NEWS RELEASE

17 December 2013

info@arGEN-X.com | www.arGEN-X.com

ARGX-110, a novel anti-CD70 antibody, meets translational development goals in dose escalation part of Phase Ib cancer study

Dose confirmed for Phase Ib safety and efficacy expansion study

17 December 2013

Breda, The Netherlands / Ghent, Belgium – arGEN-X announces that the dose-escalation part of a Phase Ib study with its lead antibody **ARGX-110** has met its translational development goals: all pre-specified biological activity measures (e.g. target engagement, effector functions, immune-modulation) were met. The study also showed that ARGX-110 has a favourable safety profile and a dose has been selected to advance into the Phase Ib safety and efficacy expansion cohorts, which will start early in 2014 and are expected to report top-line results approximately 12 months later.

ARGX-110 is a first-in-class monoclonal antibody potently blocking 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 favourable therapeutic index stem from its virtual absence in healthy tissues.

In the study, 19 patients with CD70-positive cancer were treated with escalating doses of ARGX-110, up to 10 mg/kg. The results show predictable pharmacokinetics across the dose range. No dose-limiting toxicity was identified. For Ahmad Awada, MD PhD, principal investigator of the study at the Jules Bordet Institute (Brussels, Belgium): “these results, at the clinical and immunological levels, open the door to study further the antibody as a single agent and in combination trials with small molecules and other immune checkpoint inhibitors.”

Based on these data, arGEN-X will begin enrolment to hematology and solid tumor safety and efficacy expansion cohorts early in 2014 and report top-line results approximately 12 months later. According to Alain Thibault, MD, Chief Medical Officer: “We have consistent biomarker data that confirms our understanding of CD70 and the three mechanisms of action of ARGX-110. This is speeding up our program, and we may be in a position to select promising indications for Phase II development by the end of 2014.”

For further information, please contact:

Tim Van Hauwermeiren
Chief Executive Officer
T +32 (0)9 243 40 70

Debbie Allen
Senior Director, Business Development
T +44 7974 979479

E info@arGEN-X.com

arGEN-X BVBA (R&D Center)
Technologiepark 30
9052 Zwijnaarde
Belgium

Mark Swallow
David Dible
Citigate Dewe Rogerson
T +44 207 282 2949

arGEN-X@citigatedr.co.uk

About the ARGX-110 Study

The Phase Ib study (ClinicalTrials.gov Identifier: NCT01813539) consists of a dose escalation followed by adaptive safety and efficacy expansion cohorts conducted in patients with advanced, refractory cancer. The patient enrichment strategy relies on individual tumor screening for CD70 utilizing a reproducible 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 90 CD70-positive patients with either haematological or solid tumors. The study is managed jointly by arGEN-X and a consortium of leading academic institutions in Belgium.

About arGEN-X

arGEN-X is a clinical stage human therapeutic antibody company that is rapidly developing a product pipeline using its unique suite of antibody technologies. arGEN-X is creating first and best in class antibody therapeutics with highly differentiated target product profiles. Its therapeutic antibody programs, focused on cancer and autoimmune indications, are designed to deliver tangible benefits to patients with these diseases.

www.arGEN-X.com

arGEN-X BV Willemstraat 5, 4811 AH Breda, The Netherlands

arGEN-X BVBA Technologiepark 30, 9052 Zwijnaarde, Belgium