



## **argenx Reports First Quarter 2021 Financial Results and Provides Business Update**

Japanese Marketing Authorization Application (J-MAA) for efgartigimod accepted for review by Japan's Pharmaceuticals and Medical Device Agency (PMDA) for generalized myasthenia gravis (gMG)

Management to host conference call today at 2:30 pm CEST (8:30 am ET)

**May 14, 2021**

**Breda, the Netherlands** – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today reported financial results for the first quarter 2021 and provided a business update.

"We've had a strong start to 2021 with the acceptance for review of the BLA and J-MAA for efgartigimod in gMG by the regulatory agencies in the U.S. and Japan. The submissions in China and the EU are on track and we are well-positioned for a global launch of our first-in-class FcRn antagonist. We are building an exceptional team with significant launch experience in neurology and rare disease and hope to reach patients this year," said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

"Efgartigimod has the potential to help people living with gMG as well as several other severe autoimmune diseases mediated by IgG autoantibodies. Our team is advancing registrational trials across four indications with plans to start enrollment in two additional efgartigimod indications this year. We are also broadening our reach within autoimmunity with our first-in-class C2 inhibitor, ARGX-117, from which we will have Phase 1 data mid-year. To complement our clinical pipeline, we continue to invest in our discovery capabilities through our Immunology Innovation Program and strategic technology partnerships that position us well to generate long-term value for shareholders. We are closer each day to building an integrated, innovative, global immunology organization with the goal of impacting the lives of patients," concluded Mr. Van Hauwermeiren.

### **FIRST QUARTER 2021 AND RECENT BUSINESS UPDATE**

#### **Commercial preparations on-track for global launch of IV efgartigimod for gMG, including regulatory submissions, initial salesforce hires and key stakeholder engagement efforts**

- Biologics License Application (BLA) for IV efgartigimod for treatment of gMG accepted for review by U.S. Food and Drug Administration (FDA) with target action date of December 17, 2021 under Prescription Drug User Fee Act (PDUFA)
- J-MAA submitted to Japan's PMDA and accepted for review with anticipated Japan commercial launch in 2022
- MAA expected to be filed with European Medicines Agency (EMA) in second half of 2021
- Zai Lab Limited to discuss potential accelerated regulatory pathway for approval in China with National Medical Products Administration (NMPA)
- Commercial readiness activities on-track, including:



- Continued build-out of global commercial organization, including hiring of U.S. regional business directors during first quarter
- Launched pre-approval access (PAA) program in March 2021 in U.S., Canada and Europe to open availability of efgartigimod to people living with gMG who meet the pre-approval access program criteria

**Immunology pipeline advancing with five ongoing registrational trials of efgartigimod and initial upcoming data from second potential pipeline-in a product candidate, ARGX-117**

- Enrollment ongoing in five registrational trials across four indications, including ADAPT-SC (gMG), ADHERE (chronic inflammatory demyelinating polyneuropathy or CIDP), ADVANCE and ADVANCE-SC (primary immune thrombocytopenia or ITP), and ADDRESS (pemphigus)
  - Go-forward decision confirmed in February 2021 in ADHERE trial evaluating subcutaneous (SC) efgartigimod in CIDP based on evaluation of interim safety and efficacy assessments that surpassed pre-defined threshold
  - Enrollment in trials for fifth and sixth indications to begin in 2021
  - Additional efgartigimod indications to be evaluated as part of collaboration with Zai Lab Limited
- Data expected mid-year from Phase 1 trial of C2 inhibitor, ARGX-117; Phase 2 dosing plan to be identified for indications, including multifocal motor neuropathy (MMN)
  - Phase 2 trial of MMN on track to start by end of 2021
- Combination trials of cusatuzumab remain ongoing for treatment of acute myeloid leukemia (AML) as part of global collaboration and licensing agreement with Cilag GmbH International, an affiliate of Janssen
  - Decision to initiate additional cusatuzumab studies under collaboration will be determined following review of all available data

**Immunology Innovation Program (IIP) continues to grow pipeline through wholly-owned development, partnered opportunities, asset-centric spinoff companies and the addition of strategic technology capabilities**

- Preclinical work ongoing in early-stage pipeline, including ARGX-118, ARGX-119 and ARGX-120
- 15-20 discovery programs under evaluation at any point in time that have emerged from IIP
- Initiated collaboration and license agreement with Elektrofi to explore new subcutaneous formulations for current and future pipeline candidates, including efgartigimod
  - Secured exclusivity for FcRn and one additional target
- Ongoing development of ARGX-112 (LEO Pharma), ARGX-114 (AgomAb), ARGX-115 (ABBV-151, AbbVie) and ARGX-116 (Staten Biotech) by IIP collaboration partners

