Press Release

Apogenix Announces Oral Presentation on APG101 at Upcoming 58th American Society of Hematology (ASH) Meeting & Exposition

Final Phase I trial data with APG101 in myelodysplastic syndromes to be presented

CD95-ligand inhibitor APG101 with novel mechanism of action and potential to treat disease in a new way

Heidelberg, Germany, November 3, 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 (i.e., pharmacodynamic effects on erythropoiesis) of APG101 in lower (low to intermediate) risk patients with myelodysplastic syndromes (MDS) will be presented at the upcoming American Society of Hematology (ASH) Annual Meeting & Exposition being held December 3-6, 2016 in San Diego, CA, USA.

APG101 is a fusion protein consisting of the extracellular domain of human CD95 and the Fc domain of human IgG1. APG101 binds to the CD95 ligand on effector cells as well as to soluble ligand, thus blocking the interaction between CD95 and its ligand. CD95 is overexpressed on erythroid progenitor cells in the majority of patients with lower risk MDS. Activation of CD95 negatively regulates erythrocyte production in the bone marrow and CD95 overexpression and transfusion dependency are independent predictive factors of resistance to erythropoiesis stimulating agents (ESAs). Evidence exists that, in lower risk MDS, increased apoptosis of erythroid progenitors mediated via CD95 activation results in peripheral cytopenia (i.e., anemia).

In the 20-patient study, APG101 appeared to be well tolerated in heavily transfusion-dependent lower risk, elderly, MDS patients refractory to treatment with ESAs. Treatment with APG101 was limited to 12 weeks and patients were then followed for another 24 weeks. In eight patients (40%), a significant decrease in transfusion frequency from treatment until the end of the study was observed. One patient even became transfusion independent at week 25.

Details of the presentation are as follows:
Safety and Efficacy of the CD95-Ligand Inhibitor APG101 in Transfusion-Dependent Patients with Low Risk MDS: Results from a Phase I/II Study

Abstract #228

Session Name: 637. Myelodysplastic Syndromes—Clinical Studies: Lower Risk MDS Clinical Studies

Session Date and Time: Saturday, December 3, 2016, 4:00 PM - 5:30 PM

Presentation Time: 5:15 PM

Room: Manchester Grand Hyatt San Diego, Grand Hall C

The abstract is now online on the ASH website and can be accessed here.

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 erythrpoiesis in MDS patients, APG101 potentially represents a new and innovative treatment option for anemia (and possibly other cytopenias) in 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 2005, Apogenix has raised more than 90 million euros in financing rounds and public grants, as well as upfront and milestone payments from licensing agreements. The company is based in Heidelberg, Germany.

Contact

Thomas Hoeger, Ph.D., CEO
Apogenix AG
Phone: +49 (6221) 58 60 80
E-Mail: contact@apogenix.com
Web: www.apogenix.com

Media Contacts

USA:
Matt Middleman, M.D.
Russo Partners, LLC
Phone: +1 (212) 845 4272
matt.middleman@russopartnersllc.com

Europe:
Katja Arnold, Shaun Brown
MC Services AG
Phone: +49 (89) 210 228 0
apogenix@mc-services.eu