

# argenx to provide updates on Phase 1/2 clinical trials of ARGX-110 in Acute Myeloid Leukemia and Cutaneous T-Cell Lymphoma during American Society of Hematology Annual Meeting

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Workshop to be held on Monday, December 11<sup>th</sup> at 12:00 pm EST

**December 11, 2017**

**Breda, the Netherlands / Ghent, Belgium** - argenx (Euronext & Nasdaq: ARGX) a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced that it will provide interim data from its Phase 1/2 clinical trial of ARGX-110 in acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) and an update on the Phase 2 part of its clinical trial with ARGX-110 in cutaneous T-cell lymphoma (CTCL) during a workshop being held in conjunction with the American Society of Hematology (ASH) Annual Meeting and Exposition taking place December 9-12, 2017 in Atlanta, Georgia.

The workshop is being held on Monday, December 11, 2017 at 12:00pm EST. A [live webcast](#) of the presentation will be available on the Company's website at [www.agenx.com](http://www.agenx.com). A replay of the webcast will be available for 90 days following the presentation.

argenx is evaluating the safety, tolerability and efficacy of ARGX-110 in an open-label, Phase 1/2 clinical trial in combination with azacitidine in newly diagnosed AML patients unfit for intensive chemotherapy. During the ASH workshop today, argenx will announce interim results from the dose-escalation part of the Phase 1/2 clinical trial highlighting promising preliminary data from the first set of six AML patients. All six patients showed encouraging signs of clinical activity, including complete remission (3/6), complete remission with incomplete blood count recovery (1/6) and partial response (2/6). One of the patients that achieved a complete remission bridged to allogeneic stem cell transplant after five cycles. The preliminary data from the first set of patients suggest ARGX-110 is active both at the circulating and bone marrow blast levels and at the leukemic stem cell (LSC) level.

In addition, further data will be presented from the currently ongoing Phase 1/2 clinical trial of ARGX-110 in relapsed/refractory cutaneous T-cell lymphoma (CTCL) patients with confirmed overexpression of CD70 who have failed at least one line of prior therapy. The interim data analyses are from 22 patients, including 13 patients from the Phase 1 part of the trial, which has completed recruitment, and nine patients from the Phase 2 part of the trial. Of the 22 patients under analysis, there was one complete response, two partial responses and 10 with stable disease. ARGX-110 continues to show a favorable tolerability profile in CTCL patients.

## **Poster presentation at ASH**

argenx collaborators from the University of Bern/Inselspital presented a poster at ASH highlighting the role of hypomethylating agents (HMA) in inducing upregulation of CD70 on LSCs, but not progenitor cells. There were additional data showing the synergistic effect of HMAs in combination with a variant of ARGX-110. More details can be found [here](#). These data further validate the rationale to evaluate ARGX-110 in combination with azacitidine in the ongoing Phase 1/2 clinical trial.

## **About ARGX-110**

ARGX-110 is a SIMPLE Antibody(TM) targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. ARGX-110 is designed to: i) block CD70, ii) kill cancer cells expressing CD70 through complement dependent cytotoxicity, antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity and iii) restore immune surveillance against solid tumors (*Silence K. et al. mAbs*

2014; 6 (2):523-532). ARGX-110 is currently being evaluated in patients with hematological and solid tumors, including a Phase 1/2 trial in combination with azacitidine in patients with newly diagnosed AML and high-risk MDS and the Phase 2 part of a Phase 1/2 trial in patients with relapsed/refractory CTCL. Preclinical work on ARGX-110 in AML was performed in collaboration with the Tumor Immunology Lab of Prof. A. F. Ochsenbein at the University of Bern, who won, together with Prof. Manz from the University Hospital of Zürich, the prestigious 2016 Otto Naegeli Prize for his breakthrough research on CD70/CD27 signaling with therapeutic potential for cancer patients.

### **About argenx**

argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer. We are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Our ability to execute on this focus is enabled by our suite of differentiated technologies. Our SIMPLE Antibody(TM) Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody engineering technologies are designed to enable us to expand the therapeutic index of our product candidates.

[www.agenx.com](http://www.agenx.com)

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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 argenx makes concerning the encouraging clinical data of ARGX-110; argenx's advancement of, and anticipated clinical development and regulatory milestones and plans related to ARGX-110; and 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. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in the final prospectus related to argenx's initial U.S. public offering filed with the SEC pursuant to Rule 424(b) of the Securities Act of 1933, as amended, as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.*