



## **argenx Highlights Strategic Priorities for 2022**

*Initiated global VYVGART™ (efgartigimod alfa-fcab) commercial launch*

*Expect data from five registrational trials of efgartigimod by first quarter of 2023*

*Announcing four new efgartigimod indications to be initiated in 2022: membranous nephropathy, lupus nephritis, Sjogren's syndrome, COVID-19 mediated postural orthostatic tachycardia syndrome (POTS)*

*Anticipate clinical development programs in 12 autoimmune conditions across four therapeutic franchises by end of 2022*

*Management to present at 40<sup>th</sup> Annual J.P. Morgan Healthcare Conference*

### **January 7, 2022**

**Breda, the Netherlands** – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced its strategic priorities for 2022 and highlighted recent achievements from its broad immunology pipeline. Additionally, the Company provided financial guidance for 2022.

“We enter 2022 very excited about the year ahead, having achieved our first FDA approval and initiated our commercial launch of VYVGART in the United States. With these accomplishments, we are well on our way to realizing our goal to become a leading, multi-product immunology company and believe we have the right team, a differentiated pipeline, and a sustainable innovation engine to support our vision,” commented Tim Van Hauwermeiren, Chief Executive Officer of argenx.

“Beyond this launch, we are focused on expanding and accelerating the clinical development of our efgartigimod portfolio. Toward that end, we expect to report data from five registrational trials by the end of the first quarter of 2023 and to initiate trials in four new indications this year through partnership agreements with Zai Lab and IQVIA. We believe our leadership in neonatal Fc receptor (FcRn) blockade, along with our robust immunology pipeline, position 2022 to be a transformational year for argenx,” continued Mr. Van Hauwermeiren.

### **Strategic Priorities**

The following strategic priorities for 2022 support the ‘argenx 2025’ vision to become a global, integrated immunology organization:

#### **On track for global commercial launch of VYVGART for treatment of generalized myasthenia gravis (gMG) across three continents**

- U.S. commercial launch underway following December 2021 approval by U.S. Food and Drug Administration (FDA) of VYVGART for the treatment of gMG in adult patients who are anti-acetylcholine receptor antibody positive



- Approval by Japan's Pharmaceuticals and Medical Devices Agency of Marketing Authorization Application (MAA) expected during first quarter of 2022
- Approval by European Medicines Agency of MAA expected in second half of 2022
- argenx Canada to be established in first quarter of 2022 in preparation for potential Health Canada approval and commercial launch
- Medison to file for approval in Israel in second quarter of 2022
- Zai Lab to file for approval in Greater China by mid-2022
- Additional partnership agreements expected to be announced in 2022 that would expand global patient reach

**Topline data expected from five registrational trials of efgartigimod by first quarter of 2023, which position argenx for multiple potential launches within commercial franchises by end of 2024**

- Neuromuscular franchise:
  - ADAPT-SC: Topline data of subcutaneous (SC) efgartigimod for gMG expected in first quarter of 2022
  - ADHERE: Topline data of SC efgartigimod for chronic inflammatory demyelinating polyneuropathy expected in first quarter of 2023
- Hematology franchise:
  - ADVANCE: Topline data of intravenous efgartigimod for primary immune thrombocytopenia (ITP) expected in second quarter of 2022
  - ADVANCE-SC: Topline data of SC efgartigimod for primary ITP expected in first quarter of 2023
- Dermatology franchise:
  - ADDRESS: Topline data of SC efgartigimod for pemphigus foliaceus and vulgaris expected in fourth quarter of 2022

**Efgartigimod development portfolio to expand to ten high-need autoimmune conditions by end of 2022, solidifying argenx's leadership position in FcRn blockade**

- Trial designs finalized in fifth and sixth potential indications following regulatory consultation
  - BALLAD: Registrational trial initiated at end of 2021 of SC efgartigimod for bullous pemphigoid; interim analysis planned of first 30 patients
  - ALKIVIA: Registrational trial of SC efgartigimod for idiopathic inflammatory myopathy (myositis) to initiate in first quarter of 2022; interim analysis planned of first 30 patients of each subtype (immune-mediated necrotizing myopathy, anti-synthetase syndrome and dermatomyositis)
- Through partnership agreement, Zai Lab to launch proof-of-concept trials in two new kidney conditions in 2022: lupus nephritis and membranous nephropathy
  - argenx to lead any global registrational program for each potential indication
- argenx entered into strategic partnership with IQVIA to leverage its global clinical development capabilities and accelerate expansion of efgartigimod into additional potential indications
  - Proof-of-concept trials to initiate in two autoimmune conditions:
    - Primary Sjogren's syndrome in second half of 2022



- COVID-19-mediated postural orthostatic tachycardia syndrome (POTS) in mid-2022, which is increasingly reported in patients who continue to have long-lasting symptoms after complete recovery of COVID-19 infection

#### **ARGX-117, a novel C2 inhibitor, has potential to be second pipeline-in-a-product for multiple autoimmune indications**

- Proof-of-concept trial initiated at end of 2021 in multifocal motor neuropathy
- Second proof-of-concept trial to initiate in second half of 2022 for prevention of delayed graft function and/or allograft failure after kidney transplantation

#### **Continued investment in Immunology Innovation Program to broaden autoimmune pipeline for sustained value creation opportunities**

- Phase 1 dose-escalation trial of ARGX-119, an agonist SIMPLE Antibody™ to the muscle-specific kinase receptor (MuSK), to start after Clinical Trial Application filing in fourth quarter of 2022
  - Trial will evaluate safety, tolerability, pharmacokinetics and pharmacodynamics in healthy volunteers, and also early signal detection in patients

#### **Financial Guidance**

As of December 31, 2021, argenx had approximately \$2.3 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 half of its available cash in 2022. The increased spend will support the global VYVGART launches, clinical development of efgartigimod and ARGX-117 in 12 total indications, investment in the global supply chain, and continued focus on pipeline expansion through the Immunology Innovation Program.

#### **40<sup>th</sup> Annual J.P. Morgan Healthcare Conference Presentation and Webcast**

Mr. Van Hauwermeiren will highlight these updates in a corporate presentation at the virtual 40<sup>th</sup> Annual J.P. Morgan Healthcare Conference on Monday, January 10, 2022 at 7:30 a.m. ET. The live webcast of the presentation may be accessed under Investors on the [argenx website](#). A replay will be available for 30 days following the presentation.

#### **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 FDA approved neonatal Fc receptor blocker, VYVGART™ (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. 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 its goal to become a leading, multi-product immunology company; focus on expansion and acceleration of clinical development of its efgartigimod portfolio; the timing and its expectations with respect to reporting data from registrational trials and initiate trials in new indications; the intended results of its strategy including global launch preparation and argenx 2025 vision to become a global, integrated immunology organization; its plans for global commercialization launch of VYVGART across three continents; expectation of Japan’s MAA approval of VYVGART during the first quarter of 2022 and expected approval by European Medicines Agency of MAA in the second half of 2022; establishment of argenx Canada in the first quarter of 2022 and preparation for potential Health Canada approval and commercial launch; plans for Medison to file for approval in Israel in second quarter of 2022, and Zai Lab to file for approval in greater China by mid-2022; partnership agreements expected to be announced in 2022; expectations with respect to potential commercial franchise launches; development of the efgartigimod portfolio for additional indications; its clinical development and regulatory plans, including the timing, design and outcome of ongoing and planned clinical trials and preclinical activities and the timing and outcome of regulatory filings and approvals; its expectations with respect to its use of available cash and liquidity needs for 2022; and its belief in transformational potential of year 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.*