argenx reports fourth quarter business update and full year 2016 financial results

Management to host conference call today at 3 pm CET / 10 am EDT

15 March 2017

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext Brussels: 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 fourth quarter business update and full year results for 2016, in accordance with IFRS as adopted by the European Union.

The full year results will be discussed during a conference call and webcast presentation today at 3 pm CET / 10 am EDT. To participate in the conference call, please select your phone number below, and use the confirmation code **75576807**. The webcast may be accessed on the homepage of the argenx website at www.argenx.com or by clicking here.

"The past year was one of significant growth for argenx, and we have seen the momentum maintained into the first months of 2017. We continued to build our proprietary pipeline and advanced both our lead programs, ARGX-113 and ARGX-110, through key safety and early efficacy inflection points. Our early studies guided us on the attributes of each drug and enabled us to choose the indications we believe were best-suited for Phase 2 study. By the end of the first quarter, we plan to launch four proof-of-concept Phase 2 studies: MG and ITP for ARGX-113, and AML and TCL for ARGX-110," commented Tim Van Hauwermeiren, CEO of argenx. "We were also busy outside the clinic with the start of our collaboration with AbbVie for our novel immuno-oncology product, ARGX-115, under which we received an upfront payment of $40 million and through the expansion of our shareholder base with blue-chip U.S. investors resulting in a €46 million investment over the course of 2016."

FOURTH QUARTER 2016 AND RECENT HIGHLIGHTS

- Dosed first patient with ARGX-113 in Phase 2 proof-of-concept study for treatment of myasthenia gravis (MG).
- Hosted workshop in conjunction with American Society of Hematology (ASH) Annual Meeting and provided updates on clinical data from multiple ascending dose (MAD) Phase 1 study with ARGX-113 in healthy volunteers showing comparable pharmacodynamics (PD) and pharmacokinetic (PK) patterns between lower dose (10 mg/kg) and higher dose (25 mg/kg).
- Initiated Phase 1/2 clinical trial in combination with standard of care, azacytidine, in newly diagnosed acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS) patients.
- Published new preclinical data in Journal of Experimental Medicine on CD70/CD27 pathway that provide further biological rationale for ARGX-110 therapy for treatment of AML.
- Presented further efficacy and safety data from ongoing Phase 1b study in relapsed/refractory T-cell lymphoma (TCL) patients at ASH workshop.
- Announced that Staten Biotech exercised its exclusive option to license ARGX-116, an anti-ApoC3 SIMPLE Antibody™ with therapeutic potential in dyslipidemia.

- Announced the extension of our strategic partnership with Shire for a further year until May 30, 2018.

FINANCIAL HIGHLIGHTS (as on December 31, 2016) (compared to financial highlights as on December 31, 2015)

- Operating income of €17.2 million (December 31, 2015: €10.0 million).
- Net loss of €21.4 million (December 31, 2015: €15.3 million).
- Cash position of €96.7 million (cash, cash-equivalents and current financial assets) allowing us to pursue development of our pipeline as planned.

DETAILS OF OPERATIONAL RESULTS

Products in Clinical Development:

ARGX-113

- Initiated Phase 2 proof-of-concept study for treatment of MG (Jan 2017).
- Hosted workshop in conjunction with American Society of Hematology (ASH) Annual Meeting (December 2016) and provided updates on clinical data from multiple ascending dose (MAD) Phase 1 study showing comparable PD and PK patterns between lower dose (10 mg/kg) and higher dose (25 mg/kg). In addition, preclinical proof-of-concept data supporting MG and primary immune thrombocytopenia (ITP) as lead indications for Phase 2 clinical trials were presented and feasibility of subcutaneous dosing was illustrated in a preclinical setting.
- Announced full data from Phase 1 single ascending dose (SAD) and MAD studies that showed ARGX-113 to be well-tolerated at doses up to 25 mg/kg with promising PD effects relating to speed, depth and duration of IgG reduction (Sept 2016).

ARGX-110

T-cell lymphoma:

- Presented further efficacy and safety data from ongoing Phase 1b study in relapsed/refractory TCL patients at ASH workshop (December, 2016). Five out of 10 patients show encouraging signs of clinical activity including partial response (3/10) and stable disease (2/10). No dose-limiting toxicities were observed.
- Announced efficacy and safety data from ongoing Phase 1 expansion study in patients with TCL during European Hematology Association (EHA) Annual Congress (June 2016).
- Expansion cohort in cutaneous TCL (CTCL) patients treated with ARGX-110 monotherapy is planned to start by end of first quarter 2017.

