



# argenx reports third quarter 2018 financial results and provides business update

October 25, 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 financial results and provided a business update for the third quarter ended September 30, 2018.

"The proof-of-concept data that we have generated in the last year from our Phase 2 clinical trials in generalized myasthenia gravis (gMG), immune thrombocytopenia (ITP) and pemphigus vulgaris (PV) support efgartigimod's (ARGX-113) potential in severe autoimmune disease, and we are committed to advancing and expanding this clinical program as quickly as possible. We continue to see potential differentiation of our molecule among the anti-FcRn class of therapies in terms of tolerability, improvement in disease scores, and stage of development. We are now evaluating our lead candidate in four indications, two formulations to accommodate tailored therapy, and in one registration trial with another expected to launch next year," commented Tim Van Hauwermeiren, CEO of argenx. "Our second program, cusatuzumab (ARGX-110), will follow quickly as we enroll newly diagnosed, elderly acute myeloid leukemia (AML) patients in a Phase 2 clinical trial. We plan to show the full Phase 1 data in December during our annual American Society of Hematology (ASH) workshop, along with the full dataset from the Phase 2 clinical trial of efgartigimod in ITP."

"We believe we have differentiated antibody design capabilities and continue to show this through reproducible value creation with the robust clinical datasets from our wholly-owned programs, successes from our collaborations including the in-licensing by AbbVie of ARGX-115, and the pipeline we grow using novel targets from esteemed academic institutions."

## THIRD QUARTER 2018 AND RECENT HIGHLIGHTS

### Pipeline Updates:

#### **Efgartigimod (ARGX-113):**

- | Reported positive topline results from Phase 2 proof-of-concept trial of intravenous (IV) efgartigimod in primary ITP:
  - | Well-tolerated, consistent with efgartigimod clinical trials to-date.
  - | Clinically meaningful platelet count improvements seen across doses and ITP patient classifications, correlating with consistent reduction in Immunoglobulin G levels.
  - | Showed separation from placebo at increasing response thresholds, with response rates of 46% and 58% in primary trial and first dosing of open-label extension study, respectively.
- | Announced plans to advance IV efgartigimod into Phase 3 development in ITP in second half of 2019 and subcutaneous efgartigimod into Phase 2 trial in ITP in first half of 2019.
- | Dosed first patient in global Phase 3 registration trial of efgartigimod in patients with gMG.
  - | Phase 3 trial, if results are positive, expected to serve as basis to submit Biologics License Application (BLA) in U.S. and for marketing authorization in Japan, based on feedback from U.S. Food and Drug Administration (FDA) and Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.
- | Data from Phase 2 proof-of-concept trial of efgartigimod in PV on track to read out in first half of 2019.
- | Announced chronic inflammatory demyelinating polyneuropathy (CIDP) as fourth indication for efgartigimod with Phase 2 proof-of-concept trial expected to start in first half of 2019.

#### **Cusatuzumab (ARGX-110):**

- | Enrollment ongoing of initial 21 patients in Phase 2 part of Phase 1/2 proof-of-concept trial of 10 mg/kg cusatuzumab in combination with standard of care azacytidine in newly diagnosed, elderly AML and myelodysplastic syndromes patients who are unfit for chemotherapy.

### Corporate Updates:

- | AbbVie exercised its exclusive option to license ARGX-115, a novel immuno-oncology antibody targeting glycoprotein A repetitions predominant (GARP).
- | argenx received preclinical milestone in its strategic collaboration with Shire plc. The milestone, for which an undisclosed payment has been received, was triggered by Shire exercising its exclusive option to in-license an antibody discovered and developed using argenx's proprietary SIMPLE Antibody™ platform and Fc engineering technologies.

## **FINANCIAL HIGHLIGHTS (as of September 30, 2018) (compared to financial highlights as of September 30, 2017)**

- | Raised approximately \$300.6 million in gross proceeds in U.S. public offering from sale of 3,475,000 American Depositary Shares (ADSs) at a price to the public of \$86.50 per ADS; proceeds to be used to advance efgartigimod program in ITP, launch efgartigimod program in CIDP, further scale up manufacturing in advance of potential commercial operations, and expand argenx organization.
- | Operating income of €24.5 million (September 30, 2017: €30.5 million).
- | Total comprehensive loss of €36.5 million (September 30, 2017: €16.5 million).
- | Cash position of €582.3 million (cash, cash-equivalents and current financial assets) allowing argenx to pursue development of its

pipeline in severe autoimmune diseases and cancer (September 30, 2017: €161.7 million).

## UPCOMING CLINICAL MILESTONES

- | Present full dataset from Phase 2 proof-of-concept trial of efgartigimod in ITP at workshop around ASH Annual Meeting (San Diego, December 3, 2018).
- | Report full data from Phase 1 dose-escalation trial of cusatuzumab in AML at workshop around ASH.
- | Report full data from Phase 2 proof-of-concept trial of efgartigimod in PV in first half of 2019.
- | Launch Phase 2 clinical trial in ITP using subcutaneous formulation of efgartigimod in first half of 2019.
- | Launch Phase 2 clinical trial of efgartigimod in CIDP in first half of 2019.

