

Press Release

Apogenix – Positive Results from APG101 Phase II Clinical Trial Published in *Clinical Cancer Research*

Heidelberg, Germany, Oct. 28, 2014 – Apogenix, a clinical stage biopharmaceutical company, announced today that the final data of the completed phase II clinical trial with APG101 in recurrent glioblastoma has been published in the peer-reviewed journal *Clinical Cancer Research*.

The data demonstrates that treatment with APG101, a CD95 ligand-binding fusion protein, in combination with radiotherapy is an innovative concept that has shown clinical superiority in all study endpoints compared to treatment with radiotherapy alone. Both progression-free survival at six months, the primary endpoint of the trial, and median progression-free survival were met with statistical significance. In addition, an epigenetic biomarker was identified that indicates response to treatment with APG101. The trial showed a significant increase in median overall survival in biomarker-positive patients treated with APG101, as previously reported.

“The development of a companion diagnostic based on this epigenetic biomarker will allow the identification of glioblastoma patients most likely to benefit from treatment with APG101,” said Harald Fricke, M.D., Chief Medical Officer of Apogenix. “We are working closely with the regulatory authorities to make APG101 available to patients as soon as possible.”

The abstract of the publication can be accessed at the website of [Clinical Cancer Research](#).

About the Phase II Trial in Recurrent Glioblastoma

A total of 84 patients at 25 clinical sites in Germany, Austria, and Russia participated in this randomized controlled phase II efficacy trial in recurrent glioblastoma. Patients were eligible for inclusion if they suffered from first or second relapse of glioblastoma and were refractory to standard therapy. Patients randomized into the APG101 arm were treated until further disease progression. At this time, five surviving patients in the treatment group and one patient in the control group are still being monitored in order to collect overall survival data.

About Apogenix

Apogenix develops protein therapeutics that could transform the treatment of life-threatening diseases by targeting critical pathways involved in the growth, migration, and apoptosis of diseased cells. The company’s lead drug candidate APG101 is currently being evaluated in patients with glioblastoma – a disease with a tremendous need for new and effective therapies. A randomized controlled phase II trial in recurrent glioblastoma has shown that APG101 prolongs overall survival and improves quality of life, while exhibiting an excellent safety profile. Apogenix is also developing a companion diagnostic to identify patients who may respond best to treatment with APG101.

Since its inception in fall 2005, Apogenix has raised more than 50 million euros from its investors and was awarded public grants totaling 8.5 million euros. The company is based in Heidelberg, Germany.



About APG101

Apogenix' lead drug candidate APG101 is a fully human fusion protein that consists of the extracellular domain of the CD95 receptor and the Fc portion of an IgG antibody. The interaction between the CD95 ligand and the CD95 receptor activates an intracellular signaling pathway that stimulates the invasive growth and migration of tumor cells, such as glioblastoma cells. APG101 binds to the CD95 ligand and thus inhibits activation of the CD95 signaling pathway, resulting in reduced tumor cell growth and migration. APG101's unique mode of action supports its significant potential for the treatment of other life-threatening diseases, such as myelodysplastic syndromes as well as solid tumors beyond glioblastoma. APG101 was granted orphan drug status for the treatment of glioma in the EU and for the treatment of glioblastoma and myelodysplastic syndromes in the US.

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