Acute Myeloid Leukemia:

- Initiated Phase 1/2 clinical trial in combination with standard of care, azacytidine, in newly diagnosed AML or high-risk MDS patients (December 2016).
- Published new preclinical data in Journal of Experimental Medicine on CD70/CD27 pathway that provide further biological rationale for ARGX-110 therapy for treatment of AML (December 2016).

ARGX-111

- Concluded safety expansion cohort of the Phase 1b study. The current focus is on partnering ARGX-111 ahead of any Phase 2 study.
- Announced data published in conjunction with American Society of Clinical Oncology (ASCO) 2016 Annual Meeting (June 2016) presenting efficacy and safety data from Phase 1 expansion study in patients with mesenchymal-epithelial transition factor (MET)-amplified tumors. The data showed no drug-related serious adverse events above doses of 3 mg/kg and signs of biological activity.

Products in Preclinical Development

ARGX-115

- Announced collaboration with AbbVie S.À.R.L. to develop and commercialize ARGX-115. Under the agreement, we will conduct research and development up to completion of investigational new drug (IND)-enabling studies. Upon successful completion of IND-enabling studies, AbbVie may exercise an exclusive option to license ARGX-115 and assume responsibility for further clinical development and commercialization.
- Received an upfront payment of $40 million for the exclusive option and have potential to receive $20 million in near-term preclinical milestones. argenx is also eligible to receive additional development, regulatory and commercial payments up to $625 million upon achievement of pre-determined milestones as well as tiered royalties on net sales at percentages ranging from the mid-single digits to the lower teens.

Collaborations

- Announced that Staten Biotech exercised its exclusive option to license ARGX-116, an anti-ApoC3 SIMPLE Antibody™ with therapeutic potential in dyslipidemia. This collaboration is the latest to stem from the Innovative Access Program.
- Continued collaboration with Shire AG to discover and develop novel human therapeutic antibodies to address diverse rare and unmet diseases. argenx announced the extension of its strategic partnership with Shire for a further year until May 30, 2018.
- Advanced alliance with LEO Pharma A/S and received preclinical milestone payment in relation to the lead cell line selection for manufacture of licensed SIMPLE Antibody candidate ARGX-112 in development for treatment of inflammatory skin conditions.
- Reported that partner Bird Rock Bio, Inc (formerly Anaphore, Inc. and RuiYi, Inc.) announced data on gerilimzumab, a novel SIMPLE Antibody equipped with our proprietary NHance® technology neutralizing the IL-6 cytokine. ARGX-109 was reported to be well-tolerated with no serious adverse events and prolonged half-life in circulation, supporting low, infrequent dosing and the potential for favorable pricing. Bird Rock Bio received approval to initiate a Phase 2 study in Brazil for rheumatoid arthritis.

Corporate

- 49 granted and 107 pending patents
- Expanded to 58 employees in support of expansion of the business

- Recognized by Frost & Sullivan with 2016 European Frost & Sullivan Award for Technology Innovation for SIMPLE Antibody™ platform, as it yields unprecedented epitope coverage, allowing to interaction with disease biology in a much more precise manner.
- Moved to new office and laboratory space, which consists of approximately 1,500 square meters, located in Zwijnaarde, Belgium.

OUTLOOK 2017

We continue to implement our business plan through advancing our deep pipeline of differentiated antibody-based therapies, including ARGX-113, ARGX-110, ARGX-115 and ARGX-112, the forging of collaborations with a select number of pharmaceutical companies and the strengthening of our shareholder base.

In 2017, we aim to execute our ambitious business plan as follows:

- We aim to launch the Phase 2 proof-of-concept study for ARGX-113 in ITP in March 2017 as well as a Phase 1 healthy volunteer study with a subcutaneous formulation of ARGX-113 during the second half of the year.
- We aim to launch the Phase 2 proof-of-concept study for ARGX-110 in relapsed/refractory cutaneous TCL in March 2017.
- We aim to provide an update on the recruitment status of both the MG and the ITP Phase 2 clinical trials for ARGX-113 during the second half of the year.
- We aim to provide an update on our Phase 1/2 clinical trial in AML and the Phase 2 clinical trial in CTCL for ARGX-110 during the second half of the year.
- We plan to report the full data of our finalized Phase 1 clinical trial for ARGX-111 during the first half of the year.
- We aim to announce the launch of a novel pipeline program.
- We aim to announce one or more Innovative Access Program initiatives during the course of the year.

