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Apogenix: APG101 Exceeds Expectations with Controlled Phase II Clinical Trial

The biopharmaceutical company Apogenix GmbH announced today that the phase II clinical proof of concept trial with APG101 as treatment of recurrent glioblastoma has met and exceeded expectations in the final analysis of the data. In this randomized controlled clinical study the patients were treated either with a combination of APG101 plus radiotherapy (APG101+RT group) or radiotherapy alone (RT group). The primary objective of the trial was to increase the percentage of patients reaching progression free survival for six months (PFS6) by >100 percent.

In addition, all the important secondary endpoints evaluated so far, including safety and tolerability, indicate that APG101 is a potent new treatment option for glioblastoma, with an excellent safety profile. The quality of life (QoL) as measured by a standardized questionnaire was maintained and even improved in 67 percent of the patients in the APG101+RT group, but worsened in 66 percent of patients in the RT Group. In addition, in more than 50 percent of the APG101 treated patients medication with corticosteroids could be reduced or even stopped compared to only 28 percent of patients from the RT group. During treatment with APG101 for up to two years, no drug-related serious adverse events were observed.

Prof Wolfgang Wick of the Clinical Cooperation Unit Neuro-Oncology, German Cancer Research Center and Department of Neuro-Oncology, University Hospital of Heidelberg, the Principle Investigator, said: "The present study is an unexpectedly huge step forward in the development of new and innovative therapeutic concepts for patients with glioblastoma. The magnitude of the therapeutic effect of APG101 compensated the relatively small size of the study. More than 20 percent of relapsed patients being free of progression after 6 months in a controlled trial was last observed some 10 years ago when temozolomide was introduced into the care of glioblastoma patients."

Better treatment of brain tumors confirmed

"The immediate patient benefit of APG101 is substantiated by the positive effect of the compound on the quality of life. This study represents a new development in the treatment of brain tumors that not only promises a clinical benefit but proves it in a randomized controlled clinical study and thus fuels the hope for better patient care," Prof Wick added. "The trial was designed as a randomized controlled phase II proof of concept study in GBM, which is an exception in phase II development, but in this way it was clearly demonstrated to our investors and potential licensing partners that APG101 is efficacious and offers a new treatment option for glioblastoma patients," said Dr Harald Fricke, Chief Medical Officer of Apogenix GmbH. "We will now accelerate discussions with a number of pharma and biotech companies to decide on the next development steps plus potential new indications in order to make this innovative drug available to patients as soon and as widely as possible."

The phase II, open label, randomized clinical trial recruited 84 patients in 25 centers throughout Germany, Austria, and Russia. Glioblastoma patients were eligible for inclusion if they had suffered from a first or second relapse and if they no longer responded to treatment with temozolomide. Patients participated in this study until tumour progression. Apogenix is currently planning a phase II proof of concept trial with APG101 in Myelodysplastic syndromes (MDS). The trial is expected to begin in the first half 2013.

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