arGEN-X completes recruitment of first cohort of 15 patients with CD70-positive solid tumors into its Phase 1b expansion trial with ARGX-110

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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, has completed enrolment of a first cohort of 15 patients with CD70-positive solid tumors into an open-label Phase 1b expansion trial with ARGX-110, a novel anti-CD70 therapeutic antibody. Recruitment of a second cohort of 15 patients with CD70-positive hematological malignancies is ongoing. The primary objective of the expansion trial is to select one or more indications to take forward into further clinical trials.

"We have seen favorable safety profiles, as well as encouraging initial signs of efficacy from the dose escalation portion of the study of ARGX-110 in both solid and hematological tumors. Based on these initial results, we have focused enrollment of the expansion phase on CD70-positive patients with those histologies that have shown biological activity to date," commented Alain Thibault, Chief Medical Officer of arGEN-X. "Enrollment of the second cohort of 15 patients with CD70-positive hematological malignancies is ongoing. We expect to report topline results from the expansion phase of the trial and select indications for further clinical studies in the second half of 2015."

In the initial dose-escalation phase of the Phase 1b study, ARGX-110 demonstrated a good safety profile with no dose-limiting toxicities seen in the 26 patients treated. Encouraging signs of efficacy were also observed, and as of September 2014, prolonged stabilization of disease (progression-free survival of six months or longer) was observed in five patients with renal cell carcinoma, platinum-refractory ovarian cancer, head and neck cancer, myoepithelial carcinoma and mesothelioma, respectively. Two of these patients demonstrated stable disease for over 12 months. In addition, activity was seen in two patients with distinct forms of T-cell lymphoma, one a complete response (CR) in a patient with Sézary syndrome.

About ARGX-110

ARGX-110 is a first-in-class monoclonal antibody that potently blocks CD70-induced tumor proliferation and tumor escape from immune surveillance. In addition, the POTELLIGENT®-enhanced antibody-dependent cellular cytotoxicity (ADCC) of ARGX-110 enables selective destruction of CD70-positive tumor cells. CD70 is overexpressed in the majority of cancer patients tested to date. Expectations of a favorable therapeutic index stem from its virtual absence in healthy tissues.

About the ARGX-110 Phase 1b study

The Phase 1b study (ClinicalTrials.gov Identifier: NCT01813539) with ARGX-110 consists of a dose-escalation phase followed by adaptive safety and efficacy expansion cohorts, one in solid tumors and one in hematological cancers, conducted in patients with advanced, refractory cancer. The patient enrichment strategy relies on individual tumor screening for CD70 utilizing a validated immunohistochemistry method. In addition to traditional clinical and PK/PD endpoints, biomarkers documenting the three modes of action of ARGX-110 are being evaluated. Patient enrolment is

planned at approximately 60 CD70-positive patients with either hematological or solid tumors. The study is managed jointly by arGEN-X and a consortium of leading academic institutions in Belgium.

Data from the study will be used to select one or more indications for further clinical trials.

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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.

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