



argenx Highlights 2023 Strategic Priorities Across Immunology Pipeline

Reported \$402 million in preliminary full-year 2022 global net VYVGART sales*

ADHERE topline results now expected in second quarter of 2023; Stage B enrollment has surpassed projected target of 130 patients

Registrational trial of efgartigimod in thyroid eye disease (TED) to start in 2023; additional proof-of-concept trials to start in ANCA-associated vasculitis and antibody mediated rejection (AMR)

Submission for marketing approval in Japan of VYVGART for immune thrombocytopenia (ITP) expected in mid-2023

Amsterdam, the Netherlands – January 9, 2022 – argenx SE (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 2023 and provided preliminary financial results for the full year 2022, including global net product sales of VYVGART® (efgartigimod alfa-fcab).

“We had a landmark year in 2022, marking our first as a fully integrated immunology company transforming the treatment paradigm of generalized myasthenia gravis, and one which will stand as only the very beginning of what we expect to achieve as an organization,” said Tim Van Hauwermeiren, Chief Executive Officer, argenx. “Looking forward, we will be expanding our patient reach both geographically and through the anticipated U.S. approval and launch of subcutaneous efgartigimod in March. By the end of 2023, we will be active in 15 IgG- and complement-mediated autoimmune diseases as we work to uncover the full breadth of our differentiated pipeline with key data readouts from additional indications of efgartigimod, as well as ARGX-117 and ARGX-119.”

2023 Strategic Priorities

argenx will focus on four strategic priorities in 2023 to drive sustained growth and value creation as part of its 'argenx 2025' vision and a path to profitability.

Reach More Patients with VYVGART

argenx is planning for multi-dimensional expansion to reach more patients with VYVGART, its first-in-class neonatal Fc receptor blocker. This includes generalized myasthenia gravis (gMG) patients through regulatory approvals in new regions and the launch of its subcutaneous (SC) product offering, as well as a new autoimmune indication with the VYVGART regulatory submission for ITP in Japan.

- ▮ Prescription Drug User Fee Act (PDUFA) target action date of March 20, 2023, for U.S. Food and Drug Administration approval decision on SC efgartigimod for gMG
- ▮ Regulatory approval decision on SC efgartigimod for gMG expected in EU in fourth quarter of 2023
- ▮ Submission for marketing approval of SC efgartigimod for gMG expected in Japan in first quarter of 2023
- ▮ Regulatory approval decisions of VYVGART for gMG expected in Canada in third quarter of 2023 and in China and Israel by end of 2023
- ▮ gMG launch in France, United Kingdom and Italy expected by year-end 2023 following review of respective reimbursement dossiers
- ▮ Submission for Japan marketing approval of VYVGART for ITP expected in mid-2023

Pioneer Development of FcRn Class with New Clinical and Translational Data

argenx aims to solidify its FcRn leadership by expanding the scope of IgG-mediated autoimmune diseases in development and further demonstrating the potential of FcRn blockade with three Phase 3 trial readouts, one proof-of-concept trial readout, and a commitment to a 'bedside-to-bench' translational biology effort. By the end of 2023, efgartigimod is expected to be approved, in regulatory review or in development in 13 severe autoimmune diseases.

- ▮ ADHERE: Topline data in chronic inflammatory demyelinating polyneuropathy (CIDP) now expected in second quarter of 2023; Stage B enrollment has surpassed the initial projected target of 130 patients
- ▮ ADDRESS: Topline data in pemphigus expected in second half of 2023
- ▮ ADVANCE-SC: Topline data from SC trial in ITP expected in second half of 2023
- ▮ Proof-of-concept data in post-COVID-19 postural orthostatic tachycardia syndrome (PC-POTS) expected in fourth quarter of 2023
- ▮ Registrational trial to start in TED in fourth quarter of 2023
- ▮ Proof-of-concept trials to start in ANCA-associated vasculitis and AMR in kidney transplant in fourth quarter of 2023; AAV trial to be run through IQVIA collaboration
- ▮ Externally sponsored research studies to launch in IgG-mediated neuromuscular autoimmune diseases in 2023
- ▮ Translational work ongoing to understand potential disease-modifying effect of FcRn mechanism

Drive Earlier-Stage Immunology Opportunities Towards Clinical Proof-of-Concept

Beyond efgartigimod, argenx is advancing a robust portfolio of innovative clinical programs, including ARGX-117 (C2 inhibitor) and ARGX-119 (muscle-specific kinase (MuSK) agonist). Both programs have the potential to be first-in-class opportunities for multiple severe autoimmune indications.

- ▮ ARDA: Interim data from proof-of-concept trial of ARGX-117 in multifocal motor neuropathy expected mid-2023
- ▮ Proof-of-concept trial of ARGX-117 expected to start following regulatory discussions for prevention of delayed graft function after kidney transplantation
- ▮ Dermatomyositis selected as third autoimmune indication for development of ARGX-117
- ▮ Phase 1 dose-escalation trial of ARGX-119 in healthy volunteers to start in first quarter of 2023 with subsequent Phase 1b trial to assess early signal detection in patients

Build Immunology Innovation Ecosystem to Drive Long-Term Pipeline Growth

argenx continues to invest in its discovery engine, the Immunology Innovation Program, to foster a robust innovation ecosystem and drive early-stage pipeline growth. argenx expects to nominate one new development candidate in 2023.

Preliminary* Fourth Quarter and Full Year 2022 Financial Results

argenx also announced today preliminary* global net VYVGART revenues for the fourth quarter and full-year 2022 of approximately \$175 million and \$402 million, respectively.

As of December 31, 2022, argenx had approximately \$2.2 billion in cash, cash equivalents and current financial assets*. Based on its current operating plans and a projected 2023 cash burn of approximately \$500 million, argenx expects its existing cash, cash equivalents and current financial assets, together with anticipated future product revenues, to fund the company to profitability.

* - The preliminary selected financial results are unaudited, subject to adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results in March 2023.

41st Annual J.P. Morgan Healthcare Conference Presentation and Webcast

Mr. Van Hauwermeiren will highlight these updates in a corporate presentation at the 41st Annual J.P. Morgan Healthcare Conference today, Monday, January 9, 2023, at 9:00 a.m. PT. 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 approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan and the EU. 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 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 preliminary financial results for the full year 2022; its expectations of future profitability; its plans for geographic expansion; the anticipated launch of its subcutaneous (SC) product in the U.S.; the initiation, timing, progress and results of its anticipated clinical development, data readouts and regulatory milestones and plans; its strategic priorities, including the timing and outcome of regulatory filings and regulatory approvals, and anticipated expansions in generalized myasthenia gravis (gMG) and IgG-mediated autoimmune diseases; the potential of its innovative clinical programs; and the nomination of new development candidates. 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. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.