Press Release

Apogenix Granted Orphan Designation by the European Commission for Asunercept to Treat Myelodysplastic Syndromes

Orphan designations facilitate the development and authorization of medicines for rare diseases, as assessed by the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products

Heidelberg, Germany, October 05, 2017 – Apogenix AG, a biopharmaceutical company developing next-generation immuno-oncology therapeutics, announced today that its lead product candidate, asunercept (APG101), has been granted orphan designation from the European Commission (EC) for the treatment of myelodysplastic syndromes (MDS). MDS is a bone marrow disorder characterized by ineffective hematopoiesis (blood cell formation) and can lead to severe anemia. Patients often suffer from life-threatening infections and are at risk of developing acute myeloid leukemia.

Orphan designation includes access to a centralized marketing authorization procedure for the European Union, ten years of protection from market competition with similar medicines in similar indications and fee reductions for consultations with the EMA. Earlier, asunercept received Orphan Drug Designation for MDS from the US Food and Drug Administration (FDA).

Dr. Harald Fricke, Chief Medical Officer of Apogenix, commented: "The vast majority of patients suffering from MDS are anemic and dependent on frequent regular blood transfusions. Asunercept prevents premature death of red blood cells in the bone marrow and thus reduces the need of blood transfusions, even making them superfluous in many patients. We are highly encouraged by the data from our clinical phase I trial with asunercept in these patients and are currently preparing to initiate a clinical phase II proof-of-concept trial to further evaluate the efficacy of asunercept in MDS."

Asunercept has been evaluated in an open label, single-arm phase I clinical trial in 20 patients with low to intermediate risk MDS, in which treatment with asunercept was well tolerated and led to a significant decrease in transfusion frequency. In addition, investigation of parameters involved in erythropoiesis delineated how asunercept stimulates the production of red blood cells in these patients.

Asunercept binds to the CD95 ligand (CD95L) and blocks the activation of the CD95 receptor. Excessive stimulation of the CD95 receptor on hematopoietic precursor cells in the bone marrow of MDS patients inhibits erythropoiesis. As a result, transfusion-dependent anemia develops, which is refractory to erythropoiesis-stimulating agents. Treatment with asunercept, which inhibits the CD95 system, addresses this major cause of the disorder.

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 decreases 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 asunercept (APG101)

Apogenix' 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 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 100 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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