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## Clinical Trials

# Antisense receives approval to conduct cancer drug trials in Korea, Taiwan

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Antisense Pharma has reported that the South Korean health agency KFDA and the Taiwanese health agency TFDA have granted their approvals to conduct clinical studies of the anti-cancer drug trabedersen for patients with high-grade brain tumours.

Trabedersen is a first-in-class gene silencing antisense compound designed to inhibit the tumour factor - transforming growth factor beta 2 (TGF- $\beta$ 2) at its translational level.

The efficacy and tolerability of trabedersen for high-grade glioma was observed in a randomised and actively controlled Phase IIb study.

Trabedersen is currently in clinical development for indications such as advanced pancreas carcinoma, malignant melanoma and colorectal carcinoma.

In addition to South Korea and Taiwan, a total of 13 countries are now participating in the international pivotal study.

The randomised and actively controlled Phase III study SAPPHERE will begin at selected medical centres in South Korea and Taiwan during the first quarter of 2011

Antisense Pharma chief medical officer Dr Hubert Heinrichs said the excellent exchange with the regulatory authorities in South Korea and Taiwan has led to a prompt granting of approvals.

"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," Heinrichs added.