SYNIMMUNE GmbH Initiates First-in-Human Study of Fc-Optimized Antibody FLYSYN for the Treatment of Acute Myeloid Leukemia

Tuebingen, 30 May 2017 - SYNIMMUNE GmbH, a biotechnology company focusing on the development of innovative and effective anti-tumor antibodies for orphan hematopoietic malignancies, announced today that the Company has recently initiated a *first-in-human* clinical study of FLYSYN, a novel Fc-optimized antibody, for the treatment of acute myeloid leukemia (AML).

The phase I study of FLYSYN is being conducted at the University Hospital Tuebingen and at the University Hospital Ulm in Germany and will enroll up to 28 AML patients with minimal residual disease. Four patient cohorts will receive increasing doses of FLYSYN, each as a single intravenous infusion. The dose escalation phase will be followed by an expansion cohort phase to assess initial efficacy.

The primary endpoints of the study are safety and tolerability. Secondary endpoints include immunogenicity, pharmacokinetics and pharmacodynamics as well as preliminary efficacy in terms of overall response rate and duration of response. Patients will be followed for up to 18 months. Preliminary results from the trial are expected in 2018, the trial is projected to complete in early 2019.

“The initiation of this phase I study with FLYSYN is a major milestone for SYNIMMUNE, as this is the first antibody from our pipeline to be tested in humans,” said Dr. Martin Steiner, CEO of SYNIMMUNE GmbH. “The key goals of this study are to determine the maximum tolerated dose and to assess the preliminary therapeutic effect of FLYSYN in AML patients with minimal residual disease. Today, the majority of these patients relapse within several months. Our antibody is intended to delay or even prevent such relapse. We therefore believe that, if proven safe and effective, FLYSYN could become an attractive treatment option for many AML patients.”

About FLYSYN:

The chimeric and Fc-optimized IgG1 antibody FLYSYN binds specifically and with high avidity to the human *fms*-like tyrosine kinase 3 (FLT3). An increased expression of this cell surface receptor is measured on leukemic blast cells in 70-100% of AML patients, while only small amounts of FLT3 are expressed on monocytes and progenitor stem cells, avoiding off-target binding and stem cell toxicity. Therefore, FLT3 is a suitable and highly selective target for therapeutic antibodies to treat leukemia patients. FLYSYN contains a genetic optimization of its Fc-part, resulting in optimized binding to cells expressing the Fc receptor, particularly Natural Killer (NK) cells, and thus in substantially improved antibody-dependent cell-mediated cytotoxicity (ADCC).

FLYSYN is a monospecific antibody for the treatment of AML patients at a stage of minimal residual disease (MRD). Most AML patients achieve complete remission (CR) with MRD after regular chemotherapy, but the majority relapses to AML within several months, requiring additional courses of chemotherapy or stem cell transplantation. FLYSYN is intended to delay or prevent such relapse in AML patients with MRD.

About SYNIMMUNE:

SYNIMMUNE GmbH is a biotechnology company dedicated to the development of innovative and effective mono- and bispecific anti-tumor antibodies for the treatment of patients suffering from life-threatening diseases, with a focus on orphan hematopoietic malignancies. SYNIMMUNE's lead product candidate is the antibody FLYSYN, which is currently in a *first-in-human* phase I clinical study in acute myeloid leukemia (AML). SYNIMMUNE GmbH is a spin-off of the Department of Immunology of the University of Tuebingen. The Company is financed by grants from the German Ministry of Education and Research (BMBF) within its GO-Bio program as well as investments by the German KfW and private equity. For more information, please visit: www.synimmune.de

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