argenx reports second quarter business update and half-year 2018 financial results

Management to host conference call today at 3 p.m. CEST / 9 a.m. EDT
August 2, 2018

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 second quarter business update and half-year financial results for 2018.

These half-year results and this business update will be discussed during a conference call and webcast presentation today at 3 p.m. CEST/ 9 a.m. EDT. To participate in the conference call, please select your phone number below, and use the confirmation code 7669735. The webcast may be accessed on the homepage of the argenx website at www.argenx.com or by clicking here.

"We made significant progress recently in building a pipeline-in-a-product opportunity around our lead candidate efgartigimod (ARGX-113) as we study its potential to treat a range of severe autoimmune diseases, including validation of its mechanism of action across two indications based on the proof-of-concept data from the Phase 2 clinical trial in generalized myasthenia gravis (gMG) and the early evidence of disease control from the first cohort of patients in our Phase 2 pemphigus vulgaris (PV) clinical trial. These results strengthen our conviction that reducing pathogenic autoantibodies may offer an innovative approach to treating gMG and PV and could give rise to potential therapeutic benefits in other conditions that are similarly mediated. We look forward to a productive second half of 2018 around efgartigimod with topline data from the Phase 2 immune thrombocytopenia clinical trial expected before the end of the third quarter and the launch of a Phase 3 clinical trial in gMG before the end of the year," commented Tim Van Hauwermeiren, CEO of argenx.

"We are also advancing a deep pipeline of differentiated antibodies beyond efgartigimod. We continue to enroll the Phase 2 clinical trial of ARGX-110 in acute myeloid leukemia (AML) and expect to report full data from the Phase 1 dose-escalation clinical trial in December around the American Society of Hematology (ASH) Annual Meeting. We achieved key milestones in our collaborations with AbbVie and Leo Pharma this quarter and have continued to showcase our ability to grow our pipeline through our productive Innovative Access Program."

SECOND QUARTER 2018 AND RECENT BUSINESS HIGHLIGHTS

Efgartigimod Program

Full Phase 2 Myasthenia Gravis Data: Presented complete data from Phase 2 clinical trial of efgartigimod in gMG at the American Academy of Neurology (AAN) Annual Meeting.

- Data showed clinical improvement of efgartigimod over placebo through entire 10-week duration of the trial.
- Clinical benefit in the treatment group maximized as of one week after administration of last dose, achieving statistical significance over the placebo group on the Myasthenia Gravis Activity-of-Daily-Living (MG-ADL) score.
- All patients in the treatment arm showed reduction of total IgG levels, and clinically meaningful disease improvement was found to correlate with a reduction in pathogenic IgG levels.
- Efgartigimod was well-tolerated in all patients, with most adverse events (AEs) characterized as mild and deemed unrelated to the study drug. No serious or severe AEs were reported.

End-of-Phase 2 Meeting with FDA: Received feedback from the U.S. Food and Drug Administration (FDA) during the end-of-Phase 2 meeting on the framework of our Phase 3 program for efgartigimod in gMG.

- Global Phase 3 clinical trial expected to evaluate the efficacy of a 10 mg/kg intravenous (IV) dose of efgartigimod in approximately 150 gMG patients over a 26-week period.
- argenx expects to enroll in the trial both AChR autoantibody positive patients and AChR autoantibody negative patients whose disease is driven by MuSK and LRP4 autoantibodies, among others.
- Patients in the Phase 3 clinical trial would be able to roll over into an open-label extension study for a period of one year.

Interim Data from First Cohort in Phase 2 PV Trial: Reported interim data from the first cohort of our Phase 2 proof-of-concept clinical trial of efgartigimod for the treatment of PV.

