



## **argenx Reports First Quarter 2022 Financial Results and Provides Business Update**

- \$21.2 million in VYVGART® (efgartigimod alfa-fcab) net product sales during initial quarter of U.S. commercial launch
- Met primary endpoint in Phase 3 ADVANCE trial of VYVGART for treatment of primary immune thrombocytopenia (ITP)
  - Japan commercial launch of VYVGART on track to start this month
  - Management to host conference call today at 2:30 pm CET (8:30 am ET)

### **May 5, 2022**

**Breda, the Netherlands** – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today reported financial results for the first quarter 2022 and provided a business update.

In a separate press release issued today, argenx also announced positive results from the Phase 3 ADVANCE trial evaluating VYVGART for the treatment of adult patients with ITP. The primary endpoint, demonstrating a significantly higher proportion of VYVGART-treated patients achieved a sustained platelet response than patients receiving placebo, and additional key secondary endpoints were met.

“Our VYVGART commercial launch is off to a strong start, underscoring the significant unmet need for a new treatment option in gMG. We are very encouraged by the early demand from patients and physicians and our team continues to meet the challenge with outstanding execution and deep engagement with our key stakeholders. We look forward to our imminent commercial launch in Japan and an upcoming regulatory decision in Europe, which support our goal to make VYVGART available worldwide. We are confident that the relationships we are building today with the gMG community will establish a strong foundation to continue to deliver on behalf of patients,” commented Tim Van Hauwermeiren, Chief Executive Officer of argenx.

“The positive readout from our first registrational ITP trial highlights the promise of efgartigimod as a pipeline-in-a-product with the potential to reach a variety of IgG-mediated autoimmune diseases, even beyond the ten indications we are currently evaluating. We are on track to achieve our argenx 2025 goal to build the next great immunology company while bringing breakthrough innovations to patients and creating long-term value for our stakeholders.”

### **FIRST QUARTER 2022 AND RECENT BUSINESS UPDATE**

#### **VYVGART Launch Progress**

VYVGART is the first-approved neonatal Fc receptor (FcRn) blocker in the U.S. and Japan. VYVGART is approved in the U.S. for the treatment of adult generalized myasthenia gravis (gMG) patients who are anti-acetylcholine receptor (AChR) antibody positive and in Japan for adult gMG patients. The global



launch strategy is on track to make VYVGART available in Europe, China and Canada, as well as select additional regions.

- Generated net product revenues of \$21.2 million for first full quarter of VYVGART commercial launch in U.S.
- Japan commercial launch to start this month following addition of VYVGART to National Health Insurance (NHI) drug price list on April 20, 2022
- Decision from European Medicines Agency on Marketing Authorization Application expected in second half of 2022
- Zai Lab to file for approval in China in mid-2022 and Medison in Israel in second quarter of 2022

### **Efgartigimod Research and Development**

argenx is positioned to expand its leadership position in FcRn blockade to include ten total autoimmune indications by the end of 2022. Six registrational trials are ongoing with four new proof-of-concept trials to start this year across multiple therapeutic franchises.

- **Neuromuscular franchise**
  - o Biologics License Application (BLA) on track to be filed by end of year for subcutaneous (SC) efgartigimod for gMG, following positive topline results from Phase 3 ADAPT-SC trial
  - o Topline data from registrational ADHERE trial of SC efgartigimod for chronic inflammatory demyelinating polyneuropathy (CIDP) expected in first quarter of 2023
  - o Registrational ALKIVIA trial on track to start this quarter for three subtypes of idiopathic inflammatory myopathies (myositis), including immune-mediated necrotizing myopathy, anti-synthetase syndrome and dermatomyositis; interim analysis planned of first 30 patients of each subtype
- **Hematology franchise**
  - o Positive topline data of VYVGART for primary ITP reported today
    - Primary endpoint was met; significantly higher proportion of patients receiving VYVGART achieved a sustained platelet response than patients receiving placebo
    - Statistically significant separation from placebo in key platelet-derived secondary endpoints
    - Safety and tolerability profile confirmed in second indication
  - o Topline data from second registrational ADVANCE-SC trial of SC efgartigimod for primary ITP expected in first quarter of 2023
- **Dermatology franchise**
  - o Enrollment expanded in registrational ADDRESS trial of SC efgartigimod for pemphigus vulgaris and foliaceus in order to manage ongoing impact of war in Ukraine; topline data now expected in second half of 2023
  - o Registrational BALLAD trial ongoing of SC efgartigimod for bullous pemphigoid with interim analysis planned of first 40 patients
- **Proof-of-concept trials to be launched in collaboration with Zai Lab and IQVIA**



- Zai Lab to launch Phase 2 trials in lupus nephritis and membranous nephropathy in 2022 with argenx to lead global registrational programs for each potential indication
- IQVIA to launch Phase 2 trials in primary Sjogren's syndrome in second half of 2022 and COVID-19-mediated postural orthostatic tachycardia syndrome (POTS) in mid-2022

### **Pipeline Progress**

argenx is developing ARGX-117 and ARGX-119, which both have pipeline-in-a-product potential for multiple autoimmune indications.

