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Antisense Pharma Receives Approval for Clinical Studies in South Korea and Taiwan in Malignant ...

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With this approval, the Southeast Asian health agencies KFDA and TFDA have paved the way for the implementation of the pivotal Phase III study SAPPHIRE with the TGF- β 2 inhibitor trabedersen

Regensburg, Germany, February 2, 2011 / [b3c newswire](#) / - The biopharmaceutical company [Antisense Pharma](#) today announced that the South Korean health agency KFDA as well as the Taiwanese health agency TFDA have granted their approvals for the implementation of clinical studies using the anti-cancer drug trabedersen for patients with high-grade brain tumors. [Trabedersen](#) is a gene-silencing substance inhibiting the tumor factor Transforming Growth Factor beta 2 (TGF- β 2) at its translational level. The efficacy and tolerability of trabedersen for high-grade glioma has already been demonstrated during [a randomized and actively controlled Phase IIb study](#).¹ The substance is currently also in clinical development for indications such as advanced pancreas carcinoma, malignant melanoma and colorectal carcinoma. The involvement of Southeast Asian countries for clinical testing of trabedersen is part of Antisense Pharma's strategic development program for the global marketing of this compound. Including South Korea and Taiwan, a total of 13 countries are now participating in the international pivotal study.

High unmet need for medical innovations for patients with highly malignant glioma

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[The randomized and actively controlled Phase III study SAPHIRE](#) is scheduled to begin at selected medical centers in South Korea and Taiwan during the first quarter of 2011. The medical demand for therapies against high-grade brain tumors remains to be high: according to the World Health Organization (WHO), Southeast Asia annually has more than 13,000 incident cases of central nervous system tumors, with a mortality rate of more than 77%.² “Our pivotal Phase III study not only meets the enormous interest in trabedersen of South Korean and Taiwanese physicians, who – just as their colleagues from all over the world – have so far no satisfactory medical treatment to provide to their critically ill patients suffering from malignant brain tumors“, explains Dr. Karl-Hermann Schlingensiepen, Chief Executive Officer of Antisense Pharma. “The global involvement of neurosurgeons and neurooncologists for the clinical development of trabedersen also allows us to introduce them to our completely new therapy concept at an early stage. This means that by the time trabedersen will be launched, these doctors will be familiar with the concept and can leverage their clinical practice experience.”

Smooth approvals by KFDA and TFDA

“The excellent exchange with the regulatory authorities in South Korea and Taiwan has led to a prompt granting of approvals, thus confirming the professional work of our team and Antisense Pharma’s expertise in clinical drug development“, comments Dr. Hubert Heinrichs, Chief Medical Officer of Antisense Pharma. “Key factors for the decision taken by KFDA and TFDA have surely been the very encouraging results of previous clinical studies which confirm the safety, tolerability and efficacy of trabedersen.”

About Antisense Pharma GmbH - www.antisense-pharma.com

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 medications specifically block the synthesis of key cancer proteins. Antisense Pharma has clinical trials running that involve patients with brain tumors, advanced pancreatic carcinoma, malignant melanoma and colorectal carcinoma. Therapies for other indications are under preclinical development. The company has been honored with the German Founder’s Award and the Bavarian Innovation Award and in 2009 received the Innovation Prize TOP 100.

About Trabedersen (AP 12009) and TGF-β2

Trabedersen is a first-in-class gene silencing antisense compound – a phosphorothioate oligodeoxynucleotide – designed to selectively downregulate the production of transforming growth factor-beta 2 (TGF-β2) at the translational level. TGF-β2 plays a pivotal role as a multimodal cytokine by regulating key mechanisms of tumor progression. Immunosuppression, invasion and metastasis, proliferation and angiogenesis are simultaneously promoted by TGF-β2 in a variety of malignant tumors. Therefore Trabedersen is a targeted multimodal therapy and one of the very promising immunotherapeutic approaches in the oncological field. Besides in high grade glioma, trabedersen is also being

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investigated in other aggressive cancers which over-express TGF- β 2: Trabedersen is being systemically administered intravenously (i.v.) in adult patients with advanced pancreatic carcinoma, malignant melanoma, or advanced colorectal carcinoma in an ongoing Phase I/II study.

About High-Grade Glioma

Anaplastic astrocytoma (AA) and glioblastoma multiforma (GBM) are the two most common forms of primary brain tumors and are diseases with high unmet medical need. Adults as well as children may be affected, although the peak age is 45-65 years. Current therapies comprise surgery, radiation and/or chemotherapy. Despite recent advances, the prognosis for these patients is still poor, with a high proportion dying within two years after initial diagnosis. Antisense Pharma is the sponsor of the pivotal international SAPPHIRE clinical Phase III study, investigating the efficacy and safety of trabedersen (AP 12009) in adult patients.

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¹ [Bogdahn U et al. Targeted therapy for high-grade glioma with the TGF- \$\beta\$ 2 inhibitor trabedersen: results of a randomized and controlled phase IIb study. *Neuro Oncol*, 2010, doi:10.1093/neuonc/noq142](#)

² [Globocan 2008, //globocan.iarc.fr](#)

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