argenx receives feedback from FDA in end-of-phase 2 meeting for efgartigimod in myasthenia gravis

- Global pivotal Phase 3 clinical trial of efgartigimod in myasthenia gravis on track to initiate before end of 2018 -

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Breda, the Netherlands / Ghent, Belgium - argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced the receipt of guidance from the U.S. Food & Drug Administration (FDA) following an End-of-Phase 2 meeting. The company has identified the key elements of the trial design and CMC framework of the Phase 3 program to support a Biologics License Application (BLA) for efgartigimod in generalized myasthenia gravis (gMG).

argenx expects to initiate a global pivotal Phase 3 clinical trial of efgartigimod in gMG before the end of 2018. The placebo-controlled 26-week trial is expected to evaluate the efficacy of a 10 mg/kg dose of efgartigimod in approximately 150 gMG patients, including both AChR autoantibody positive and AChR autoantibody negative patients. In addition, patients can roll over into an open-label extension study for a period of one year.

"The outcome of the End-of-Phase 2 meeting is an important step in our strategic plan to advance efgartigimod in gMG patients. We plan to proceed with one study and one dose for our path to approval, and to include AChR autoantibody negative patients in our recruitment plan as this subset represents a particular high unmet need among the MG population," commented Nicolas Leupin, CMO of argenx. "We believe our Phase 3 clinical trial, in combination with the positive Phase 2 data, has the potential to support a BLA submission. We will continue to work very closely with the regulatory authorities as we advance efgartigimod towards approval to help patients suffering from this severe autoimmune disease."

About efgartigimod
Efgartigimod (ARGX-113) is an investigational therapy for IgG-mediated autoimmune diseases and was designed to exploit the natural interaction between IgG antibodies and the recycling receptor FcRn. Efgartigimod is the Fc-portion of an antibody that has been modified by the argenx proprietary ABDEG(TM) technology to increase its affinity for FcRn beyond that of normal IgG antibodies. As a result, efgartigimod blocks antibody recycling through FcRn binding and leads to fast depletion of the autoimmune disease-causing IgG autoantibodies. The development work on efgartigimod is done in close collaboration with Prof. E. Sally Ward (University of Texas Southwestern Medical and Texas A&M University Health Science Center, a part of Texas A&M University (TAMHSC)).

About argenx
argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. We are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Our ability to execute on this focus is enabled by our suite of differentiated technologies. Our SIMPLE Antibody™Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody engineering technologies are designed to enable us to expand the therapeutic index of our product candidates.
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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," "estimates," "anticipates," "expects," "intends," "may," "will," or "should," and include statements argenx makes concerning the intended results of its strategy and argenx's advancement of, and anticipated clinical development and regulatory milestones and plans, including the trial design and CMC framework of the Phase 3 program to support a NDABLA for efgartigimod (ARGX-113) in generalized gMG; the timing of the initiation of a global pivotal Phase 3 clinical trial of ARGX-113; the timing of expected data readouts, related to ARGX-113; the potential of the Phase 3 clinical trial, in combination with the positive Phase 2 data, to support a BLA submission,; the momentum of its product candidate pipeline as well as the advancement of, and anticipated clinical development and regulatory milestones and plans related to, and data readouts for, argenx's product candidates and clinical trials; and interaction with regulators, including the potential approval of our current or future drug 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, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, 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.