Press Release

Apogenix’ APG350 Effectively Induces Apoptosis of Tumor Cells via TRAIL Pathway Independent of Fcγ Cross-Linking

Data Published in *Molecular Cancer Therapeutics* Underlines Potential of Drug Candidate in Cancer Treatment

Heidelberg, Germany, Dec. 5, 2013 – Apogenix, a clinical stage biopharmaceutical company, announced today that the data published in the December issue of *Molecular Cancer Therapeutics* demonstrate effective antitumor activity of the company’s drug candidate APG350, an activator for TRAIL receptors. The publication shows that APG350’s novel molecular structure allows for potent induction of apoptosis of tumor cells independent of the innate immune system, thus overcoming the limitations of other TRAIL receptor agonists.

“Due to the potential role of the TRAIL pathway in the treatment of cancer, there have been several attempts to develop substances for therapeutic use that utilize this pathway,” said Harald Fricke, M.D., Chief Medical Officer and Chief Operating Officer of Apogenix. “However, to date, none of these approaches have been successful in clinical trials. APG350 was designed to optimize both the activation of TRAIL receptors on tumor cells as well as the pharmacokinetic properties of the substance. Its unique molecular structure ensures effectiveness without the need for cross-linking via Fcγ receptors on immune cells. Since such cross-linking cannot be effectively achieved in the human body, previous TRAIL receptor agonists have ultimately failed to show antitumor efficacy in clinical studies.”

“In the different colon carcinoma animal models that we examined, treatment with APG350 resulted in efficient induction of tumor-specific apoptosis and consequently the complete remission of the tumors. Because activation of the TRAIL signaling pathway is possible in many tumor types, APG350 has the potential for wide use in oncology. We are convinced that this novel drug design concept will be successful in clinical applications,” Harald Fricke concluded.

The publication titled “APG350 Induces Superior Clustering of TRAIL Receptors and Shows Therapeutic Antitumor Efficacy Independent of Cross-Linking via Fcγ Receptors” will appear in the print edition of *Molecular Cancer Therapeutics* tomorrow. The data are the result of a close collaboration of Apogenix with Prof. Simone Fulda, M.D., from the University Hospital Frankfurt, Germany, and Prof. Peter Hohenberger, M.D., from the University Medical Centre Mannheim, Germany. The electronic version of the publication is already available to subscribers of *Molecular Cancer Therapeutics* through the website of the American Association for Cancer Research.
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 tumor cells. The company has already completed a successful phase II trial with its lead drug candidate, APG101, in patients with recurrent glioblastoma. Apogenix’ TRAIL receptor agonists, which include the prototype APG350, are currently in preclinical development for the treatment of solid tumors.
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 APG350
Apogenix’ TRAIL receptor agonists, such as the prototype APG350, are fully human fusion proteins that consist of two single-chain TRAIL molecules fused covalently to the Fc portion of a human IgG molecule. They can be produced with good yields using standard laboratory techniques and have a half-life of up to 24 hours. Preliminary toxicological investigations have shown an excellent tolerability of these drug candidates. In 2012, Apogenix started GMP cell line development for two candidate proteins. The data available to date indicate that Apogenix’ TRAIL receptor agonists can also be produced with good yields at industrial scale. The company is currently working on the process development for the future production of clinical trial material.

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