**Strong balance sheet and expanded Board of Directors support transition into integrated, global immunology organization**

- Completed public offering of 3,593,750 ordinary shares in February 2021 with gross proceeds of \$1.15 billion
- Implemented transition agreement for Chief Financial Officer Eric Castaldi as part of evolution to commercial-stage company; recruitment efforts ongoing for U.S.-based successor
- Proposed resolutions presented during Annual General Meeting of Shareholders were approved, including:



- Appointment to Board of Directors of Yvonne Greenstreet, President and Chief Operating Officer of Alnylam
- Re-appointment of Anthony Rosenberg to Board of Directors
- Approval of new remuneration policy

**argenx to host virtual R&D Day on July 20, 2021 to share long-term corporate vision, disclose additional potential efgartigimod indications and provide updates across immunology pipeline.**

#### FIRST QUARTER 2021 FINANCIAL RESULTS (CONSOLIDATED)

(in thousands of \$ except for shares and EPS)	Three Months Ended		
	March 31,		
	2021	2020	Variance
Revenue	\$ 158,155	\$ 21,139	\$ 137,017
Other operating income	9,260	4,672	4,588
<b>Total operating income</b>	<b>167,415</b>	<b>25,811</b>	<b>141,604</b>
Research and development expenses	(122,328)	(104,661)	(17,666)
Selling, general and administrative expenses	(56,253)	(27,609)	(28,644)
<b>Total operating expenses</b>	<b>(178,580)</b>	<b>(132,270)</b>	<b>(46,310)</b>
Change in fair value on non-current financial assets	11,152	0	11,152
<b>Operating loss</b>	<b>\$ (13)</b>	<b>\$ (106,459)</b>	<b>\$ 106,446</b>
Financial income/(expenses)	(420)	(3,591)	3,171
Exchange gain/(losses)	(28,817)	22,985	(51,802)
<b>Loss before taxes</b>	<b>\$ (29,249)</b>	<b>\$ (87,064)</b>	<b>\$ 57,815</b>
Income taxes	(11,184)	(1,200)	(9,984)
<b>Loss for the period and total comprehensive loss</b>	<b>\$ (40,433)</b>	<b>\$ (88,264)</b>	<b>\$ 47,831</b>
Weighted average number of shares outstanding	49,946,515	42,786,194	
Basic and diluted profit/(loss) per share (in \$)	(0.81)	(2.06)	
Net increase/(decrease) in cash, cash equivalents and current financial assets compared to year-end 2020 and 2019	910,903	(70,318)	
Cash, cash equivalents and current financial assets at the end of the period	2,907,355	1,430,343	

#### DETAILS OF THE FINANCIAL RESULTS

As of January 1, 2021, the Company changed its functional and presentation currency from euro to U.S. dollars, which results in reporting its financial highlights in U.S. dollar as compared to euro in prior periods. Historical financials have been converted at the average exchange rate of the related period.

Cash, cash equivalents and current financial assets totaled \$2,907.4 million on March 31, 2021, compared to \$1,996.5 million on December 31, 2020. The increase in cash, cash equivalents and current financial assets resulted primarily from (i) the closing of a global offering, which resulted in the receipt of \$1,092.1 million in net proceeds in February 2021, (ii) the net receipt of a \$73.1 million non-creditable, non-refundable development cost-sharing payment in the form of newly issued Zai Lab shares received as part of the strategic collaboration for efgartigimod in Greater China, partially



offset by (iii) the payment of \$98.0 million related to the purchase of a priority review voucher from Bayer HealthCare Pharmaceuticals and other net cash flows used in operating activities.

Total operating income increased by \$141.6 million for the three months ended March 31, 2021 to \$167.4 million, compared to \$25.8 million for the three months ended March 31, 2020. The increase was primarily due to the closing of the strategic collaboration for efgartigimod with Zai Lab, resulting in the recognition of \$151.9 million in collaboration revenue.

Research and development expenses increased by \$17.7 million for the three months ended March 31, 2021 to \$122.3 million, compared to \$104.7 million for the three months ended March 31, 2020. The increase in the first three months of 2021 resulted primarily from higher external research and development expenses, mainly related to the efgartigimod program in multiple indications and other clinical and preclinical programs. Furthermore, the research and development personnel expenses increased due to a planned increase in headcount and the increased costs of the share-based payment compensation plans related to the grant of stock options.

