argenx launches Phase I trial with subcutaneous formulation of ARGX-113

Subcutaneous formulation intended for chronic therapy setting

October 30, 2017

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 that the first subject has been dosed in a Phase I clinical trial evaluating the pharmacokinetics (PK), pharmacodynamics (PD), safety and tolerability of a subcutaneously administered formulation of ARGX-113 in healthy volunteers.

"We are developing a subcutaneous formulation of ARGX-113 to offer greater convenience for patients with severe auto-immune conditions requiring long term treatment. This treatment option could represent a significant advancement over current standard of care in the treatment of these types of chronic diseases," commented Nicolas Leupin, Chief Medical Officer of argenx. "In preclinical studies, we were highly encouraged to see that the subcutaneous formulation showed a similar PK and PD profile to that of the intravenous formulation. We look forward to comparing these healthy volunteer data with the preclinical data and data from our clinical trials."

The open-label, non-controlled Phase I clinical trial will enroll up to 32 healthy volunteers to evaluate the PK, PD, safety and tolerability of a subcutaneous formulation compared to an intravenous formulation of ARGX-113 being administered in our ongoing Phase II clinical trials. The doses selected for this subcutaneous Phase I clinical trial are aligned with doses used in the continuing Phase II clinical trials of ARGX-113 using the intravenous formulation.

ARGX-113 is currently being tested in three Phase II clinical trials in myasthenia gravis (MG), immune thrombocytopenia (ITP) and pemphigus vulgaris (PV) using the intravenous formulation. Topline data for MG and ITP are expected in the first quarter at the latest and second half of 2018, respectively. Interim results from the PV trial are expected during the second half of 2018. In a Phase I clinical trial with healthy volunteers, the intravenous formulation was reported to be well-tolerated across multiple doses and dosing regimens with promising pharmacodynamic effects relating to speed, depth and duration of Immunoglobulin G (IgG) reduction.

About ARGX-113
ARGX-113 is an investigational 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 IgGs. 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 is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune 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(TM) 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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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 related to ARGX-113. 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 the final prospectus related to argenx's initial U.S. public offering filed with the SEC pursuant to Rule 424(b) of the Securities Act of 1933, as amended, 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.