Press Release

Apogenix Reports Topline Results from Phase I Trial in Myelodysplastic Syndromes with APG101

Data Show that APG101 Decreases Number of Transfusions in Low to Intermediate-1 Risk Transfusion-Dependent MDS Patients

Heidelberg, Germany, June 15, 2016 – Apogenix, a biopharmaceutical company developing next-generation immuno-oncology therapeutics, today announced final topline results from a Phase I trial evaluating APG101 in low to intermediate-1 risk transfusion-dependent patients with myelodysplastic syndromes (MDS). The study showed that APG101 was well tolerated. In addition, the trial showed that APG101 efficiently stimulates erythropoiesis in these patients.

The single arm Phase I trial enrolled twenty patients with low to intermediate-1 risk MDS who were transfusion dependent. Patients had to be refractory to erythropoietin-stimulating agents (ESAs). The patients were treated with APG101 over a period of three months and followed for an additional six months. An extension of treatment was not intended. The primary objectives of the study were safety and tolerability. Secondary objectives included changes in transfusion frequency and changes in parameters involved in erythropoiesis.

In the study, treatment with APG101 led to a significant decrease in transfusion frequency for more than six months (end of follow up period) in 44% of the patients. In addition, measurements of parameters involved in erythropoiesis (i.e., number and function of progenitor cells) further supported the activity of APG101 in this patient population. This evidence of *in vivo* activity of APG101 confirms *in vitro* data recently published (Oncotarget Vol. 7 No. 12, 2016). More details from the final results of the study are being submitted for presentation at a major medical meeting later this year.

“The topline data from this Phase I trial continue to support the activity of APG101 in MDS patients,” said Harald Fricke, M.D., Chief Medical Officer. “We were particularly excited to see that APG101 appeared to decrease the number of transfusions required by this very sick patient population. Our next step will be to initiate a Phase II trial in MDS to evaluate APG101 in various doses in combination with an erythropoietin-stimulating agent, and we are currently soliciting input from key opinion leaders on the design of that trial.”

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 significantly decrease in patients with this disorder. As a result, MDS patients frequently suffer from sudden bleeding and life-threatening infections. In addition, they are at risk of developing acute myeloid leukemia, a type of blood cancer.

About APG101

Apogenix's 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 negatively regulates erythrocyte production in MDS patients, APG101 directly addresses the cause of the disorder and could thus potentially provide a cure for MDS.

About Apogenix

Apogenix is a private company developing 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.

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