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Aveo, Astellas report cancer trial results

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Singapore: Aveo Oncology and Astellas Pharma announced overall survival (OS) for tivozanib, an investigational agent, from the phase III TIVO-1 (Tivozanib versus sorafenib in first line advanced RCC) study in patients with advanced renal cell carcinoma (RCC).

The final OS analysis, as specified by the protocol, shows a median OS of 28.8 months (95 percent confidence interval [CI]: 22.5-NA) for tivozanib versus a median OS of 29.3 months (95 percent CI: 29.3-NA) for the comparator arm, sorafenib. No statistical difference between the two arms (HR=1.245, p=0.105) was observed.

Overall survival is a secondary endpoint of the TIVO-1 study. A one-sided crossover for patients randomized to the sorafenib (comparator) arm was offered pursuant to a separate, long-term treatment protocol to allow trial participants to receive tivozanib upon disease progression. This resulted in a substantial difference in the use of subsequent therapies.

Of the patients who discontinued their initial therapy, 10 percent originally on the tivozanib arm received subsequent anti-VEGF therapy (36 percet received any subsequent therapy) while 70 percent of patients originally on the comparator arm received subsequent anti-VEGF therapy (74 percent received any subsequent therapy).

Principal investigator Mr Robert J Motzer, attending physician, genitourinary oncology service, Memorial Sloan-Kettering Cancer Center, and professor of medicine, Weill Medical College, Cornell University, New York, said that, "It's encouraging to see that patients in the study who received tivozanib had a median overall survival of 28.8 months, particularly given that these patients received minimal subsequent therapy. The safety and efficacy results from TIVO-1 and other clinical trials of tivozanib in advanced RCC suggest it may provide an important new first line treatment option for patients with this aggressive disease."

In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS), the primary endpoint of the study, when compared with sorafenib. The FDA has accepted the tivozanib NDA for filing, and according to the timelines established by the Prescription Drug User Fee Act (PDUFA), the review of the NDA is expected to be complete by July 28, 2013. Other data being presented at ASCO GU show the anti-tumor activity of tivozanib following treatment with sorafenib resulted in a median PFS of 8.4 months and response rate of 13 percent.

These data have matured and have been updated from the initial ASCO GU abstract submission (abstract #364), and will be included in the poster. Additional TIVO-1 data relating to subset analyses (abstracts #354 and #361) and quality of life (abstract #355) will also be included in posters presented at ASCO GU.

Dr William Slichenmyer, chief medical officer, Aveo, said that, "We believe that these data being presented at ASCO GU reinforce the positive efficacy results and safety profile of tivozanib in patients with advanced RCC."

"We are excited to be working with AVEO in our efforts to bring tivozanib to patients who are in need of new therapeutic options," added Dr Stephen Eck, vice president of medical oncology, Astellas Pharma Global Development.