



# argenx Announces UK MHRA Approval of VYVGART for the Treatment of Generalized Myasthenia Gravis

*VYVGART is the first neonatal Fc receptor (FcRn) blocker approved in the UK for the treatment of adults living with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive*

*68% of anti-AChR antibody positive gMG patients treated with VYVGART were responders (n=44/65) on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale compared with 30% of patients treated with placebo (n=19/64) (p<0.0001) during the first treatment cycle in the Phase 3 ADAPT trial*

*argenx is committed to collaborating with local authorities to facilitate broad and rapid access to VYVGART for eligible patients*

**MARCH 15, 2023**

**Amsterdam, the Netherlands** — argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for VYVGART® (efgartigimod alfa-fcab) as an add-on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive<sup>1</sup>.

"We are pleased to announce this latest regulatory approval of VYVGART, another exciting advancement toward our vision of making our innovation available to as many patients as possible," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "As we seek to redefine the treatment of this debilitating disease, we look forward to close collaboration with the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) to support broad and rapid access to this new treatment option, connecting eligible gMG patients in the UK to the care they need."

The MHRA approval of VYVGART is based on results from the global Phase 3 ADAPT trial, which were published in the July 2021 issue of [The Lancet Neurology](#). The ADAPT trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale following treatment with efgartigimod compared with placebo (68% vs. 30%; p<0.0001). Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for four or more consecutive weeks during the first treatment cycle<sup>2</sup>.

There were also significantly more responders on the Quantitative Myasthenia Gravis (QMG) scale following treatment with efgartigimod compared with placebo (63% vs. 14%; p<0.0001). Responders were defined as having at least a three-point reduction on the QMG scale sustained for four or more consecutive weeks during the first treatment cycle.

VYVGART had a demonstrated safety profile in the ADAPT clinical trial. The most commonly reported adverse reactions that occurred more frequently with VYVGART than placebo were upper respiratory tract infections (10.7% following treatment with efgartigimod vs. 4.8% of placebo) and urinary tract infections (9.5% vs. 4.8%).

"gMG can impact patients and caregivers in every area of life – many are faced with the difficult choice of taking significant time away from work, giving up hobbies or spending less time with their loved ones. VYVGART is the first-and-only FcRn blocking treatment to receive approval in UK, offering patients and their families a new treatment option that is targeted to the underlying pathogenesis of the disease and supported by strong efficacy, safety and tolerability data," said Prof Saiju Jacob, Consultant Neurologist at the University Hospitals Birmingham. "The marketing authorization of VYVGART is great news for the gMG community in the UK, providing a newer treatment option which along with the existing drugs will hopefully reduce the burden of this debilitating disease."

VYVGART was granted a Promising Innovative Medicine (PIM) designation by the MHRA in November 2021, as well as a [positive scientific opinion under the Early Access to Medicines Scheme](#) in May 2022.

## About Phase 3 ADAPT Trial

The Phase 3 ADAPT trial was a 26-week randomized, double-blind, placebo-controlled, multi-center, global trial evaluating the safety and efficacy of efgartigimod in adult patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the trial. Patients were randomized in a 1:1 ratio to receive efgartigimod or placebo, in addition to stable doses of their current gMG treatment. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by subsequent treatment cycles based on clinical evaluation. The primary endpoint was the comparison of percentage of MG-ADL responders in the first treatment cycle between efgartigimod and placebo treatment groups in the anti-AChR antibody positive population<sup>2</sup>.

## About VYVGART

VYVGART (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. It is the first and only approved FcRn blocker. VYVGART is approved in the United States, Europe and the UK for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive, and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs).

## About Generalized Myasthenia Gravis

Generalized myasthenia gravis (gMG) is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness. Approximately 85% of people with MG progress

to gMG within 24 months<sup>2</sup>, where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population<sup>3</sup>.

### 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., the EU, Japan and the UK.

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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 the commercialization of VYVGART<sup>®</sup> in the UK, the access of patients to VYVGART and the impact thereof on reducing the burden of gMG. 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.*

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<sup>1</sup> VYVGART UK Summary of Product Characteristics

<sup>2</sup> Howard JF et al. Lancet Neurol 2021;20(7):526-536.

<sup>3</sup> Behn et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277