**Abstract # C121**

**A Phase I QT Study of Tivozanib in Patients with Advanced Solid Tumors**

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**Introduction**

Preclinical and clinical studies have shown that tivozanib displays strong vascular endothelial growth factor receptors (VEGFRs) -1, -2, and -3 inhibition. Results from a study of tivozanib in patients with solid tumors, obtained retrospectively from previous Phase 1, II, and III trials, indicate strong relationship between tivozanib peak plasma concentrations and QTcF interval.

To currently be being treated in Phase I trials, patients with small cell carcinomas and Phase I/II trials of other solid tumors.

Based on these results, future clinical trials may not require intensive ECG monitoring. This suggests that tivozanib’s QTcF accumulation observed a after 3 weeks of treatment is consistent with the expected clinical relevance.

**Methods**

- To evaluate the ECG QTcF interval and morphology following treatment with tivozanib in patients with small cell carcinomas.
- To determine the safety of the drug change to QTcF duration in patients with solid tumors.
- To assess the correlation between tivozanib peak plasma concentrations and QTcF interval.

**Study Design**

- **Study Objective:** Evaluating the ECG QTcF interval and QTcF morphology following treatment with tivozanib in patients with solid tumors.
- **Study Design:** Open-label Phase I-B single-arm multiple-dose escalation study.
- **Study Population:** Patients with small cell carcinomas or Phase I/II trials of other solid tumors.
- **Study Endpoints:**
  - Primary endpoint: Change from baseline in QTcF interval at 24-h post-dose.
  - Secondary endpoints:
    - Change from baseline in QTcF interval at 24-h post-dose.
    - Change from baseline in QTcF interval at 24-h post-dose.

**Study Participants**

- **Baseline QTcF interval:** Requirements for inclusion.
- **Discontinuation Criteria:** Criteria for discontinuation.
- **Safety Monitoring:** Monitoring procedures.

**Study Outcomes**

- **Safety Outcomes:** Summary of adverse events.
- **Efficacy Outcomes:** Summary of efficacy results.
- **QTcF Interval:** Summary of QTcF interval results.

**Results**

- **Safety Outcomes:** Summary of adverse events.
- **Efficacy Outcomes:** Summary of efficacy results.
- **QTcF Interval:** Summary of QTcF interval results.

**Conclusions**

- The study results indicate that tivozanib’s QTcF accumulation observed a after 3 weeks of treatment is consistent with the expected clinical relevance.
- Future clinical trials may not require intensive ECG monitoring.
- The study suggests that tivozanib’s QTcF accumulation observed a after 3 weeks of treatment is consistent with the expected clinical relevance.

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**References**


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