- ARGX-117 (C2 inhibitor)
  - Proof-of-concept ARDA trial ongoing to evaluate safety, tolerability, and potential dosing regimen in multifocal motor neuropathy (MMN)
  - Phase 2 proof-of-concept trial expected to start in 2022 for prevention of delayed graft function and/or allograft failure after kidney transplantation
- ARGX-119 (muscle-specific kinase (MuSK) agonist)
  - Phase 1 dose-escalation trial in healthy volunteers expected to start after Clinical Trial Application filing in fourth quarter of 2022
  - A subsequent Phase 1b trial will assess early signal detection in patients with congenital myasthenic syndrome and MuSK-associated myasthenia gravis

### **Upcoming Medical Meeting Presentations**

- 14<sup>th</sup> Myasthenia Gravis Foundation of America International Conference on Myasthenia and Related Disorders (May 10-12, Miami, FL)
- Society for Investigative Dermatology Annual Meeting (May 18-21, Portland, Oregon)
- Annual Meeting of the Japanese Society of Neurology (May 18-22, Tokyo, Japan)
- 8<sup>th</sup> Congress of the European Academy of Neurology (June 25-28, Vienna, Austria)
- 17<sup>th</sup> International Congress on Neuromuscular Diseases (July 5-9, Brussels, Belgium)



## FIRST QUARTER 2022 FINANCIAL RESULTS (CONSOLIDATED)

(in thousands of \$ except for shares and EPS)	Three Months Ended		
	March 31,		
	2022	2021	Variance
Product net sales	\$ 21,163	\$ —	\$ 21,163
Collaboration revenue	2,249	158,155	(155,906)
Other operating income	8,068	20,412	(12,344)
<b>Total operating income</b>	<b>31,480</b>	<b>178,567</b>	<b>(147,087)</b>
Cost of sales	(1,372)	—	(1,372)
Research and development expenses	(151,968)	(122,328)	(29,640)
Selling, general and administrative expenses	(100,866)	(56,253)	(44,613)
<b>Total operating expenses</b>	<b>(254,206)</b>	<b>(178,580)</b>	<b>(75,626)</b>
<b>Operating loss</b>	<b>\$ (222,726)</b>	<b>\$ (13)</b>	<b>\$ (222,713)</b>
Financial income	821	764	57
Financial expenses	(953)	(1,184)	231
Exchange gains/(losses)	(7,213)	(28,817)	21,604
<b>Loss before taxes</b>	<b>\$ (230,072)</b>	<b>\$ (29,249)</b>	<b>\$ (200,823)</b>
Income tax (expense) / benefit	\$ 2,885	\$ (11,184)	\$ 14,069
<b>Loss for the period</b>	<b>\$ (227,187)</b>	<b>\$ (40,433)</b>	<b>\$ (186,754)</b>
Weighted average number of shares outstanding	52,084,335	49,946,515	
Basic and diluted loss per share (in \$)	(4.36)	(0.81)	
Net increase/(decrease) in cash and cash equivalents and current financial assets compared to year-end 2021 and 2020	\$ 518,656	\$ 910,903	
Cash and cash equivalents and current financial assets at the end of the period	\$ 2,855,384	\$ 2,907,355	

### DETAILS OF THE FINANCIAL RESULTS

**Total operating income** for the three months ended March 31, 2022 was \$31.5 million, compared to \$178.6 million for the three months ended March 31, 2021, and consists of:

- **Product net sales** from sales of VYVGART in the U.S. for the three months ended March 31, 2022 were \$21.2 million, following the approval of VYVGART by the U.S. Food and Drug



Administration (FDA) on December 17, 2021. No product sales were recognized during the comparable prior period.

- **Collaboration revenue** for the three months ended March 31, 2022 was \$2.2 million, compared to \$158.2 million for three months ended March 31, 2021, resulting in a decrease of \$155.9 million. The collaboration revenue for the three months ended March 31, 2021 was primarily attributable to the closing of the strategic collaboration for efgartigimod with Zai Lab, resulting in the recognition of \$151.9 million in collaboration revenue.
- **Other operating income** for the three months ended March 31, 2022 was \$8.1 million, compared to \$20.4 million for three months ended March 31, 2021, resulting in a decrease of \$12.3 million. During the three months ended March 31, 2021, the fair value of the argenx profit share in AgomAb Therapeutics NV increased by \$11.2 million. There was no change in the fair value during the three months ended March 31, 2022.

