



# argenx reports fourth quarter business update and full year 2018 financial results

February 28, 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 fourth quarter business update and full year results for 2018.

The full year results will be discussed during a conference call and webcast presentation today at 3 pm CET/9 am EST. To participate in the conference call, please select your phone number below and use the confirmation code **9795988**. The webcast may be accessed on the homepage of the argenx website at [www.argenx.com](http://www.argenx.com) or by clicking [here](#).

“By translating fundamental immunology breakthroughs into novel product candidates, we have built a robust pipeline of differentiated antibodies with the potential to truly impact patients' lives,” commented Tim Van Hauwermeiren, CEO of argenx. “We made great progress in 2018 with our wholly owned lead asset efgartigimod, advancing development across four severe autoimmune indications, in both intravenous and subcutaneous formulations. We signed a transformational global collaboration and license agreement with Janssen to develop cusatuzumab in AML while retaining key commercial rights to the product in the U.S. We also announced that AbbVie exercised its option to in-license ARGX-115 targeting GARP.

“Based on our deep and diversified product candidate portfolio, a solid cash position and an ambitious business plan we are facing an abundance of opportunity ahead in 2019. We will continue to build out our novel pipeline through our Innovative Access Program and our commercial capabilities as we drive enrollment of the Phase 3 ADAPT trial of efgartigimod in gMG and plan for the start of a second Phase 3 trial in ITP.”

## FOURTH QUARTER 2018 AND RECENT HIGHLIGHTS

argenx continues to build a deep pipeline of differentiated antibody-based product candidates, including wholly-owned efgartigimod for the treatment of severe autoimmune diseases and cusatuzumab for the treatment of acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) in collaboration with Janssen. Through its Innovative Access Program, argenx grows its proprietary and partnered pipeline by leveraging its antibody expertise to match fundamental biology breakthroughs at leading research institutions.

### Efgartigimod (ARGX-113) Program

- | Full Phase 2 immune thrombocytopenia (ITP) trial data presented during American Society of Hematology (ASH) Annual Meeting
  - | Correlation between IgG antibody reduction, platelet count increase and reduction of bleeding events following efgartigimod treatment.
  - | Increasing separation between treatment arms and placebo at increasing response thresholds observed, with response rates of 46% and 67% in primary trial and first dosing cycle of open-label extension trial, respectively.
  - | Primary endpoint analysis revealed efgartigimod to be well-tolerated in all patients consistent with tolerability analysis from Phase 1 healthy volunteer study.
- | Orphan drug designation granted in February 2019 by U.S. Food and Drug Administration (FDA) for use for primary ITP.
  - | argenx additionally received orphan drug designation for efgartigimod in generalized myasthenia gravis (gMG) from FDA and the European Medicines Agency, which was announced, respectively, in September 2017 and March 2018.
- | By mid-2019, argenx expects to close its ongoing open-label extension study as part of the completed Phase 2 proof-of-concept trial in ITP in anticipation of the start of a more chronic dosing regimen in its Phase 3 trial.

### Cusatuzumab (ARGX-110) Program

- | Updated Phase 1/2 AML trial data in combination with azacitidine presented during ASH Annual Meeting.
  - | Overall response rate (ORR) of 92% in 12 newly diagnosed AML patients unfit for intensive chemotherapy, including 10 patients (91%) with a complete remission with or without hematologic recovery (CR/CRi) and 1 patient (9%) with partial remission (PR).
  - | Five patients (42%) achieved minimal residual disease (MRD) negativity. Translational data demonstrated that cusatuzumab monotherapy and in combination with azacitidine significantly reduced leukemic stem cells in the bone marrow of AML patients.
  - | Well-tolerated with no exacerbation of azacitidine toxicity.
- | Orphan drug designation granted by FDA in January 2019 for use of cusatuzumab for AML.

