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arGEN-X announces positive preclinical results for ARGX-113

Data support ARGX-113 as a potential breakthrough concept for management of flares in severe autoimmune diseases

19 August 2014

Breda, the Netherlands / Ghent, Belgium – arGEN-X N.V. (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, announced today the results of a preclinical study assessing the pharmacokinetic and pharmacodynamic (PK/PD) behaviors of ARGX-113, the Company's most advanced autoimmune product candidate. The data proved ARGX-113 to be highly effective in rapidly clearing a tracer antibody from circulation in a dose-dependent manner in non-human primates, thus acting as a surrogate of autoantibody clearance.

ARGX-113 is a proprietary antibody fragment based on the company's ABDEG™ technology, which modulates the process of antibody recycling. ARGX-113 works by preventing pathogenic autoantibodies, i.e. those that target and damage healthy tissues, from being recycled, promoting their degradation and thereby removing, or clearing, them from the circulation.

"Pathogenic autoantibodies are a key mediator in a number of serious autoimmune diseases including myasthenia gravis, skin blistering diseases and idiopathic thrombocytopenic purpura (ITP). The potential ability of ARGX-113 to effectively clear the pathogenic autoantibodies from the systemic circulation represents a breakthrough disease management concept," said Torsten Dreier, Ph.D., Chief Development Officer of arGEN-X. "This preclinical PK/PD study provides a solid proof of concept for the ability of ARGX-113 to eliminate pathogenic antibodies, while sparing the broader immune response. We are now preparing for a GLP toxicology study in support of a first clinical study with ARGX-113."

In this preclinical study, non-human primates were administered with ARGX-113, initially in single escalating doses to study the effects of the drug on tracer antibody and total IgG levels. A subsequent phase was completed with optimized, repeat dosing of ARGX-113 to understand the drug's effect on total IgG clearance. Single cycle intravenous immunoglobulin (IVIg) was used as the comparator in the study. IVIg is the current standard of care in treating life-threatening flares in autoimmune diseases. In addition to ARGX-113 proving highly effective in rapidly clearing the tracer antibody from circulation in a dose-dependent manner, the following results were seen:

- Repeat administration of ARGX-113 showed a rapid, transient depletion of total IgG levels, reaching the desired target range and exceeding the effect observed at a single dose.
- Both single and repeat dose administrations of ARGX-113 showed faster and more extensive tracer IgG clearance compared to IVIg.
- Total IgA, IgM and serum albumin levels remained unaffected by ARGX-113 treatment.

arGEN-X expects to submit a Clinical Trial Application (CTA) for ARGX-113 to the applicable regulatory body in the second half of 2015, proposing the initiation of a Phase 1 study in healthy volunteers to establish safety and tolerability of the drug.

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About arGEN-X

arGEN-X is a clinical-stage biopharmaceutical company focused on creating and developing differentiated therapeutic antibodies for the treatment of cancer and severe autoimmune diseases. arGEN-X has generated a pipeline of differentiated clinical and preclinical antibody candidates using its SIMPLE Antibody™ discovery platform. SIMPLE Antibody™ has a particular strength in addressing novel, complex disease targets that are difficult to access using established antibody technology platforms. Proprietary Fc engineering technologies (NHance® and ABDEG™) and POTELLIGENT® technology (licensed from BioWa, inc.) further enhance the therapeutic properties of SIMPLE Antibody™ leads in terms of tissue penetration/residence time in the body, ability to clear disease targets or pathogenic antibodies and cell-killing potency through Antibody-Dependent Cell-mediated Cytotoxicity (ADCC), respectively. arGEN-X has leveraged its suite of antibody technologies in forging strategic collaborations with pharmaceutical and biotechnology companies to provide new approaches to diseases with unmet medical needs.

arGEN-X is listed on the Euronext Brussels exchange under the symbol ARGX.

www.arGEN-X.com

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POTELLIGENT® is a trademark of BioWa Inc.

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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 arGEN-X 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. arGEN-X' actual results may differ materially from those predicted by the forward-looking statements. arGEN-X undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.