- Rapid disease control observed in four of the six mild-to-moderate PV patients treated, and efgartigimod was well-tolerated in all treated PV patients.
- Strong pharmacodynamic effect correlated with an improvement in Pemphigus Disease Area Index (PDAI) score, characterized by the start of healing of existing lesions and absence of formation of new lesions.
- Independent Data Monitoring Committee recommended advancing to cohort 2 with an increased dosing frequency and dosing duration during the maintenance phase.

Phase 1 Data using Subcutaneous Formulation: Announced data from the Phase 1 study of the subcutaneous (SC) formulation of efgartigimod, demonstrating comparable characteristics to the IV formulation, including half-life, pharmacodynamics and tolerability.

- Data showed that repeat exposure to SC efgartigimod can maintain IgG suppression at a steady state, with the possibility to dose up or down based on patient needs.
- argenx intends to explore various dosing schedules with the SC formulation to best address patient needs, including an IV loading dose followed by SC maintenance as one possible schedule.

ARGX-110 Program

Ongoing Enrollment in Phase 2 Trial of ARGX-110 in AML: argenx expects to enroll an initial 21 patients in the ongoing Phase 2 part of the Phase 1/2 proof-of-concept trial of ARGX-110 in combination with standard of care azacytidine in newly diagnosed, elderly AML and high-risk myelodysplastic syndromes patients who are unfit for chemotherapy. The Company expects to use the selected ARGX-110 dose of 10 mg/kg as determined from the dose-escalation part of the trial.

Corporate Updates

- Received second preclinical milestone payment under the development agreement with AbbVie for ARGX-115 targeting novel immune checkpoints in oncology.
- Received third preclinical milestone payment from collaboration with LEO Pharma following approval of our clinical trial application (CTA) filing for ARGX-112 to treat inflammatory skin disorders.
- Received a milestone payment from the strategic collaboration with Shire triggered by Shire exercising its exclusive option to in-license an antibody discovered and developed using the Company's proprietary SIMPLE Antibody(TM) platform and Fc engineering technologies.
- Appointed R. Keith Woods as Chief Operating Officer.

- Selected for BEL 20 Index representing the 20 largest companies traded on Euronext Brussels, subject to meeting Euronext Index Family criteria and review.

UPCOMING MILESTONES

- Advance efgartigimod into Phase 3 clinical development in gMG before the end of 2018.
- Report topline data from the Phase 2 proof-of-concept trial for efgartigimod in immune thrombocytopenia (ITP) before the end of the third quarter of 2018 and present the full dataset at a workshop around the ASH Annual Meeting.
- Report full data from the Phase 2 trial of efgartigimod in PV in the first half of 2019.
- Report full data of the dose-escalation phase of the AML Phase 1/2 clinical trial and the cutaneous T-cell lymphoma Phase 2 clinical trial of ARGX-110 around the ASH Annual Meeting.

HALF-YEAR 2018 FINANCIAL RESULTS

	Six months ended June 30, 2018	**Six months ended June 30, 2017**	**Variance**
(in thousands of €)			
Revenue	17,910	22,448	(4,538)
Other operating income	2,588	1,436	1,152
Total operating income	**20,498**	**23,884**	**(3,386)**
Research and development expenses	(34,371)	(25,592)	(8,779)
Selling, general and administrative expenses	(11,514)	(5,045)	(6,469)
Operating loss	**(25,387)**	**(6,753)**	**(18,634)**
Financial income	1,256	9	1,247
Financial expenses	0	0	0
Exchange gains/(losses)	4,024	(854)	4,878
Loss before taxes	**(20,107)**	**(7,598)**	**(12,509)**
Income tax benefit/(expense)	31	(597)	628
Loss for the period and total comprehensive loss	**(20,076)**	**(8,195)**	**(11,881)**
Net increase / (decrease) in cash, cash-equivalents and current financial assets compared to year-end 2017 and 2016	**(20,922)**	**76,701**	
Cash, cash-equivalents and current financial assets at the end of the period	**338,852**	**173,429**	

Total operating income was €20.5 million for the six months ended June 30, 2018, compared to €23.9 million for the six months ended June 30, 2017. The decrease in operating income in 2018 was primarily due to a decrease of €4.5 million in revenue primarily from the completion of the preclinical activities under our ongoing collaboration with LEO Pharma. The decrease was offset by an increase in other operating income of €1.2 million, mainly driven by an increase in payroll tax rebates for employing certain research and development personnel.

