

# argenx Enters Into Agreement To Acquire Priority Review Voucher

#### November 23, 2020

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced that the company has agreed to acquire a U.S. Food and Drug Administration (FDA) Priority Review Voucher (PRV) from Bayer Healthcare Pharmaceuticals, Inc for \$98 million. A PRV entitles the holder to FDA priority review of a single New Drug Application or Biologics License Application (BLA), which reduces the target review time and may potentially lead to an expedited approval.

argenx expects to redeem the PRV for a future marketing application for its FcRn antagonist efgartigimod. It will not be used for the BLA filing of intravenous efgartigimod in generalized myasthenia gravis, which is on track to be submitted in 2020.

"Efgartigimod has the potential to offer a new therapy option to patients with severe autoimmune diseases. We are currently advancing both an intravenous and subcutaneous formulation, which we believe will capture variability in patient preferences around dosing schedule and convenience, and will allow us to reach the most number of patients. Through this investment in a PRV, we'll be able to seek expedited review of a future marketing application and build additional optionality into our development plans for efgartigimod," said Tim Van Hauwermeiren, Chief Executive Officer of argenx.

The closing of the acquisition of the PRV is subject to customary closing conditions, including clearance under the Hart-Scott Rodino (HSR) Antitrust Improvements Act.

# **About Efgartigimod**

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation. Blocking FcRn reduces IgG antibody levels representing a logical potential therapeutic approach for several autoimmune diseases known to be driven by disease-causing IgG antibodies, including: myasthenia gravis (MG), a chronic disease that causes muscle weakness; pemphigus vulgaris (PV), a chronic disease characterized by severe blistering of the skin; immune thrombocytopenia (ITP), a chronic bruising and bleeding disease; and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disease leading to impaired motor function.

## **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 efgartigimed 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, and Japan. For more information, visit <a href="https://www.argenx.com">www.argenx.com</a> and follow us on LinkedIn at <a href="https://www.linkedin.com/company/argenx/">https://www.linkedin.com/company/argenx/</a>.

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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 forwardlooking 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 the closing of the acquisition of the PRV; the expected benefits of the PRV; the timing of the BLA filing of IV efgartigimod in generalized myasthenia gravis; the timing and outcome of FDA feedback regarding its proposed strategy for a bridging study between the intravenous (IV) and subcutaneous (SC) formulations of efgartigimod in gMG; the expected benefits of IV and SC formulations of efgartigimod; the therapeutic potential of its product candidates; and the intended results of its strategy. 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 ability to satisfy closing conditions for the acquisition of the PRV, the occurrence of any event that could give rise to the termination of the PRV acquisition agreement, the ability to recognize the anticipated benefits of the PRV acquisition, the effects of the COVID-19 pandemic, the inherent uncertainties associated with 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.