**Introduction**

Tivozanib is a potent and orally available tyrosine kinase inhibitor of vascular endothelial growth factor (VEGF) receptors 1, 2, and 3. It has a long half-life and can be administered orally. Currently, tivozanib is being tested in a Phase III study in patients with renal cell carcinoma and Phase I/II studies of tivozanib combined with FOLFOX6 in patients with advanced GI tumors.

**Methods**

This open-label, Phase Ib study (NCT00660153) sought to determine the MTD, dose-limiting toxicity, and assess the anti-neoplastic activity of tivozanib combined with mFOLFOX6 in patients with advanced GI tumors.

**Results**

The combination of tivozanib and mFOLFOX6 demonstrated encouraging anti-neoplastic activity in patients with advanced GI tumors, with 30.8% of patients achieving a partial response. The disease control rate was 73.1%. Median duration of exposure to tivozanib was 5.2 months (range 0–26 months).

**Conclusions**

Tivozanib was administered once daily in 4-week cycles (3 weeks on/1 week off) with mFOLFOX6. The combination of tivozanib and mFOLFOX6 demonstrated encouraging anti-neoplastic activity in patients with advanced GI tumors, with 30.8% of patients achieving a partial response. The disease control rate was 73.1%. Median duration of exposure to tivozanib was 5.2 months (range 0–26 months).