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AVEO, Astellas file NDA for tivozanib

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Singapore: US-based AVEO Oncology and Astellas Pharma have submitted a new drug application (NDA) to the US Food and Drug Administration (FDA) seeking approval for tivozanib in patients with advanced renal cell carcinoma (RCC). Tivozanib is designed to target the vascular endothelial growth factor (VEGF) pathway, a clinically validated target in RCC and other solid tumors.

The NDA submission is based on results of the global phase III TIVO-1 (Tivozanib Versus Sorafenib in 1st line Advanced RCC) trial, a randomized superiority-designed pivotal trial evaluating the efficacy and safety of tivozanib compared to sorafenib in 517 patients with advanced RCC who had no prior treatment with a systemic therapy, as well as data from 17 clinical studies involving over 1,000 subjects who received tivozanib. In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS) versus sorafenib, an approved targeted agent, and a favorable tolerability profile.

Results from the study were first presented in early June 2012 at the American Society of Clinical Oncology (ASCO) 2012 annual meeting in Chicago.