argenx launches Phase II study of ARGX-110 as a monotherapy in relapsed/refractory CTCL patients

Interim data expected by end of 2017

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Breda, the Netherlands/Ghent, Belgium - argenx (Euronext Brussels: 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 the initiation of a Phase II trial of ARGX-110 as a monotherapy in patients with relapsed/refractory cutaneous T-cell lymphoma (CTCL). ARGX-110 is the Company's SIMPLE Antibody(TM) targeting CD70.

"We have previously observed evidence of biological activity and a promising safety profile in several CD70-positive CTCL patients treated in an ongoing Phase I safety-expansion cohort, resulting in several patients with partial response or stable disease. Based on these preliminary results, we opted to further evaluate ARGX-110 as a monotherapy in an exploratory Phase II study to demonstrate the intrinsic activity of the drug in relapsed/refractory CTCL patients and to broaden our efficacy database," commented Nicolas Leupin, CMO of argenx. "This marks the second Phase 1/2 study of ARGX-110 with the first having launched in December 2016 as a combination therapy with standard of care in AML."

The Phase II clinical trial will enroll up to 10 additional relapsed/refractory CTCL patients, and will be conducted at multiple centers in Europe. The primary endpoints of the trial are safety and efficacy and secondary endpoints include pharmacokinetics and immunogenicity. Interim data are expected by the end of 2017, and we expect to report topline data in the second half of 2018.

ARGX-110 is also being studied as a combination therapy with standard of care azacitidine in newly diagnosed, elderly acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS) patients.

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 works in three ways: i) blocks growth of tumor cells, ii) kills cancer cells and iii) restores immune surveillance against tumors (Silence K. et al. mAbs 2014; 6 (2):523-532). ARGX-110 is currently being evaluated in a

Phase II combination trial in patients with newly diagnosed acute myeloid leukaemia (AML) and high-risk myelodysplastic syndrome and a Phase II trial in patients with relapsed/refractory cutaneous T-cell lymphoma (CTCL). Preclinical work on ARGX-110 in AML was done 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 CTCL

Lymphoma is the most common type of blood cancer. TCL accounts for 6% of all cases of lymphoma and can be divided into subtypes such as peripheral TCL (PTCL), angioimmunoblastic TCL (AITL), anaplastic large cell lymphoma (ALCL), and CTCL. According to the Cutaneous Lymphoma Foundation, the incidence of CTCL in the United States is approximately 3,000 new cases per year. The two most common types of CTCL are mycosis fungoides, representing approximately 50% of CTCL patients, and a more advanced form known as Sezary syndrome, representing approximately 15% of CTCL patients. In both mycosis fungoides and Sezary syndrome, visible skin lesions offer an ongoing means with which to monitor both the progression of disease and the impact of treatment. Sezary syndrome is distinguished by the presence of malignant lymphocytes in the blood, an extensive rash covering over 80% of the body and tumors visible on the skin.

About argenx

argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune 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 AntibodyTM 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.

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