### Collaborations

- | Entered global collaboration and license agreement with Halozyme for ENHANZE® technology (February 2019).
  - | Gained access to ENHANZE® subcutaneous delivery technology for up to three targets, including exclusive rights to develop therapeutic products targeting human neonatal Fc receptor FcRn.
  - | Upfront payment of \$30 million paid to Halozyme with potential future payments up to \$160 million per selected target subject to achievement of specified development, regulatory and sales-based milestones.
- | Entered exclusive global collaboration and license agreement with Janssen for cusatuzumab
  - | Deal totaling up to \$1.6 billion, plus royalties ranging from the low double digits to the high teens, to develop cusatuzumab in AML, MDS and other hematological malignancies.

- Received \$300 million upfront cash payment, and Johnson & Johnson Innovation made equity investment of €176.7 million (\$200.0 million based on exchange rate on date of signing) in argenx, representing 4.68% of then-outstanding share capital.
- argenx retains right to co-promote cusatuzumab in the U.S. and share such royalties with Janssen on a 50-50 basis.

## Corporate Updates

- Awarded €2.6 million grant from Flanders Innovation and Entrepreneurship (VLAIO) agency to explore new applications and modes of action of proprietary ABDEG™ technology, the Fc engineering technology used in the design of efgartigimod to augment clearance of disease-causing autoantibodies.
- Selected for BEL 20 Index on Euronext Brussels and awarded 'Best BEL 20 Company' for 2018.
- Intellectual property portfolio (which includes both owned and in-licensed patent rights) now includes 105 granted and 106 pending patents, covering lead assets and core technologies.
- Company expanded to 132 employees and consultants in support of growing business needs.

## OUTLOOK 2019

In 2019, argenx expects to execute on its business plan towards the below milestones:

- Continue enrollment of efgartigimod in ongoing Phase 3 ADAPT and ADAPT+ trials in gMG
- Launch Phase 3 clinical trial with efgartigimod in ITP in second half of 2019
- Launch Phase 2 clinical trial with subcutaneous formulation of efgartigimod in ITP in first half of 2019
- Launch cohort 3 of Phase 2 proof-of-concept trial of efgartigimod in pemphigus vulgaris in first half of 2019
- Launch Phase 2 clinical trial with efgartigimod in chronic inflammatory demyelinating polyneuropathy before end of 2019
- Launch Phase 1 clinical trial with subcutaneous ENHANZE® formulation of efgartigimod in healthy volunteers
- Host R&D day (May 22, 2019) to present new pipeline programs ARGX-117 and ARGX-118

## YEAR 2018 FINANCIAL RESULTS (CONSOLIDATED)

in thousands of €	Year Ended		
	December 31,		
	2018	2017	Variance
Revenue	€ 21,482	€ 36,415	€ (14,933)
Other operating income	7,749	4,841	2,908
<b>Total operating income</b>	<b>29,231</b>	<b>41,256</b>	<b>(12,025)</b>
Research and development expenses	(83,609)	(51,740)	(31,869)
Selling, general and administrative expenses	(27,471)	(12,448)	(15,023)
<b>Operating loss</b>	<b>€ (81,849)</b>	<b>€ (22,932)</b>	<b>€ (58,917)</b>
Financial income	3,694	1,250	2,444
Financial expenses	—	—	—
Exchange gains/(losses)	12,308	(5,797)	18,105
<b>Loss before taxes</b>	<b>€ (65,847)</b>	<b>€ (27,479)</b>	<b>€ (38,368)</b>
Income tax expense	€ (794)	€ (597)	€ (197)
<b>Loss for the year and total comprehensive loss</b>	<b>€ (66,641)</b>	<b>€ (28,076)</b>	<b>€ (38,565)</b>
Net increase in cash, cash equivalents and current financial assets compared to year-end 2017 and 2016	204,795	263,047	
Cash, cash equivalents and current financial assets at the end of the period	564,569	359,775	

## Details of the Financial Results

Cash, cash equivalents and current financial assets totaled €564.6 million as of December 31, 2018, compared to €359.8 million on December 31, 2017. The increase in the year-end cash balance on December 31, 2018 resulted primarily from €240.9 million of net proceeds received from the follow-on public offering of American Depositary Shares on the Nasdaq Global Select Market in September 2018.