Selling, general and administrative expenses totaled \$56.3 million for the three months ended March 31, 2021, compared to \$27.6 million for the three months ended March 31, 2020. The increase resulted primarily from higher personnel expenses, including the costs of the share-based payment compensation plans related to the grant of stock options, and consulting fees linked to the preparation of a possible future commercialization of efgartigimod.

The increase in fair value on non-current financial assets amounted to \$11.2 million for the three months ended March 31, 2021, which is the result of the closing of a Series B financing round of AgomAb Therapeutics, for which the Company maintains a profit share in exchange for granting the license for the use of HGF-mimetic antibodies from the SIMPLE Antibody™ platform.

Exchange losses totaled \$28.8 million for the three months ended March 31, 2021, compared to an exchange gain of \$23.0 million for the three months ended March 31, 2020. As a result of the change in the Company's functional and presentation currency, the exchange losses for the three months ended March 31, 2021 are reflecting the unfavorable change in euro/U.S. dollar exchange rate, mainly attributable to unrealized exchange rate losses on cash, cash equivalents and current financial asset position in euro.

## **FINANCIAL GUIDANCE**

Based on current plans to fund anticipated operating expenses and capital expenditures, argenx continues to expect its 2021 cash burn to approximately double from 2020. The increased spend will support the Company's transition to an integrated immunology company, including the build-out of global commercial infrastructure and drug product inventory ahead of the expected launch of efgartigimod in gMG in the U.S, the advancement of its clinical-stage pipeline, including seven expected global trials of efgartigimod, and the continued investment in its Immunology Innovation Program.

## **EXPECTED 2021 FINANCIAL CALENDAR**

- July 29, 2021: HY 2021 financial results and business update



- October 28, 2021: Q3 2021 financial results and business update

#### **CONFERENCE CALL DETAILS**

The first quarter 2021 financial results and business update will be discussed during a conference call and webcast presentation today at 2:30 pm CEST/8:30 am ET. A webcast of the live call may be accessed on the Investors section of the argenx website at [argenx.com/investors](http://argenx.com/investors). A replay of the webcast will be available on the argenx website.

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

*Please dial in 15 minutes prior to the live call.*

Belgium	0800 389 13
France	0805 102 319
Netherlands	0800 949 4506
United Kingdom	0800 279 9489
United States	1 844 808 7140
International	1 412 902 0128

#### **About argenx**

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx is evaluating efgartigimod in multiple serious autoimmune diseases, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, Japan, and Switzerland. For more information, visit [www.argenx.com](http://www.argenx.com) and follow us on LinkedIn at <https://www.linkedin.com/company/argenx/> and Twitter at <https://twitter.com/argenxglobal>.

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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 statement that the submissions in China and the EU are on track and that it is well-positioned for a global launch of its first-in-class FcRn antagonist, including that BLA for IV efgartigimod for treatment of gMG accepted for review by the U.S. Food and Drug Administration (FDA) in March 2021 with target action date of December 17, 2021 under Prescription Drug User Fee Act (PDUFA), J-MAA submitted to Japan’s PMDA and accepted for review with anticipated Japan commercial launch in 2022, MAA expected to be filed with European Medicines Agency (EMA) in second half of 2021 and Zai Lab Limited to discuss potential accelerated regulatory pathway for approval in China with National Medical Products Administration (NMPA); statements regarding its commercial readiness; its statement that enrollment in trials for fifth and sixth indications to begin in 2021; its statement that data expected mid-year from Phase 1 trial of C2 inhibitor, ARGX-117; Phase 2 dosing plan to be identified for indications including multifocal motor neuropathy (MMN), and Phase 2 trial of MMN on track to start by end of 2021; its expectation that its 2021 cash burn will approximately double from 2020; its hope to reach patients this year; its statements regarding the therapeutic potential of Efgartigimod in patients with gMG as well as several other severe autoimmune diseases mediated by IgG autoantibodies; its plans to start enrollment in two additional efgartigimod indications this year, its expectation to have Phase 1 data mid-year for its C2 inhibitor, ARGX-117, 2021 business and financial outlook and related plans; the therapeutic potential 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; the design of future clinical trials and the timing and outcome of regulatory filings and regulatory approvals. 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 the effects of the COVID-19 pandemic, 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.*