NEWS RELEASE

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# arGEN-X starts Phase Ib expansion cohorts with ARGX-110, a novel anti-CD70 antibody, in cancer patients

Study supported by a €3.5 million IWT grant from the Flemish Government

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Breda, The Netherlands / Ghent, Belgium – arGEN-X, a clinical stage human therapeutic antibody company, announces that it has advanced ARGX-110, a novel anti-CD70 antibody, into the safety and efficacy expansion part of its Phase Ib study. The objective is to further investigate the safety of ARGX-110 in CD70-positive cancer patients with either haematological or solid tumors, and to evaluate efficacy in order to select the indications to be studied in Phase II clinical development. Top-line results are expected in about 12 months. The study is being supported by a €3.5 million grant from the Flemish Government's Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT).

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.

In the first part of the Phase Ib study, announced in December 2013, ARGX-110 showed a favorable safety profile, exhibited no dose-limiting toxicities and met all translational development goals (i.e. measures of biological activity such as target engagement, effector functions, and immune-modulation). The open-label Phase Ib expansion aims to enrol up to 75 patients at three clinical centers in Belgium (Institut Jules Bordet, UZA, and UZG) and Institut Gustave Roussy in France.

The expansion phase is part of a broader 'Transformational Medical Research' (TGO) project implemented by arGEN-X in close collaboration with leading Flemish research organizations and clinical centers and supported by IWT. The project aims to develop and further the use of innovative, adaptive clinical trial designs that leverage immunohistochemistry, biomarkers, tissue bank materials as well as clinical data to improve the chances of success with novel drug candidates. The project also involves leading academic research on

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CD70/CD27 signaling for expanding the field of cancer immunotherapy.

"We are excited to advance ARGX-110 into the expansion phase of the study. The data generated in the first phase of the study and in preclinical testing are very encouraging and reinforce our belief in the broad therapeutic potential of ARGX-110 against CD70-positive haematological and solid tumors," said Tim Van Hauwermeiren, Chief Executive Officer. "We are also delighted to receive the IWT grant, which stimulates collaboration across the Flemish life sciences cluster in search of ground-breaking translational medicines, and has provided great support for arGEN-X to advance this innovative study with ARGX-110."

Katrien Swerts, IWT Advisor and TGO coordinator, added: "On the initiative of Minister Lieten, the Flemish Government initiated the TGO program in order to stimulate the development of more effective and affordable medicines. By joining forces with universities and clinical centers, Flemish companies may be able to accelerate to speed with which they bring their innovative drugs to patients. For small and medium-sized companies, the program could have important added value as the financial support will help them test their innovative products in a faster and more extensive way. By initiating its Phase Ib expansion cohorts, arGEN-X proves that this approach is working. The company opted for an adaptive clinical trial design and is now reaping the fruits of this innovative approach."

## 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**

## About IWT

The agency for Innovation by Science and Technology (abbreviated as IWT) is the government agency founded in 1991 by the Flemish Government to support technological innovation projects in Flanders. Each year IWT distributes about EUR 300 million in subsidies for innovation projects to companies, organizations, research and educational institutions in Flanders. In addition to financial support, IWT also assists companies by, for instance helping them find the right information or the right partners at home or abroad, providing assistance with the preparation of projects for European programmes and with technology transfer throughout Europe. IWT also has an important coordination mandate aimed at promoting close cooperation among all the actors involved in technological innovation in Flanders. IWT Monitoring&Analysis, M&A for short, monitors innovation and regularly publishes studies. For more information, please visit www.iwt.be or call +32 2 209 09 00.

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