## Abstract 298: Q-TWiST analysis of tivozanib versus sorafenib in patients with advanced renal cell carcinoma (RCC) in the TIVO-3 study

Michael Szarek\*, Michael N. Needle, Brian I. Rini, Sumanta K. Pal, David F. McDermott, Michael B. Atkins, Thomas E. Hutson, Bernard Escudier

## **Background:**

- In TIVO-3, tivozanib increased progression-free survival with no difference in overall survival relative to sorafenib as 3rd- or 4th-line therapy in patients with metastatic RCC.
- We applied quality-adjusted time without symptoms of disease and toxicity (Q-TWiST) methods to quantify the net health benefits of tivozanib, in the presence of similar survival, when compared to sorafenib.

## **Methods:**

- Mean Q-TWiST was calculated by applying utility coefficients of 0.5, 1.0, and 0.5<sup>1</sup> to the 36-month restricted mean health states of time with toxicity (TOX), time without symptoms and toxicity (TWiST), and time after progression/relapse (REL), respectively.
- Relative Q-TWiST gain was defined as the mean absolute Q-TWiST difference divided by the sorafenib mean OS.

Tivozanib significantly increased quality-adjusted time without symptoms of disease and toxicity (Q-TWiST) relative to sorafenib as 3<sup>rd</sup>- or 4<sup>th</sup>-line therapy in patients with RCC

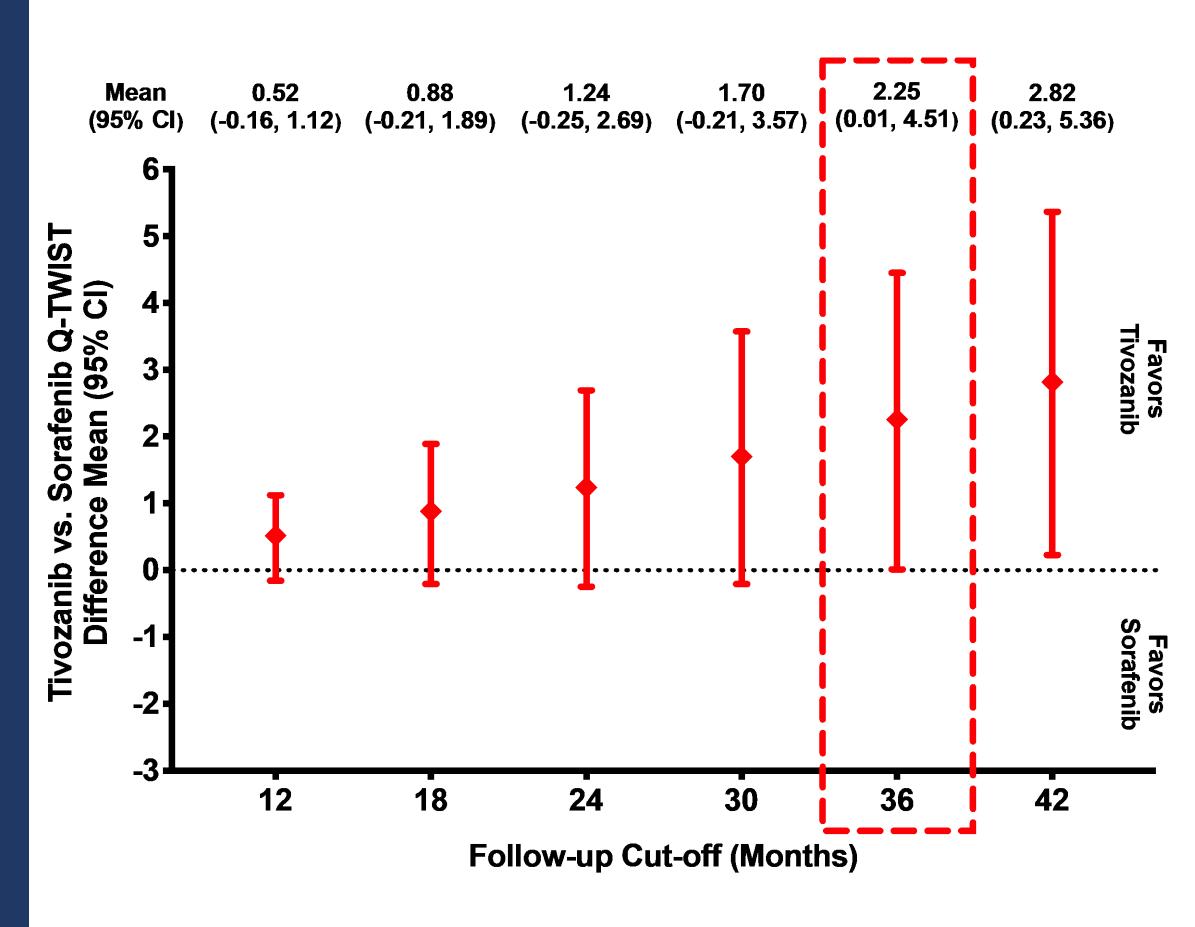
Q-TWiST may be considered an alternative patient-centered measure of tivozanib benefit in these settings

\*University of Colorado and CPC Clinical Research, Aurora CO; SUNY Downstate Health Sciences University, Brooklyn NY; michael.szarek@downstate.edu

## **Results:**

- Mean Q-TWiST was 15.04 and 12.78 months for tivozanib and sorafenib, respectively (p=0.0493).
- Relative gain for tivozanib was 11.2%.

Figure: Q-TWiST for Different Maximum Follow-up Durations for Calculation of Restricted Means.



Diamonds represent point estimate for difference in means between treatment groups and error bars represent 95% confidence intervals for the difference in means; QTWiST at 36 months was the primary endpoint, with other follow-up durations presented as sensitivity analyses. CI, confidence interval.

1 These are the utility coefficients customarily used in RCC Q-TWiST analyses. With these coefficients, the TWiST state is assumed to have greater utility to patients than the TOX and REL states.