argenx reports third quarter 2019 financial results and provides business update

- Enrollment on track for Phase 3 ADAPT trial of efgartigimod in gMG patients with topline results expected in 2H20
- Two efgartigimod trial initiations expected in 4Q19: Phase 2 proof-of-concept trial in CIDP patients and Phase 3 ADVANCE trial in primary ITP patients
- Data from Phase 1 HV trial of ENHANZE® SC formulation of efgartigimod expected by YE19

October 24, 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 third quarter ended September 30, 2019 and provided a business update.

“We have had another strong quarter of execution across our development pipeline and look forward to a busy remainder of the year that should set the stage for an exciting 2020. With efgartigimod, we are planning for three upcoming readouts, including Phase 3 ADAPT data in generalized myasthenia gravis, which remains on track with enrollment and for data readout in the second half of 2020; Phase 2 data in pemphigus vulgaris in the first half of 2020; and Phase 1 healthy volunteer data from the ENHANZE® SC formulation of efgartigimod by the end of this year, which will guide our subcutaneuous development path forward. In tandem, we plan to initiate new trials of efgartigimod, cusatuzumab and ARGX-117 as we continue to build a multitude of opportunities across our pipeline and strengthen our focus within important therapeutic franchises,” commented Tim Van Hauwermeiren, CEO of argenx.

THIRD QUARTER 2019 AND RECENT HIGHLIGHTS
argenx is executing on its “argenx 2021” vision to become a fully integrated, global immunology company, which includes its anticipated first commercial launch of efgartigimod in generalized myasthenia gravis (gMG) in 2021 and the building of two potential commercial franchises in neuromuscular and hematology with its three core assets: efgartigimod, cusatuzumab and ARGX-117.

Efgartigimod: First-in-class opportunity with potential across range of high-value autoimmune indications
Efgartigimod is a human IgG1 Fc fragment engineered for optimal blocking of FcRn. Treatment with efgartigimod is intended to result in a targeted reduction of IgG autoantibodies. argenx is evaluating efgartigimod across four indications where IgG autoantibodies are directly pathogenic, including:

- Generalized Myasthenia Gravis
    - Global, multi-center Phase 3 ADAPT clinical trial, including ADAPT+ one-year open-label extension study, currently ongoing
    - Based on current enrollment, argenx continues to expect topline data from ADAPT in second half of 2020
- Primary Immune Thrombocytopenia (ITP)
    - Global Phase 3 program to include two registrational trials to be run concurrently
    - First trial, ADVANCE, on track to start in second half of 2019 and will evaluate 10mg/kg intravenous (IV) efgartigimod on top of standard of care medication
    - Second trial to evaluate 10mg/kg IV efgartigimod to induce IgG antibody reduction and clinical response followed by fixed dose 330mg subcutaneous (SC) injectable efgartigimod to maintain clinical benefit
- Pemphigus Vulgaris (PV)
    - Interim data from ongoing Phase 2 proof-of-concept clinical trial expected in first half of 2020
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
    - Phase 2 proof-of-concept clinical trial on track to start in second half of 2019
    - Key opinion leader (KOL) event planned for December 5, 2019 to present Phase 2 trial design and market opportunity in CIDP

argenx is developing three formulations of efgartigimod to address the needs of patients, physicians and payors across indications and geographies, including IV efgartigimod and two SC formulations.

- A standalone SC formulation of efgartigimod as part of argenx's collaboration with Halozyme enabling co-formulation of efgartigimod with Halozyme's proprietary ENHANZE® drug delivery technology
    - Data from Phase 1 healthy volunteer (HV) trial expected by end of 2019
    - After Phase 1 HV trial data are available, argenx to disclose path forward for testing in patients for ENHANZE® SC formulation of efgartigimod, including potential bridging strategy in gMG
    - argenx has exclusive access to ENHANZE® technology for FcRn target
- A fixed 330mg SC injection to be dosed as maintenance treatment following IV induction; this formulation to be evaluated in second Phase 3 ITP trial

Cusatuzumab: First-in-class opportunity with potential in hematological malignancies

Cusatuzumab is an anti-CD70 monoclonal antibody being developed under an exclusive global collaboration and license agreement with Janssen for the treatment of acute myeloid leukemia (AML), high-risk myelodysplastic syndromes and other hematological malignancies.

- Phase 2 and registration-directed clinical trial of cusatuzumab currently enrolling up to 150 patients with previously untreated AML who are not eligible for intensive chemotherapy

- In two-part trial, patients will first be randomized to receive one of two dose levels of cusatuzumab (10mg/kg and 20mg/kg) in combination with azacytidine (75mg/m^2) followed by an expansion cohort to evaluate efficacy of the selected dose of cusatuzumab

ARGX-117: First-in-class anti-C2 antibody expected to enter clinic in first quarter 2020

ARGX-117 is a complement-targeting antibody against C2 with potential therapeutic applications in multiple autoimmune diseases. A Clinical Trial Application (CTA) is on track to be filed by end of 2019 with first-in-human trial expected to start in first quarter of 2020.

