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Press Release

Anti-TGF-beta Antisense AP 12009 shows very good Safety and Tolerability in Systemic Treatment of Pancreatic Carcinoma, Malignant Melanoma and Colorectal Carcinoma

CHICAGO/REGENSBURG - June 2, 2008 - The TGF-beta 2 inhibitor AP 12009, developed by Antisense Pharma, reveals very good safety and tolerability in the systemic treatment of pancreatic carcinoma, malignant melanoma and colorectal carcinoma. AP 12009, administered intravenously, showed a clear proof of concept. Patients with stage IV pancreatic carcinoma, who received AP 12009 for seven days every other week as second or third line therapy, had a median survival time of 29.6 weeks (6.8 months) after start of AP 12009 treatment. One of these patients with several liver metastases even experienced a complete response. Efficacy and safety results of the multicenter Phase I/II study were published today at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, USA (1).

In the open-label, multicenter, dose-escalation Phase I/II study patients with advanced stage pancreatic carcinoma, malignant melanoma or colorectal carcinoma were included. So far 25 patients have been treated in six cohorts. The first four cohorts received AP 12009 as 7-day on, 7-day off cycles. For this schedule, the maximum tolerated dose (MTD) was reached with two grade III thrombocytopenias as dose-limiting toxicities (DLT). These were self-limiting and required no therapeutic intervention. The third DLT was a grade III rash. Thus, the compound AP 12009 revealed excellent safety and tolerability. Very encouraging case reports were observed. One patient, diagnosed with stage IV malignant melanoma, survived more than 60 weeks after the start of AP 12009 treatment. Another patient with stage IV pancreatic carcinoma and several liver metastases had a complete response and is still alive as of March 2008 148 weeks (34 months) after the start of treatment with AP 12009.

After reaching the MTD with the 7-day on, 7-day off schedule, a second schedule with 4-day on, 10-day off cycles was initiated. Two cohorts with a total of seven patients have been treated with the second schedule, confirming the excellent safety profile of the drug. The dose escalation is still ongoing.

“Our recent data suggest, that intravenous infusion of AP 12009 is safe in patients suffering from malignant tumors, such as pancreatic carcinoma or melanoma. The survival data, observed in this Phase I/II study are very good, given the poor prognosis associated with these diseases,” said Dr. Hubert Heinrichs, Chief Medical Officer of Antisense Pharma.



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To further study the potential of the antisense treatment in pancreatic carcinoma, a Phase II study on AP 12009 in combination with the standard of care is scheduled to start in 2009. A Phase II study in malignant melanoma in combination with the current standard of treatment is currently being planned.

“The results of the Phase I/II study underscore again the high efficacy of AP 12009, which we have seen in high-grade glioma patients in the active-controlled Phase IIb study AP12009-G004. This study showed a strong survival benefit in patients treated with AP 12009 compared to standard chemotherapy treatment,” commented Dr. Karl-Hermann Schlingensiepen, CEO of Antisense Pharma. “We have made huge progress in bringing the drug AP 12009 to patients with highly malignant tumors, who are in need of better therapies that prolong survival benefited by high quality of life.”

Literature

Hilbig, A. et al. “Systemic i.v. Administration of AP 12009: Preliminary Results of a Phase I/II Study in Pancreatic Carcinoma, Malignant Melanoma, or Colorectal Carcinoma”, ASCO Annual Meeting, 2008, Abstract ID 4621

The Phase I/II study AP 12009-P001

In the open-label, multicenter, dose-escalation Phase I/II study, patients with either pancreatic carcinoma (stage IVA/IVB), metastatic melanoma (stage III/IV), or advanced colorectal carcinoma (stage III/IV) repeatedly receive intravenous infusions of AP 12009. Primary study objective is to determine the maximum tolerated dose (MTD). Further objectives include assessment of safety and tolerability, pharmacokinetics, and antitumor activity of AP 12009. An update of this ongoing study will be presented at the meeting.

AP 12009 and TGF-beta 2

AP 12009 is an antisense drug - a phosphorothioate oligodeoxynucleotide - designed to selectively downregulate the production of transforming growth factor-beta 2 (TGF-beta 2) at the translational level. TGF-beta 2 plays a pivotal role as a multimodally acting cytokine by regulating key mechanisms of tumor progression. Immunosuppression, invasion and migration, proliferation and angiogenesis are simultaneously promoted in a variety of malignant tumors. This multiple impact on cancer cells is inhibited by AP 12009.



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About Antisense Pharma GmbH

Antisense Pharma is a biopharmaceutical company located in Regensburg, Germany. The company focuses on targeted therapies for malignant tumors and is dedicated to discovering and developing drugs based on antisense technology for worldwide commercialization. The agents specifically block the synthesis of key cancer proteins. Antisense Pharma has been honored with the Bavarian Innovation Award and the German Founders Award.

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