Operating income decreased by €12.1 million for the year ended December 31, 2018 to €29.2 million, compared to €41.3 million for the year ended December 31, 2017. The decrease in 2018 was primarily related to a €11.5 million decrease in the recognition of upfront payments.

Research and development expenses totaled €83.6 million and €51.7 million for the years ended December 31, 2018 and 2017, respectively. The increase in 2018 resulted primarily from higher external research and development expenses and personnel expenses, reflecting higher clinical trials costs and manufacturing expenses related to the development of the argenx product candidate portfolio and the recruitment of additional employees to support its research and development activities. argenx employed 75 employees in its research and development functions on December 31, 2018, compared to 58 employees on December 31, 2017.

Selling, general and administrative expenses totaled €27.5 million and €12.4 million for the years ended December 31, 2018 and 2017, respectively. The increase of €15.1 million in selling, general and administrative expenses for the year ended December 31, 2018 primarily resulted from higher personnel expenses and consulting fees related to the preparation for potential future commercialization of lead product candidate efgartigimod. On December 31, 2018, argenx employed 30 employees in its selling, general and administrative functions, compared to 15 employees on December 31, 2017.

For the year ended December 31, 2018, financial income amounted to €3.7 million compared to €1.3 million for the year ended December 31, 2017. The increase of €2.4 million in 2018 related primarily to an increase in the interest received on cash, cash equivalents and current

financial assets.

Exchange gains totaled €12.3 million for the year ended December 31, 2018 compared to the €5.8 million exchange losses incurred for the year ended December 31, 2017. The increase was mainly attributable to unrealized exchange rate gains on the cash and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate in 2018.

The total comprehensive loss for the year ended December 31, 2018 was €66.6 million, compared to €28.1 million for the year ended December 31, 2017.

### **U.S. SEC and statutory financial reporting**

argenx's primary accounting standard for quarterly earnings releases and annual reports is International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). Quarterly summarized statements of profit and loss based on IFRS as issued by the IASB are available on [www.argenx.com](http://www.argenx.com).

In addition to reporting financial figures in accordance with IFRS as issued by the IASB, argenx also reports financial figures in accordance with IFRS as adopted by the European Union (EU) for statutory purposes. The consolidated statement of financial position, the consolidated statements of profit and loss, the consolidated statements of cashflow, and the consolidated statement of changes in equity are not affected by any differences between IFRS as issued by the IASB and IFRS as adopted by the EU.

The consolidated statement of profit and loss data of argenx SE as of December 31, 2018 presented in this press release is unaudited.

### **Annual Report 2018**

argenx expects to publish its 2018 Annual Report based on IFRS as issued by the IASB and its 2018 Annual Report for statutory purposes based on IFRS as adopted by the EU on March 26, 2019. These Annual Reports will be available on [www.argenx.com](http://www.argenx.com).

### **EXPECTED 2019 FINANCIAL CALENDAR**

- | May 7, 2019: Annual General Meeting
- | 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

### **Dial-in numbers:**

*Please dial in 5–10 minutes prior to 3 p.m. CET/ 9 a.m. ET using the number and conference ID below.*

#### **Confirmation Code: 9795988**

Belgium	+32 (0)2 400 9874
Belgium	0800 48740
France	+33 (0)1 767 00794
France	0805 103028
Netherlands	+31 (0)20 714 3545
Netherlands	0800 0249557
United Kingdom	+44 (0)844 571 8892
United Kingdom	0800 376 7922
United States	+1 (631) 510 7495
United States	+1 (866) 966 1396

A question and answer session will follow the presentation of the results. Go to [www.argenx.com](http://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.

### **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.

[www.argenx.com](http://www.argenx.com)

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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 2019 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.*