# argenx announces initial results from Phase 1 multiple ascending dose (MAD) study of ARGX-113 in healthy volunteers

- Data show potent reduction of IgG levels of up to 85% and a favorable safety and tolerability profile
- Phase 2 trial in myasthenia gravis expected to begin by end of 2016

**Breda, the Netherlands / Ghent, Belgium** - argenx (Euronext Brussels: ARGX), a clinical-stage biopharmaceutical company focused on creating and developing differentiated therapeutic antibodies for the treatment of cancer and severe autoimmune diseases, today announced initial results from its Phase 1 multiple ascending dose (MAD) study of ARGX-113 in healthy volunteers. The compound continues to show favorable safety and tolerability across multiple doses and dosing regimens with promising pharmacodynamics effects relating to speed, depth and duration of IgG reduction.

"We are pleased to share these preliminary results as they strongly support further study of ARGX-113 in severe autoimmune diseases. The repeated dosing in healthy volunteers resulted in very favourable PK/PD effects including specific IgG reduction of up to 85% and a long duration of effect given the simple and fast administration of the treatment," commented Nicolas Leupin, CMO of argenx. "Overall, these results confirm the potential for ARGX-113 to become a breakthrough therapy for the treatment of severe IgG-mediated autoimmune disease and we expect to start our first Phase 2 trial in myasthenia gravis by the end of 2016."

The Phase 1 double-blind, placebo-controlled study will enrol up to 68 healthy adult volunteers to evaluate the safety and tolerability of ARGX-113 and to identify a potential dose for future Phase 2 studies.

ARGX-113 is a novel approach to manage exacerbations of severe, IgG-mediated autoimmune diseases including multiple sclerosis and systemic lupus erythematosus as well as a wide range of orphan autoimmune diseases (such as myasthenia gravis, autoimmune skin blistering diseases, etc.) for which there are currently insufficient treatment options. In preclinical studies, ARGX-113 demonstrated high potency and rapid onset of action in autoantibody reduction.

### **About ARGX-113**

ARGX-113 is a potential breakthrough therapy for treatment of IgG-mediated autoimmune diseases. ARGX-113 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, ARGX-113 blocks antibody recycling and leads to fast depletion of the autoimmune disease-causing IgG autoantibodies.

## About argenx

argenx (ARGX) combines the diversity of the llama immune system with antibody engineering to advance a clinical pipeline to treat patients with cancer and autoimmune diseases. Our platforms allow us to unlock novel and complex targets and develop antibody-based drugs designed for greater efficacy and longer duration of effect. The strength of our team, our deep understanding of the biology, and our committed collaborations with industry leaders contribute to the success of our journey. <a href="https://www.argenx.com">www.argenx.com</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 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. 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' actual results may differ materially from those predicted by the forward-looking statements. argenx undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

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