Research and development expenses were €34.4 million for the six months ended June 30, 2018, compared to €25.6 million for the six months ended June 30, 2017. The increase in research and development expenses in 2018 was principally due to (i) an increase of €4.4 million in share-based compensation expense linked to the grant of stock options to our research and development employees (including an increase of €1.3 million in social security costs on stock options granted to certain Belgian and non-Belgian resident employees), (ii) an increase of €4.0 million in costs related to the advancement of the clinical development and manufacturing activities of ARGX-113 and ARGX-110 and (iii) costs associated with a planned increase in research and development headcount.

Selling, general and administrative expenses were €11.5 million for the six months ended June 30, 2018, compared to €5.0 million for the six months ended June 30, 2017. The increase of €6.5 million in selling, general and administrative expenses in 2018 is mainly explained by an increase of €6.1 million of personnel expenses resulting from (i) an increase of €4.9 million in share-based compensation expense linked to the grant of stock options to our selling, general and administrative employees (including an increase of €1.1 million in social security costs on stock options granted to certain Belgian and non-Belgian resident employees) and (ii) the recruitment of additional employees (notably in our US office) to further strengthen our selling, general and administrative activities.

Financial income and exchange gains amounted to €5.3 million for the six months ended June 30, 2018 compared to financial income and exchange losses of €0.8 million for the six months ended June 30, 2017, which was primarily attributable to unrealized exchange rate gains on our cash, cash equivalents and current financial assets position in USD linked to the favorable fluctuation of the USD exchange rate in the six months ended June 30, 2018.

The Group generated a loss for the period and total comprehensive loss of €20.1 million for the six months ended June 30, 2018, compared to a loss for the period and total comprehensive loss of €8.2 million for the six months ended June 30, 2017.

As at June 30, 2018, the Group's cash, cash equivalents and current financial assets amounted to €338.9 million, compared to €359.8 million as at December 31, 2017.

EXPECTED 2018 FINANCIAL CALENDAR:

- October 25, 2018: Third quarter 2018 business update and financial results.

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 the three antibody engineering technologies are designed to enable the expansion of the therapeutic index of the company's product candidates.

www.argenx.com

Dial-in numbers:
Please dial in 5-10 minutes prior to 3 p.m. CEST/ 9 a.m. EDT using the number and conference ID below.

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United Kingdom: +44 330 336 9411
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National free phone - USA: 888 599 8686
France: +33 1 76 77 22 57
National free phone - France: 0805 101 278
Belgium: +32 2 400 6926
National free phone - Belgium: 0800 38625
Netherlands: +31 20 703 8261
National free phone - Netherlands: 0800 265 9169

A question and answer session will follow the presentation of the results. Go to www.argenx.com to access the live audio webcast. The archived webcast will also be available (90 days) for replay shortly after the close of the call from the "Downloads" section of the argenx website.

For further information, please contact:

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

Beth DelGiacco, VP Investor Relations (US)
+1 518 424 4980
bdelgiacco@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 the intended results of its strategy and planned recruitment efforts; its financial condition, results of operation and business outlook; the sufficiency of its cash, cash equivalents and current financial assets; and the momentum of its product candidate pipeline as well as the advancement of, and anticipated clinical development and regulatory milestones and plans related to, and data readouts for, argenx's product candidates and preclinical and clinical trials; the timing of the initiation of a global pivotal Phase 3 clinical trial of efgartigimod, expected data readouts for its clinical trials and the presentation thereof, and its third quarter 2018 business update and financial results; 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.