With the expected progression of our development activities, we anticipate hiring more personnel and consultants to support the steady growth over the past year.

We will also aim to further transition our shareholder base from its historic venture capital investors to blue-chip, long-term institutional investors and increase liquidity and free float of our ordinary shares and continue our disciplined cash management. It is in this context that we will further align our corporate governance model with international standards and implement the following changes on the occasion of the annual shareholder meeting of April 26, 2017:

- John de Koning, a former representative of the historic venture capital investors, will resign as board member.
- At the same time, the Board of Directors, on the recommendation of the Remuneration and Nomination Committee, will propose the appointment of a new independent Board member, Mr. Tony Rosenberg to replace Eric Castaldi, who will remain CFO of our Group.

KEY FIGURES (CONSOLIDATED)

in thousands of euros	Year ended December 31, 2015	Year ended December 31, 2016	Variance
Revenue	6,854	14,713	7,859
Other operating income	3,101	2,439	(662)
Total operating income	**9,955**	**17,152**	**7,197**
Research and development expenses	(20,635)	(31,557)	(10,922)
General and administrative expenses	(4,925)	(7,011)	(2,086)
Operating loss	**(15,605)**	**(21,416)**	**(5,811)**
Financial income	112	73	(39)
Exchange gains/(losses)	181	(31)	(212)
Total comprehensive loss	**(15,312)**	**(21,374)**	**(6,062)**
Net increase (decrease) in cash, cash-equivalents and current financial assets compared to year end 2014 and 2015	(13,645)	54,402	68,047
Cash, cash-equivalents and current financial assets at the end of the period	42,327	96,729	54,402

DETAILS OF THE FINANCIAL RESULTS

Consolidated statement of profit and loss and other comprehensive income

- **Operating income**

Our total operating income includes revenue from our collaborations and other operating income and totaled €17.2 million in 2016 compared to €10.0 million in 2015.

To date, our revenue has consisted principally of collaboration revenue in the form of (i) upfront payments, including upfront licensing fees, (ii) milestone payments based on achievement of research and development goals and (iii) research and development service fees related to charges for full time equivalents (FTEs) at contracted rates and reimbursement of research and development expenses. In 2016, our revenue reached €14.7 million compared to €6.9 million in 2015. This increase of €7.8 million is principally explained by the payments received in connection with entering into the collaboration agreements with LEO Pharma in May 2015 and with AbbVie in April 2016.

Our other operating income corresponds to various grants, research and development incentives and payroll tax rebates received from governmental agencies. Our other operating income decreased to €2.4 million in 2016 compared to €3.1 million in 2015, as a result of a decrease in grants received from the Flemish government.

- **Operating expenses**

Our research and development (R&D) expenses totaled €31.6 million in 2016, compared to €20.6 million in 2015. The €11.0 million increase in 2016 reflects (i) increased clinical trial and product manufacturing activities, (ii) the recruitment of additional R&D personnel and consultants, and (iii) the share based payment costs recognized in compensation for the grant of stock options to our R&D personnel. In 2016, our R&D costs accounted for 82% of our total operating expenses compared to 81% in 2015. We employed the equivalent of 46.9 full time employees in our R&D department on December 31, 2016 compared to the equivalent of 31.4 full time employees at the same date in 2015.

In 2016, our general and administrative (G&A) expenses were €7.0 million compared to €4.9 million in 2015. The €2.1 million increase in 2016 is explained by (i) additional expenses incurred for supporting activities (ii) the recruitment of new employees to strengthen our G&A activities, and (iii) the share based payment costs recognized in compensation for the stock options granted to our G&A employees, consultants and Board members. Our G&A costs accounted for 18% of our total operating expenses in 2016 compared to 19% in 2015. On December 31, 2016, we employed the equivalent of 9.9 full time employees in our G&A department compared to 5.8 full time employee employees on December 31, 2015.

- **Operating loss**

Our operating loss before net financial income and tax was €21.4 million in 2016 compared to €15.6 million in 2015. This increase results primarily from the increase in our operating expenses as indicated above.

- **Financial income (Expense)**

We recorded financial income of €0.1 million in 2016 and in 2015. Our financial income reflects interest earned on our cash and cash equivalents and current financial assets.

