrative expenses totaled €25.0 million and €11.3 million for the three months ended March 31, 2020 and 2019, respectively. The increase of €13.7 million was principally linked to an increase of personnel expense, resulting from (i) higher costs of the share-based payment compensation plans related to the grant of stock options to its selling, general and administrative employees and (ii) increased costs associated with additional employees recruited to strengthen its selling, general and administrative activities, notably in preparation of the potential commercial launch of efgartigimod in the U.S., if approved.

For the three months ended March 31, 2020, financial income, which primarily relate to interests received on its cash and cash equivalents and current financial assets, amounted to €1.7 million compared to €3.5 million for the same period in 2019. Financial expense amounted to €5.0 million for the three months ended March 31, 2020 and 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 €20.8 million for the three months ended March 31, 2020 compared to €9.5 million for the three months ended March 31, 2019 and were mainly attributable to unrealized exchange rate gains on cash, cash equivalents and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate.

The total comprehensive loss for the three months ended March 31, 2020 was €80.0 million compared to a total comprehensive profit, which was principally due to the milestone payment received from AbbVie as indicated above, of €6.7 million for the three months ended March 31, 2019.

EXPECTED 2020 FINANCIAL CALENDAR:

- July 30, 2020: HY 2020 financial results & business update
- October 22, 2020: Q3 financial results & business update

CONFERENCE CALL DETAILS

The first quarter 2020 results will be discussed during a conference call and webcast presentation today at 3 pm CET/9 am ET. To participate in the conference call, please select your phone number below and use the confirmation code **6736269**. The webcast may be accessed on the homepage of the argenx website at www.argenx.com or by clicking here.

Dial-in numbers:

Please dial in 5–10 minutes prior to 3 pm CET/ 9 am ET using the number and conference ID below.

Confirmation Code: **6736269**

Belgium	+32 (0)2 793 3847
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Netherlands	+31 (0)20 0795 6614
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About argenx

argenx is a global immunology company developing antibody-based medicines for patients suffering from severe autoimmune diseases and cancer. By translating immunology breakthroughs into innovative drug candidates, argenx is building a world-class portfolio of first-in-class antibodies in both early and late clinical-stages of development. argenx is evaluating efgartigimod in multiple serious autoimmune indications and cusatuzumab in hematological malignancies in collaboration with Janssen, along with advancing earlier stage assets within its therapeutic franchises.

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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 2020 business and financial calendar and related plans; the clinical data 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. 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.