

Press Release

Preclinical Efficacy Data of Apogenix' APG101 in Myelodysplastic Syndromes (MDS) Published in *Oncotarget*

Data Demonstrate Potential of APG101 for Treatment of MDS

Heidelberg, Germany, Mar. 24, 2016 – Apogenix, a biopharmaceutical company developing next generation immuno-oncology therapeutics, announced today that the [data published in the current issue of *Oncotarget*](#) demonstrate that APG101 rescues the production of red blood cells (erythropoiesis) in bone marrow samples from patients with lower-risk myelodysplastic syndromes (MDS). By inhibiting their apoptosis, APG101 increases the number of erythrocyte precursor cells ex vivo and improves their overall proliferation rate. The observational study shows that CD95 – a receptor that can induce apoptosis of cells when triggered by the CD95 ligand – is overexpressed in two thirds of patients with lower-risk MDS, and that overexpression of CD95 is predictive of a lower response rate to erythropoiesis-stimulating agents. Erythroid response to APG101 could especially be observed in samples from MDS patients with severe impairment of erythropoiesis.

“APG101 added to cellular assays efficiently rescued the growth of erythroid progenitors in MDS patients harboring a profound defect of erythropoiesis, independent of the expression level of CD95 or CD95 ligand,” said Prof. Michaela Fontenay, corresponding author of the publication, from the Institut Cochin in Paris, France. “This study provides a rationale for further clinical investigation of this potential new therapeutic option in patients with severely impaired erythropoiesis who are resistant to erythropoiesis-stimulating agents.”

“The results of this study clearly illustrate the potential of APG101 in the treatment of lower-risk MDS patients with severe impairment of erythropoiesis,” said Harald Fricke, M.D., Chief Medical Officer of Apogenix. “Since these patients generally fail to respond to erythropoiesis-stimulating agents, there are currently no treatment options available for them. In a phase I trial in transfusion-dependent low to intermediate I risk MDS patients, Apogenix has evaluated the safety, tolerability, and efficacy of APG101. We expect the results of this clinical trial in the coming months.”

The paper titled “APG101 efficiently rescues erythropoiesis in lower risk myelodysplastic syndromes with severe impairment of hematopoiesis” was published in *Oncotarget*, Volume 7, Number 12.

About Apogenix

Apogenix develops innovative immuno-oncology therapeutics for the treatment of cancer and other malignant diseases. The company has built a promising pipeline of immuno-oncology drug candidates that target different tumor necrosis factor superfamily (TNFSF)-dependent signaling pathways, thereby restoring the immune response against tumors. Since its inception in fall 2005, Apogenix has raised more than 90 million euros in financing rounds, public grants, as well as upfront and milestone payments from licensing agreements. The company is based in Heidelberg, Germany.

About Myelodysplastic Syndromes (MDS)

MDS is a bone marrow disorder that is characterized by ineffective hematopoiesis and can lead to severe anemia. In most cases, the anemia is treated with blood transfusions that eventually result in an iron overload, which can damage the liver and other organs. At the same time, the number of thrombocytes that are responsible for coagulation and the number of leucocytes that are responsible for immune defense are significantly decreasing. As a result, MDS patients frequently suffer from sudden bleeding and life-threatening infections. In addition, they are at risk for developing acute myeloid leukemia, a type of blood cancer. A variety of different parameters are taken into account to assess the risk of developing AML. The International Prognostic Scoring System (IPSS) classifies MDS patients into four risk groups – low risk, intermediate I risk, intermediate II risk, and high risk. APG101 is being developed for patients with low and intermediate I risk.

About APG101

Apogenix' lead immuno-oncology candidate APG101 is a fully human fusion protein that consists of the extracellular domain of the CD95 receptor and the Fc domain of an IgG antibody. APG101 is being developed for the treatment of solid tumors and malignant hematological diseases. By blocking the CD95 ligand, which inhibits erythrocyte production in MDS patients, APG101 directly addresses the cause of the disorder and could thus provide a cure for MDS.

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