## Q3 2018 FINANCIAL RESULTS

|  | Nine months ended |              | Nine months ended | Nine months ended |                  |
|--|-------------------|--------------|-------------------|-------------------|------------------|
|  | September 30,     | Adjustments  | September 30,     | September 30,     |                  |
|  | 2018              | Adoption     | 2018              | 2017              |                  |
| (in thousands of €)  | IAS 18            | IFRS 15 (*)  | IFRS 15           | IAS 18            | Variance         |
| Revenue  | 17,892            | 2,031        | 19,924            | 28,422            | (8,498 )         |
| Other operating income   | 4,594             |              | 4,594             | 2,090             | 2,504            |
| <b>Total operating income</b>  | <b>22,487</b>     | <b>2,031</b> | <b>24,518</b>     | <b>30,512</b>     | <b>(5,994 )</b>  |
| Research and development expenses  | (53,352 )         | (198 )       | (53,550 )         | (36,655 )         | (16,895 )        |
| Selling, general and administrative expenses   | (18,245 )         |              | (18,245 )         | (7,339 )          | (10,906 )        |
| <b>Operating loss</b>  | <b>(49,111 )</b>  | <b>1,833</b> | <b>(47,278 )</b>  | <b>(13,482 )</b>  | <b>(33,796 )</b> |
| Financial income   | 1,983             |              | 1,983             | 88                | 1,895            |
| Exchange gains/(losses)  | 8,826             |              | 8,826             | (2,476 )          | 11,302           |
| <b>Loss before taxes</b>   | <b>(38,301 )</b>  | <b>1,833</b> | <b>(36,468 )</b>  | <b>(15,870 )</b>  | <b>(20,598 )</b> |
| Income tax benefit/(expense)   | 32                |              | 32                | (597 )            | 629              |
| <b>Loss for the period and total comprehensive loss</b>  | <b>(38,269 )</b>  | <b>1,833</b> | <b>(36,436 )</b>  | <b>(16,467 )</b>  | <b>(19,969 )</b> |
| Net increase in cash, cash-equivalents and current financial assets compared to year-end 2017 and 2016 | 222,506           |              | 222,506           | 64,989            |                  |
| Cash, cash-equivalents and current financial assets at the end of the period                           | 582,281           |              | 582,281           | 161,717           |                  |

(\*) The company has adopted IFRS 15 on January 1, 2018 using a modified retrospective approach. The impact of adopting IFRS 15 amounts to €1.8 million for the nine months ended September 30, 2018.

Total operating income was €24.5 million for the nine months ended September 30, 2018, compared to €30.5 million for the nine months ended September 30, 2017. The decrease in operating income in 2018 was due to a decrease of €8.5 million in revenue primarily related to the completion of the preclinical activities under the ongoing collaborations with LEO Pharma and AbbVie. The decrease in revenue was partially offset by an increase of €2.5 million in other operating income, mainly driven by an increase in payroll tax rebates for employing certain research and development personnel and higher grant income following the approval of two VLAIO grants in 2018.

Research and development expenses were €53.6 million for the nine months ended September 30, 2018, compared to €36.7 million for the nine months ended September 30, 2017. The increase in research and development expenses in 2018 was principally due to (i) an increase of €11.2 million in costs related to the advancement of the clinical development and manufacturing activities of argenx's product candidates efgartigimod (notably with the start of a Phase 3 registration trial in efgartigimod), cusatuzumab and ARGX-117 and (ii) an increase of €6.2 million in share-based compensation expenses linked to the grant of stock options to the Company's research and development employees (including an increase of €1.0 million in social security costs on stock options granted to certain Belgian and non-Belgian resident employees). argenx employed 89 employees and consultants in its research and development functions on September 30, 2018, compared to 71 employees and consultants on September 30, 2017.

Selling, general and administrative expenses were €18.2 million for the nine months ended September 30, 2018, compared to €7.3 million for the nine months ended September 30, 2017. The increase in selling, general and administrative expenses in 2018 is mainly explained by an increase of €9.6 million of personnel expenses resulting primarily from an increase of €7.5 million in share-based compensation expenses linked to the grant of stock options to argenx's selling, general and administrative employees (including an increase of €1.3 million in social security costs on stock options granted to certain Belgian and non-Belgian resident employees). argenx employed 31 employees and consultants in its selling, general and administration functions on September 30, 2018, compared to 19 employees and consultants on September 30, 2017.

Financial income and exchange gains amounted to €10.8 million for the nine months ended September 30, 2018, compared to financial income and exchange losses of €2.4 million for the nine months ended September 30, 2017, which was primarily attributable to €8.8 million of unrealized exchange rate gains on the Company's cash, cash equivalents and current financial assets position in USD linked to the favorable fluctuation of the USD exchange rate in the nine months ended September 30, 2018.

argenx generated a loss for the period and total comprehensive loss of €36.5 million for the nine months ended September 30, 2018, compared to a loss for the period and total comprehensive loss of €16.5 million for the nine months ended September 30, 2017.

On September 30, 2018, argenx's cash, cash equivalents and current financial assets amounted to €582.3 million, compared to €359.8 million on December 31, 2017. The significant increase in its cash balance on September 30, 2018 resulted from the follow-on U.S. public offering of ADSs on the Nasdaq Global Select Market completed in September 2018.

#### **EXPECTED 2019 FINANCIAL CALENDAR:**

- | February 28, 2019: FY 2018 business update and financial results
- | May 9, 2019: Q1 2019 business update and financial results
- | August 1, 2019: HY 2019 business update and financial results
- | October 24, 2019: Q3 2019 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<sup>TM</sup> 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 the use of its grant funds; argenx's, and its collaboration partners', advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans related to argenx's product candidates; 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. 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.*