



For further information please contact:

Antisense Pharma GmbH

Dr. Heike Specht / Public Relations
Josef-Engert-Str. 9, D-93053 Regensburg
Telefon: 0941-92013-0 / Fax: -29
e-mail: pr@antisense-pharma.com
www.antisense-pharma.com

Press Release

Antisense Pharma: Promising Phase IIb Results of Targeted Therapy with AP 12009 in Recurrent Anaplastic Astrocytoma

CHICAGO and REGENSBURG - June 21, 2007 - "In anaplastic astrocytoma, AP 12009 as a monotherapy is actually clearly superior to temozolomide," Prof. Albert Wong, M.D., Stanford University, California, U.S.A. commented on the international Phase IIb study with the TGF-beta 2-inhibitor AP 12009, under development by Antisense Pharma. Prof. Wong discussed the results of the study in the poster discussion session on central nervous system tumors at the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, USA, this month.

The Phase IIb study AP 12009-G004 is an open-label, randomized, actively-controlled, parallel-group dose-finding study to evaluate the efficacy and safety of two doses of AP 12009 in adult patients with recurrent high-grade glioma. Efficacy endpoints were tumor response assessed by central blinded MRI reading and survival. At 29 international clinical centers 134 evaluable patients (39 with anaplastic astrocytoma, AA, WHO grade III and 95 with glioblastoma, GBM, WHO grade IV) have been randomized to three arms: AP 12009 10 μ M, AP 12009 80 μ M and chemotherapy (Temozolomide or PCV) as a control. AP 12009 was administered intratumorally via one catheter as continuous high-flow microperfusion over a 7-day period every other week for up to 6 months on an outpatient treatment basis (1, 2). Post-study follow-up for survival, long-term tumor response, and safety is still ongoing. Analysis of the core phase for AA patients is completed.

Tumor response was assessed according to Macdonald criteria. The response rate for AP 12009 10 μ M in anaplastic astrocytoma patients steadily increased in the course of 14 months, whereas in the chemotherapy treatment arm a transient peak of the response rate at 6 months was not sustainable and decreased to zero at 14 months. Response rates were higher in the AP 12009 10 μ M group compared to the AP 12009 80 μ M group. The delayed time to response combined with the long duration of the response is in accordance with the postulated immunostimulatory effect of the AP 12009 treatment. Addressing this fact Prof. Wong pointed out that in this study progression free survival would have not been a good endpoint, indicating that "perhaps the endpoints for a study need to be re-evaluated for each individual agent."

The efficacy of the treatment is reflected by the prolonged median survival times for both AP 12009 treatment groups, as compared to the control group in the AA patient population. Median overall survival (mOS) in the AP 12009 10 μ M group has not yet been reached, whereas mOS for the control group is 21.1 months. 67% of the patients in the AP 12009 10 μ M group versus 42% in the control group are currently still alive.



Press Release June 21, 2007

Press Release

While central blinded reading of the GBM patient data is still ongoing, survival data were presented as well as case reports, revealing sustained long-term responses in this patient group.

As a monotherapy AP 12009 was comparable to temozolomide in glioblastoma patients. "That by itself is quite interesting," commented Prof. Wong.

Dose-finding as a primary objective of the study has been achieved, as both efficacy and safety parameters are in favor of the 10 μ M dose of AP 12009.

"I am very optimistic about this drug," Prof. Wong concluded.

An international Phase III study with AP 12009 (10 μ M) for patients with recurrent or refractory anaplastic astrocytoma in study centers at North America, Europe and Asia is currently being prepared.

Karl-Hermann Schlingensiepen, M.D., Ph.D., Chief Executive Officer of Antisense Pharma commented, "AP 12009 is an example of Antisense Pharma's commitment to meet unmet medical needs for patients and their families. The data on AP 12009 in the lead indication high-grade glioma as presented at this year's ASCO Annual Meeting represent a major achievement and are a compelling factor to drive forth the clinical development of AP 12009 in high-grade glioma and in other solid tumors."

The American Society of Clinical Oncology provides an audio version of the poster discussion by Prof. Wong. The virtual meeting presentation can be found following this link: http://www.antisense-pharma.com/publications/f_publications.htm

General Background on 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 (3, 4).

General Background on High-Grade Glioma

Anaplastic astrocytoma and glioblastoma are the two most common forms of primary brain tumor, a diagnosis with high unmet medical need. Adults as well as children can be affected, although the age peak is at 45-65 years. Current therapies comprise surgery, radiation and/or chemotherapy. Despite recent advances the prognosis for these patients is still poor, with 94% dying within two years of initial diagnosis.



Press Release June 21, 2007

Press Release

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.

Literature

- (1) Bogdahn U., et. al., A Phase IIb actively controlled study with the TGF-beta 2 inhibitor AP 12009 for recurrent or refractory Anaplastic Astrocytoma, ASCO Annual Meeting, 2007, Abstract ID 2025
- (2) Hau, P., et al., Results of an actively controlled Phase IIb study in recurrent or refractory glioblastoma patients with the TGF-beta 2 inhibitor AP 12009, ASCO Annual Meeting, 2007, Abstract ID 34563
- (3) Hau P. and Jachimczak P. et. al., Inhibition of TGF-beta 2 with AP 12009 in recurrent malignant glioma: From preclinical to Phase I/II studies, Oligonucleotides, in press
- (4) Schlingensiepen K.-H., et. al., Targeted Tumor Therapy with the TGF-beta 2 antisense compound AP 12009, Cytokine Growth Factor Reviews 17 (2006): 129-139

Disclaimer

This document contains forward-looking statements with respect to the future business of Antisense Pharma GmbH. By their nature, forward-looking statements and forecasts involve risks and uncertainties because they relate to events and depend on circumstances that could occur in the future. There is a number of factors that could cause actual results and developments to differ materially. Antisense Pharma GmbH disclaims any intent of obligation to update any of these forward-looking statements.