Quality of Life Outcomes With Futibatinib Treatment in FOENIX-CCA2, a Phase 2 Study in Patients With Intrahepatic Cholangiocarcinoma Harboring FGFR2 Gene Fusions/Rearrangements

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Background

• Clinical experience with futibatinib:
  • Faftinib is a novel, tight, selective, potent, and irreversible small-molecule inhibitor of all 5 fibroblast growth factor receptor (FGFR) isoforms in vitro and in vivo.
  • A phase 1 dose-escalation study established futibatinib 20 mg once daily (QD) as the maximum tolerated dose (MTD) and recommended futibatinib 20 mg QD as the phase 2 dose (ClinicalTrials.gov identifier: NCT02952778).
  • In the phase 1 dose-escalation/prolongation study, objective responses were observed with futibatinib in patients with advanced refractory clear cell renal cell carcinoma, breast cancer, small cell lung cancer, and gastric cancer, featuring a spectrum of FGFR activity.
  • Futibatinib demonstrated a durable response (Figure 1) in a tolerable and manageable safety profile.
  • Table 1: A list of adverse events (AEs) with a frequency of ≥10%.

• Quality of life (QoL) assessment:
  • The European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire and the EuroQol-5D (EQ-5D-3L) instrument were used to determine a visual analog scale (VAS) score of baseline health status.

• Study objectives:
  • Primary:
    • To evaluate the proportion of QLQ-C30 scores from baseline to cycle 13 with at least one score ≥10 points worse compared to baseline.
  • Secondary:
    • To evaluate the proportion of VAS scores from baseline to cycle 13 that remained ≥10 points worse compared to baseline.

Methods

• FOENIX-CCA2 is an ongoing, open-label, phase 2 study that enrolled patients with a nonsmall-cell lung cancer (NSCLC) or cholangiocarcinoma (CCA) with FGFR2 gene fusions/Rearrangements who had received prior systemic therapy.

• Patient population:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

• Study design:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

• Treatment:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

• Outcomes:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

• End points:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

• Analysis:
  • ECOG PS and QoL deterioration during treatment
  • ECOG PS 0 or 1
  • grenade
  • grenade

Conclusions

These PRO data are the first to be reported for an FGFR inhibitor in the iCCA patient population. The PRO data provide evidence that FGFR2-targeting treatment may not adversely impact patient QoL, and overall health status showed a trend toward improvement over the course of treatment. Future studies will determine whether QoL improvements translate into clinical benefit.