UPCOMING MILESTONES

- Before the end of 2019, argenx expects:
  - Data from Phase 1 HV trial of ENHANZE® SC formulation of efgartigimod after which argenx will communicate on path forward for testing in patients with this co-formulation
  - Start of first Phase 3 ADVANCE trial of efgartigimod in primary ITP
  - Start of Phase 2 proof-of-concept trial of efgartigimod in CIDP
- In 2020, argenx expects:
  - Data from Phase 2 proof-of-concept trial of efgartigimod in PV in first half
  - First-in-human Phase 1 trial to start with ARGX-117 in first quarter
  - Data from global Phase 3 ADAPT trial of efgartigimod in gMG in second half
  - Announcement of fifth indication with efgartigimod and new pipeline asset ARGX-119
  - Update from ongoing cusatuzumab development

FINANCIAL OUTLOOK

- Based on current development plan, argenx expects that its cash, cash equivalents and investments will fund planned operating and capital expense requirements up to the expected launch of efgartigimod in gMG in 2021. This development plan excludes any potential upcoming milestone payments under existing collaborations.
- With the advancement of development of efgartigimod across indications, build-out of the argenx commercial organization, commitment to fund 40% of the development plan for cusatuzumab, and the expansion of its business plan, argenx expects operating and capital expense requirements to continue to increase year-over-year.

THIRD QUARTER 2019 FINANCIAL RESULTS

in thousands of €
Revenue
Other operating income
Total operating income

Research and development expenses
Selling, general and administrative expenses
Operating loss
Financial income
Financial expenses
Exchange gain/(losses)
Profit/(Loss) before taxes
Income tax expense
Profit/(Loss) for the period and total comprehensive loss
Weighted average number of shares outstanding
Basic and diluted profit/(loss) per share (in €)

Net increase in cash, cash equivalents and current financial assets compared to year-end 2018 and 2017
Cash, cash equivalents and current financial assets at the end of the period

Details of Financial Results

Cash, cash equivalents and current financial assets totaled €923.2 million on September 30, 2019, compared to €564.6 million on December 31, 2018 and €582.3 million on September 30, 2018. The increase in the cash balance on September 30, 2019 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 €36.7 million for the nine months ended September 30, 2019 to reach €61.2 million, compared to €24.5 million for the nine months ended September 30, 2018. Revenue increased by €32.3 million, which was primarily related to the partial recognition of the upfront payment received and the recognition of research and development (R&D) service fees under the Janssen collaboration agreement. Other operating income increased by €4.3 million, resulting mainly from an increase in payroll tax rebates for employing certain R&D personnel and an increase in R&D tax incentives.

R&D expenses increased by €69.2 million for the nine months ended September 30, 2019 to €122.8 million, compared to €53.6 million for the nine months ended September 30, 2018. The increase resulted primarily from higher external R&D 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 R&D activities.

Selling, general and administrative (SG&A) expenses totaled €41.7 million and €18.2 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of €23.5 million in SG&A expenses primarily resulted from higher personnel expenses and consulting fees related to preparation for potential commercialization of argenx's lead product candidate efgartigimod.

For the nine months ended September 30, 2019, financial income amounted to €10.9 million, compared to €2.0 million for the nine months ended September 30, 2018. The increase of €8.9 million related primarily to an increase in interest received on cash, cash equivalents and current financial assets.

Exchange gains totaled €26.9 million for the nine months ended September 30, 2019, compared to the €8.8 million for the nine months ended September 30, 2018. The increase was mainly attributable to unrealized exchange rate gains on the cash, cash equivalents and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate in the first nine months of 2019.

Income tax expense totaled €4.4 million for the nine months ended September 30, 2019. In August 2019, the Belgian tax authority issued an assessment for the year ended December 31, 2016 in the amount of €4.9 million, including penalties, but excluding interest. argenx expects to file a formal protest letter against this tax assessment.

Total comprehensive loss for the nine months ended September 30, 2019 was €70.1 million, compared to a total comprehensive loss of €36.4 million for the nine months ended September 30, 2018.

EXPECTED 2020 FINANCIAL CALENDAR

- February 27, 2020: FY 2019 financial results and business update
- May 14, 2020: Q1 2020 financial results and business update
- July 30, 2020: HY 2020 financial results and business update
- October 22, 2020: Q3 2020 financial results and business update

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 and 2020 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.