

Press Release

Publication in *Cancer Management and Research* Underlines the Potential of Apogenix' Asunercept for the Treatment of Other Malignancies Beyond Glioblastoma and MDS

Heidelberg, Germany, September 2, 2019 – Apogenix, a biopharmaceutical company developing next generation immuno-oncology therapeutics, announced today that a [new publication in *Cancer Management and Research*](#)¹ reviews asunercept as a promising treatment option for patients with other malignancies beyond glioblastoma and myelodysplastic syndromes (MDS). Published evidence suggests that CD95 and CD95 ligand (CD95L) play a critical role in maintaining T cell responses in the tumor microenvironment (TME). CD95/CD95L signaling has been shown to promote the escape of tumor cells from immune surveillance and their resistance to available therapeutic options. It further affects the differentiation and infiltration of T-effector cells into the TME, suggesting that CD95L may act as an immune checkpoint. As high levels of CD95L have been detected in tissue samples of patients with melanoma, breast, colon, renal, bladder, prostate, head and neck, pancreatic, and ovarian cancer, the inhibition of the CD95/CD95L pathway with asunercept may represent a promising novel therapeutic approach in cancer immunotherapy.

Asunercept is a first-in-class, fully human fusion protein that selectively binds to CD95L, thereby disrupting CD95/CD95L signaling. In a proof-of-concept phase II trial in patients with recurrent glioblastoma, treatment with asunercept in combination with radiotherapy has demonstrated clinical efficacy compared to treatment with radiotherapy alone. The five-year overall survival rate for patients treated with asunercept in combination with radiotherapy was 7 percent compared to 0 percent of patients treated with radiotherapy alone. No drug-related serious adverse events were observed during treatment with asunercept in combination with radiotherapy, underlining the very good safety and tolerability of asunercept. Moreover, as presented at ASCO 2019, treatment with asunercept in combination with radiotherapy significantly prolonged the time to deterioration and maintained the quality of life for patients with recurrent glioblastoma versus radiotherapy alone.

As a selective CD95L inhibitor, asunercept offers broad potential applicability to other malignancies with abnormal CD95/CD95L signaling. In MDS, for example, asunercept protects erythroid progenitors from CD95L-induced apoptosis, thereby restoring erythropoiesis. In a clinical trial in patients with low and intermediate-I-risk MDS, asunercept stimulated erythropoiesis and led to a clear decrease in transfusion frequency.

Targeting the CD95/CD95L pathway with asunercept may therefore constitute an innovative treatment approach for MDS and other hematological malignancies characterized by high levels of CD95L expression. Combined with its potential in solid tumors beyond glioblastoma, asunercept represents a promising treatment option for a variety of cancer indications and warrants further clinical investigation.

¹ Krendyukov A and Gieffers C (2019). Asunercept as an innovative therapeutic approach for recurrent glioblastoma and other malignancies. *Cancer Manag Res.* 11:8095-8100. doi: 10.2147/CMAR.S216675



About Apogenix

Apogenix is a private company developing innovative immuno-oncology therapeutics for the treatment of solid tumors and hematological malignancies. The company's pipeline of immuno-oncology drug candidates targets different tumor necrosis factor (TNF) superfamily-dependent signaling pathways, thereby restoring the immune response against tumors. Checkpoint inhibitor asunercept, the company's lead immuno-oncology candidate, is in late-stage clinical development with PRIME (PRiority MEDicines) designation by the European Medicines Agency for the treatment of glioblastoma. Based on its proprietary technology platform for the construction of novel TNF superfamily receptor agonists (HERA-ligands), Apogenix develops CD40, CD27, GITR, HVEM, and 4-1BB receptor agonists for cancer immunotherapy. The TRAIL receptor agonist program was outlicensed to AbbVie. AbbVie has initiated a phase I trial with TRAIL receptor agonist ABBV-621 in patients suffering from solid tumors, non-Hodgkins's lymphoma, or acute myeloid leukemia.

About Asunercept

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. It is being developed for the treatment of solid tumors and hematological malignancies. Asunercept was granted orphan drug designation for the treatment of glioblastoma and myelodysplastic syndromes (MDS) in both the EU and the US and PRIME (PRiority MEDicines) designation by the European Medicines Agency for the treatment of glioblastoma. Asunercept is exclusively licensed to CANbridge Life Sciences under a development and commercialization license covering China, Macao, Hong Kong, and Taiwan.

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