A retrospective subgroup analysis evaluated efficacy by RCC biology and immunohistochemistry status only where available. Patients were “immunohistochemistry positive” if they were scored positive for VEGFR2, as assessed by immunohistochemistry.

**Results**

**Patients**

272 patients with locally advanced or metastatic RCC were enrolled between October 2007 and July 2008 and received at least 1 dose of study medication (range, 0.03–34.7 months). The population was 272 patients: 132 (49%) male and 140 (51%) female. The median age was 60 (range, 24–87) years and the median duration of treatment was 8.5 months (range, 0.03–34.7 months).

**Efficacy**

- **Overall Response Rate (ORR)**: 35% (95% CI, 27%–44%).
- **Progression-Free Survival (PFS)**: Median PFS was 14.8 months (95% CI, 11.9–16.5) for patients with clear cell RCC who had undergone nephrectomy.
- **Other responses**: 11% (95% CI, 7.0%–15.2%) partial response, 52% (95% CI, 43%–61%) stable disease, and 34% (95% CI, 26%–43%) progressive disease.

**Safety and Tolerability**

- **Grade 3/4 Adverse Events**: Hypertension was the most common adverse event, observed in 14% of patients, followed by fatigue (10%), dysphonia (8%), and dyspepsia (6%).
- **Other events**: Nephropathy (4%), neutropenia (2%), anemia (2%), vomiting (2%), diarrhea (1%), and constipation (1%).

**Conclusion**

Based on these results, tivozanib is currently being evaluated in nephrectomized patients with advanced RCC in the global phase 3 TIVO-1 trial.