argenx announces first patient dosed in Phase II proof-of-concept study of ARGX-113 for the treatment of primary immune thrombocytopenia

-Topline data from the study expected in second half of 2018-

31 March 2017

Breda, the Netherlands / Ghent, Belgium - argenx (Euronext Brussels: 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 Phase II proof-of-concept study of ARGX-113 in patients with primary immune thrombocytopenia (ITP).

"The initiation of the second Phase II trial for our lead candidate, ARGX-113, is an important milestone for the company as it exemplifies the breadth of potential this compound has to address a wide variety of diseases that are driven by pathogenic IgGs," commented Nicolas Leupin, CMO of argenx. "We believe ARGX-113 could be a breakthrough therapy in an indication like ITP where current therapies do not adequately address symptoms or achieve remissions."

The double-blind, placebo controlled Phase II study will enrol up to 36 ITP patients with platelet levels lower than 30 million per milliliter. ARGX-113 will be dosed on top of current standard of care, corticosteroids and/or immunomodulatory agents and/or TPO-R agonists. The primary endpoints of the trial are safety and tolerability and secondary endpoints include effect on platelet count and use of rescue treatment, and an assessment of pharmacokinetics (PK) and pharmacodynamic (PD) markers.

In Phase I clinical trial, ARGX-113 demonstrated favorable safety and tolerability across multiple doses and dosing regimens with promising pharmacodynamics effects relating to speed, depth and duration of IgG reduction.

About ARGX-113
We are developing our lead product candidate, ARGX-113, for the treatment of patients with myasthenia gravis and primary immune thrombocytopenia, both of which are rare and severe autoimmune diseases associated with high levels of pathogenic IgGs. Few innovative biologic treatments have been approved addressing these circulating auto-antibodies and severe unmet medical need exists. ARGX-113 is the Fc-portion of an antibody and utilizes our ABDEG engineering technology. It is designed to block the recycling of IgG antibodies, which results in their removal from circulation. The development work on ARGX-113 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 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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