Press Release

Apogenix Reports Final Phase I MDS Data at this Year´s American Society of Hematology (ASH) Meeting

CD95-ligand inhibitor asunercept with novel mechanism of action shows clinical efficacy in Phase I trial for treatment of low and intermediate risk patients suffering from myelodysplastic syndromes (MDS)

Heidelberg, Germany, December 5, 2016 – Apogenix, a biopharmaceutical company developing next-generation immuno-oncology therapeutics, today announced that the final data from the Phase I clinical trial evaluating the safety and efficacy of asunercept (APG101) in lower (low and intermediate) risk patients with MDS were presented in an oral presentation at this year´s ASH meeting on December 3, 2016 in San Diego, CA, USA.

Asunercept is a fusion protein consisting of the extracellular domain of human CD95-receptor and the Fc domain of a human IgG1 antibody. Asunercept binds to the CD95-ligand on cells as well as to the soluble ligand, thus blocking the interaction between CD95-receptor and its cognate ligand. CD95-receptor is overexpressed on erythroid progenitor cells in the majority of patients with lower-risk MDS. Activation of CD95-receptor blocks erythrocyte production in the bone marrow. Its overexpression is a predictive factor of resistance to erythropoiesis stimulating agents (ESAs).

In this Phase I study, all 20 patients enrolled were eligible for inclusion if they suffered from anemia resulting in a high transfusion burden, had hemoglobin levels of less than 10 g/dL, and were refractory to ESAs. Patients received once-weekly asunercept infusions for 12 weeks. Eight of the 20 patients (40%) showed a marked reduction of transfusion frequency for 6 months (end of observation period). Asunercept was generally well tolerated with no reported grade 3 or higher related adverse events. The most common treatment-emergent adverse events included peripheral edema (6 patients), urinary tract infection (4 patients), and oral herpes (3 patients).

“MDS patients display inappropriately increased CD95-receptor mediated signaling in the bone marrow, resulting in ineffective erythropoiesis,” Prof W.K. Hofmann, head of the Department of Oncology & Hematology at the University Mannheim Heidelberg and study investigator, explained. “Asunercept inhibits this signaling pathway and promotes early- and late-stage erythroid differentiation, thereby correcting the ineffective erythropoiesis.”

“Even though the study was only designed as a safety and pharmacodynamic Phase I trial, the results of short-term asunercept treatment in lower-risk MDS patients are very exciting,” Harald Fricke, MD, Chief Medical Officer of Apogenix, said. “There is a substantial unmet medical need for patients who are refractory to treatment with ESAs and we look forward to continuing development of asunercept for this important indication.”

Based on the effect of asunercept on early- and late-stage erythroid differentiation and the encouraging clinical activity in these patients, additional clinical Phase II studies are in preparation to test asunercept in lower-risk MDS patients with resistance to ESA treatment.

About Asunercept (APG101)

Apogenix's lead immuno-oncology candidate asunercept is a fully human fusion protein that consists of the extracellular domain of the CD95-receptor and the Fc domain of an IgG1 antibody. Asunercept is being developed for the treatment of solid tumors and malignant hematological diseases. The World Health Organization (WHO) has recently assigned the international nonproprietary name (INN) "asunercept" for APG101.

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 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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