

## Press Release

### **Apogenix' APG101 Demonstrates Significant Prolongation of Overall Survival in Biomarker-Positive Patients in Phase II Trial for the Treatment of Recurrent Glioblastoma**

#### **Topline Data Will Be Presented at Biotech Showcase**

- **Identification of a predictive epigenetic biomarker**
- **Significant increase in median overall survival in biomarker-positive patients (p=0.003)**
- **Excellent safety profile and very good tolerability of APG101**

**Heidelberg, Germany, Jan. 13, 2014** – Apogenix, a clinical stage biopharmaceutical company, announced today the successful completion of its phase II proof-of-concept trial with APG101 in patients with recurrent glioblastoma. All endpoints of the randomized controlled trial that compared the efficacy and safety of a combination therapy of APG101 and radiotherapy versus radiotherapy alone were achieved or exceeded. During treatment with APG101 for up to two years, no drug-related serious adverse events were observed, underlining the excellent safety profile and very good tolerability of APG101. The study's primary endpoint – progression-free survival at six months (PFS6) – was met with a statistically significant fivefold improvement in the rate of patients reaching PFS6, as previously reported. The results demonstrate that patients having a newly-identified epigenetic biomarker associated with the CD95 ligand – the target of APG101 – experienced the greatest benefit from treatment with APG101. The trial showed a statistically significant (p=0.003) prolongation of overall survival in biomarker-positive patients treated with APG101, with a median overall survival of 16.1 months compared to 6.5 months in patients treated with radiotherapy alone. This biomarker will be validated in future clinical trials and in additional indications.

“The results of the trial have exceeded our expectations,” said Harald Fricke, M.D., Chief Medical Officer of Apogenix. “Besides Temodar® and Gliadel®, APG101 is the first drug candidate in nearly 20 years that has demonstrated a substantial increase in overall survival in a randomized controlled phase II trial. All clinical endpoints show a clear advantage of the treatment group over the control group and thus demonstrate the clinical efficacy of APG101 in the treatment of recurrent glioblastoma.”

“We are currently developing a companion diagnostic to identify patients who will most likely respond best to treatment with APG101, so glioblastoma patients can benefit from a personalized treatment approach. Apogenix is in close consultation with the regulatory authorities EMA and FDA to agree on a development strategy toward rapid approval of APG101 for the treatment of glioblastoma,” Harald Fricke added.

The complete data set will be published in a high-impact medical journal. Thomas Hoeger, Ph.D., Chief Executive Officer of Apogenix, will present a summary of the results at the Biotech Showcase™ in San Francisco. The presentation will take place on Tuesday, Jan. 14, at 4 p.m. PST at the Parc 55 Wyndham San Francisco – Union Square.

### **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, there are still seven surviving patients in the treatment group and one patient in the control group who are 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.

### **Contact**

Thomas Hoeger, Ph.D., CEO/CFO  
Apogenix GmbH  
Phone: +49 (6221) 58 60 80  
E-Mail: [contact@apogenix.com](mailto:contact@apogenix.com)  
Web: [www.apogenix.com](http://www.apogenix.com)

### **Media Contacts**

USA:  
Martina Schwarzkopf, Ph.D.  
Russo Partners, LLC  
Phone: +1 (212) 845 4292  
[martina.schwarzkopf@russopartnersllc.com](mailto:martina.schwarzkopf@russopartnersllc.com)

Europe:  
Raimund Gabriel  
MC Services AG  
Phone: +49 (89) 210 228 30  
[raimund.gabriel@mc-services.eu](mailto:raimund.gabriel@mc-services.eu)