**Total operating expenses** for the three months ended March 31, 2022 were \$254.2 million, compared to \$178.6 million for the three months ended March 31, 2021, and consists of:

- **Cost of sales** for the three months ended March 31, 2022 amounted to \$1.4 million. The cost of sales was recognized with respect to the sale of VYVGART in the U.S. during the first quarter of 2022. There was no cost of sales recognized in the comparable prior period.
- **Research and development expenses** increased by \$29.6 million for the three months ended March 31, 2022 to \$152.0 million, compared to \$122.3 million for the three months ended March 31, 2021. The increase resulted primarily from higher external research and development expenses, mainly related to the efgartigimod program in various indications and other clinical and preclinical programs.
- **Selling, general and administrative expenses** totaled \$100.9 million for the three months ended March 31, 2022, compared to \$56.3 million for the three months ended March 31, 2021. The increase resulted primarily from higher professional and marketing fees linked to the commercialization of VYVGART in the U.S. and Japan and higher personnel expenses increased due to a planned increase in headcount.

**Exchange losses** totaled \$7.2 million for the three months ended March 31, 2022, compared to \$28.9 million for the three months ended March 31, 2021 and are mainly attributable to unrealized exchange rate losses on cash, cash equivalents and current financial assets position in Euro.

**Income tax** totaled \$2.9 million of tax income for the three months ended March 31, 2022, compared to \$11.2 million of tax expense for the comparable prior period. Tax income for the three months ended March 31, 2022 consists of \$5.0 million of income tax expense and \$7.9 million of deferred tax income, compared to \$6.2 million of income tax expense and \$5 million of deferred tax expense for the comparable prior period.

**Net loss** for the three months ended March 31, 2022 was \$227.2 million compared to \$40.4 million for the comparable prior year period. On a per weighted average share basis, the net loss was \$4.36 and \$0.81 for the three months ended March 31, 2022 and 2021, respectively.



**Cash, cash equivalents and current financial assets** totaled \$2,855.4 million as of March 31, 2022, compared to \$2,336.7 million as of December 31, 2021. The increase in cash and cash equivalents and current financial assets resulted primarily from the closing of a global offering of shares, including a U.S. offering and a European private placement, which resulted in the receipt of \$761.0 million in net proceeds in March 2022, partially offset by the net cash flows used in operating activities, primarily towards the commercial launch of VYVGART in the U.S. and Japan and continued investment in pipeline expansion.

#### **FINANCIAL GUIDANCE**

As of March 31, 2022, argenx had \$2.9 billion in cash, cash equivalents and current financial assets. Based on current plans to fund anticipated operating expenses and capital expenditures, argenx expects to utilize approximately \$1 billion of its available cash in 2022. The increased spend will support the global VYVGART launches, clinical development of efgartigimod in 10 indications and ARGX-117 in two indications, investment in the global supply chain, and continued focus on pipeline expansion through the Immunology Innovation Program.

#### **EXPECTED 2022 FINANCIAL CALENDAR**

- July 28, 2022: HY 2022 financial results and business update
- October 27, 2022: Q3 2022 financial results and business update

#### **CONFERENCE CALL DETAILS**

The first quarter 2022 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](https://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.*

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

*Use the access code 073235 to join the call. Please dial in 15 minutes prior to the live call.*

Belgium	32 800 548 13
United Kingdom	44 808 189 6484
United States	1 844 200 6205
All other locations	1 929 526 1599

#### **About argenx**

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. 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 developed and is commercializing the first-and-only approved neonatal Fc receptor (FcRn) blocker in the U.S. and Japan. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage



experimental medicines within its therapeutic franchises. For more information, visit [www.argenx.com](http://www.argenx.com) and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

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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,” “hope,” “estimates,” “anticipates,” “expects,” “intends,” “may,” “will,” or “should” and include statements argenx makes concerning execution of its global launch strategy and expected therapy delivery to patients in Japan, Europe, China and Canada; the expected long-term safety, tolerability and efficacy of VYVGART® (efgartigimod alfa-fcab) in adult patients with Primary Immune thrombocytopenia; its expectation concerning its development pipeline and ability to deliver shareholder value as a result thereof; development of efgartigimod in up to ten indications and ARGX-117 in up to two indications by end of 2022; expected advancement of ARGX-119 into first-in-human studies; expected broad U.S. policy coverage of VYVGART by the end of second quarter 2022; the estimated number of covered patients in the U.S.; anticipated pathway for approval in Japan and launch in the second quarter of 2022; plans for Medison to file for approval in Israel in second quarter of 2022; partnership agreements expected to be announced in 2022; the timing and its expectations with respect to reporting data from registrational trials; expectations with respect to expansion of efgartigimod portfolio into ten indications by end of 2022; expected launch and timing of proof of concept trials, including by Zai Labs and IQVIA, and dose escalation trials in 2022; and its expectations with respect to its use of available cash and liquidity needs for 2022. 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.*