

## **SYNIMMUNE GmbH Reports Interim Results of First-in-Human Study of Fc-Optimized Antibody FLYSYN for the Treatment of Acute Myeloid Leukemia**

**Tübingen, Germany, 10 December 2019** - SYNIMMUNE GmbH, a biotechnology company focusing on the development of innovative and effective anti-tumor antibodies for orphan hematopoietic malignancies, announced today that interim results of its first-in-human clinical study of FLYSYN, a novel Fc-optimized antibody, for the treatment of acute myeloid leukemia (AML) were presented at the 61<sup>st</sup> American Society of Hematology (ASH) Annual Meeting in Orlando, Florida. The data were presented in a poster titled “Interim Results of a First in Human Study with the Fc-Optimized FLT3 Antibody FLYSYN for Treatment of Acute Myeloid Leukemia with Minimal Residual Disease”.

The phase I study of FLYSYN is being conducted at multiple centers in Germany (University Hospitals of Tübingen, Ulm, Heidelberg, Hanover and Leipzig) and will enroll up to 31 AML patients that have achieved a complete morphological remission but display minimal residual disease (MRD). The poster reports on an interim analysis of 21 adult patients (median age: 60 years) who were treated in 5 cohorts receiving a single administration of increasing doses of FLYSYN (0.5 to 45 mg/m<sup>2</sup> body surface area).

FLYSYN was very well tolerated and only one patient experienced grade 3 neutropenia which was potentially related to FLYSYN treatment. Other adverse events of grade 1 or 2 included gastrointestinal toxicities and laboratory abnormalities which were manageable with supportive care. No dose limiting toxicities occurred during the dose-escalation phase and no anti-drug antibodies were detected after treatment.

A total of 7 patients (33%) achieved an MRD response defined as a log reduction of expression of an MRD marker gene and one patient achieved an enduring complete molecular remission (MRD negative) for more than one year.

“Our data indicate that FLYSYN is safe and very well tolerated. The preliminary efficacy data are promising. We are very much looking forward to further test FLYSYN as monotherapy for MRD positive AML patients,” commented Prof. Helmut Salih, Principle Investigator of the study and Medical Director of the Clinical Collaboration Unit Translational Immunology at Tübingen University Hospital.

“These interim results are very encouraging and we are looking forward to further results from the last treatment cohort of 10 patients who will receive three repetitive doses of 15 mg/m<sup>2</sup> body surface area of FLYSYN by mid-2020,” said Dr. Martin Steiner, CEO of SYNIMMUNE GmbH. “Today, the majority of AML patients with MRD relapse within several months. We are looking forward to continue development of FLYSYN, which is intended to delay or even prevent such relapse, and we believe that FLYSYN could become an attractive maintenance 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 myeloid precursor cells in 70-100% of AML patients, while only small amounts of FLT3 are expressed on monocytes and progenitor stem cells, thereby avoiding off-target effects 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 Natural Killer (NK) cells and thus 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 GmbH:**

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 Tübingen initially supported by the GO-Bio program from the German Ministry of Education and Research (BMBF). The Company is financed by investments by the German KfW and private equity. For more information, please visit: [www.synimmune.de](http://www.synimmune.de)

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