arGEN-X Completes Recruitment of First Cohort of 15 Patients with CD70-Positive Hematological Malignancies into its Phase 1b Expansion Trial with ARGX-110

Based on evidence of activity, T-cell lymphomas selected as indication for initial efficacy studies

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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 the first expansion cohort of 15 patients with CD70-positive hematological malignancies, part of an ongoing open-label Phase 1b trial with ARGX-110, a novel anti-CD70 therapeutic antibody.

"We are very pleased to have completed recruitment of our first hematology expansion cohort and to advance our development plan for ARGX-110," said Alain Thibault, Chief Medical Officer at arGEN-X. "While we continue to study ARGX-110 across many indications, we saw clear potential in T-cell lymphoma which prompted us to initiate an efficacy study to begin this quarter, nine months ahead of schedule."

Given the breadth of potential of ARGX-110 across many hematological malignancies, the Company designed the adaptive open-label Phase 1b study to allow enrichment of cohorts in select indications based on promising biological activity during the study.

ARGX-110 is concurrently being evaluated in a first expansion cohort of 15 patients with CD-70 solid tumors. Topline results from both the hematological and solid tumor expansion cohorts are expected in the second half of 2015.

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

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 and France.

In the initial dose-escalation of the Phase 1b study, ARGX-110 demonstrated a favorable safety profile with no dose-limiting toxicities seen in the 26 patients treated. Encouraging signs of efficacy were also observed, and as of October 2014, prolonged stabilization of disease (progression-free survival of six months or longer) was observed in patients with renal cell carcinoma, platinum-refractory ovarian cancer, head and neck cancer, and mesothelioma, respectively. Direct antitumor activity was demonstrated in two patients with T-cell lymphoma, including a hematological complete response (CR) in a patient with Sézary syndrome.

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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