- **Exchange Gains (Losses)**

The exchange loss of €0.03 million recorded in 2016 and the gains of €0.2 million in 2015 are linked to foreign exchange differences arising from the translation of foreign currency transactions and foreign currency monetary assets and liabilities.

- **Total comprehensive loss for the period**

In the year ended December 31, 2016, we generated a total comprehensive loss of €21.4 million compared to a total comprehensive loss of €15.3 million in 2015. Notwithstanding the significant increase in our operating income over the period, this increase of €6.1 million in total comprehensive loss in 2016 results from (i) the increase of R&D expenses in relation with our manufacturing and clinical activities, (ii) the increase in G&A expenses incurred for our supporting activities (iii) and the share based payment costs recognized in compensation for the stock options granted to our employees, consultants and Board members.

Consolidated statement of financial position

- **Assets**

Our main current assets consist of our cash, cash equivalents and current financial assets.
On December 31, 2016, our cash, cash equivalents and current financial assets amounted to €96.7 million compared to €42.3 million on December 31, 2015.

- **Liabilities**

Our current liabilities relate primarily to trade and other payables and deferred revenue from our collaboration agreements with pharmaceutical and biotechnology companies.
On December 31, 2016 our trade payables and other payables were €12.2 million compared to €4.5 million on December 31, 2015. These amounts include accruals and invoices received but not yet paid, mainly in relation with our manufacturing and clinical development activities.

Our deferred revenue totaled €30.2 million on December 31, 2016 compared to €4.1 million on December 31, 2015. The increase in 2016 mainly relates to the upfront payments received from our collaboration agreements with LEO Pharma in May 2015 and with AbbVie in April 2016.

We have no loans outstanding or long term financial lease commitments at the end of 2016.

Consolidated statement of cash flows

- **Cash flow from operating activities**

Cash flow from operating activities represented a net inflow of €10.6 million in 2016 compared to a net outflow of €13.9 million in 2015. The net cash inflow in 2016 results primarily from the upfront payment of $40 million (€35.1 million as of the date the payment was received) from AbbVie in April 2016.

- **Cash flow from investing activities**

Cash flow from investing activities represented a net outflow of €0.8 million in 2016 compared to a net inflow of €16.8 million in 2015. The net cash outflow in 2016 results from investments in office, laboratory and IT equipment.

- **Cash flow from financing activities**

Cash flow from financing activities represented a net inflow of €44.6 million in 2016 compared to a net inflow €0.2 million in 2015. The net cash inflow in 2016 is attributed to two private placements of our ordinary shares issued to institutional investors in January and June 2016 for total gross proceeds of €46 million.

FINANCIAL CALENDAR:

- April 26, 2017: Annual General Meeting
- May 4, 2017: Q1 2017 Business Update and financial results
- August 24, 2017: Half year 2017 Business Update and financial results
- October 26, 2017: Q3 2017 Business Update and financial results

Dial-In Numbers:

Participant Free Call Dial-In Numbers:
UK 0800 694 0257

Participant Standard International Dial-In:
UK Standard International +44 (0) 1452 555 566

Participant UK Local Call Dial-In Numbers:
UK 0844 493 3800
UK National Call0871 700 0345

Participant Local Call Dial-In Numbers:

Australia	0290 371 687
Austria	0192 865 68
Belgium	0817 000 61
Croatia	0177 766 11
Czech Republic	2288 804 60
Denmark	3272 7625
Finland	0923 195 187
France	0176 742 428
Germany	0692 222 3479
Germany	0692 222 4918
Hungary	0618 088 303
India	0223 098 5304
Ireland	0143 196 48
Ireland	0150 601 53
Italy	0236 008 146
Latvia	6778 2516
Luxembourg	2088 0695
Netherlands	0207 176 886
New Zealand	0992 917 07
Norway	2156 3013
Poland	2230 701 18
Romania	0318 144 957
Russia	4996 771 036
Slovenia	0160 093 64
South Africa	2110 032 02
Spain	9141 436 69
Sweden	0850 336 434
Switzerland	0565 800 007
USA	1631 510 7498

About argenx

argenx a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. We are 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. Our ability to execute on this focus is enabled by our suite of differentiated technologies. Our SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody engineering technologies are designed to enable us to expand the therapeutic index of our 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 the intended results of its strategy; 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, argenx's product candidates and clinical trials. 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. 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.