argenx doses first patient in global Phase 3 registration trial of efgartigimod for the treatment of generalized myasthenia gravis

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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 dosing of the first patient in a global Phase 3 registration trial of efgartigimod (ARGX-113) in patients with generalized myasthenia gravis (gMG).

"The dosing of the first patient represents an important milestone in advancing efgartigimod towards registration with the hopes of providing more therapeutic options for gMG patients globally. With planned enrollment of 150 patients, this will be the broadest trial of its kind in gMG, and the first to address both acetylcholine receptor (AChR) autoantibody positive as well as AChR autoantibody negative patients like those with MuSK MG," commented Nicolas Leupin, CMO of argenx. "Our Phase 2 results in gMG demonstrated rapid and sustained benefits in disease scores, correlating with a fast and deep reduction of auto-antibodies and a favorable tolerability profile, which we will continue to study in the Phase 3 trial."

The randomized, double-blind, placebo-controlled, multicenter trial will enroll approximately 150 patients with gMG in North America, Europe and Japan. The global Phase 3 trial will evaluate the efficacy of a 10 mg/kg intravenous (IV) dose of efgartigimod over a 26-week period. The company expects to enroll AChR autoantibody positive patients and also AChR autoantibody negative patients whose disease is driven primarily by MuSK and LRP4 autoantibodies. The decision to include both patient subgroups results from the significant IgG reductions seen across all four IgG isotypes in the Phase 2 MG trial and the Phase 1 healthy volunteer trial. Patients in the Phase 3 clinical trial will be able to roll over into an open-label extension trial for a period of one year. The primary endpoint of the trial is efficacy as assessed by the Myasthenia Gravis Activities of Daily Living (MG-ADL) score

and secondary and other endpoints include additional efficacy, safety, tolerability, quality of life and impact on normal daily activities measures.

In the Phase 2 clinical trial of efgartigimod in gMG, data showed clinical improvement of efgartigimod over placebo results through the entire 11-week duration of the trial. Efgartigimod was well-tolerated in all patients, with most adverse events (AEs) characterized as mild and deemed unrelated to the study drug. No serious or severe AEs were reported.

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. The company is 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. argenx`s ability to execute on this focus is enabled by its suite of differentiated technologies. The SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows argenx to exploit novel and complex targets, and its three complementary Fc engineering technologies are designed to expand the therapeutic index of its product candidates.
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