Study design

- Participants randomized in a 1:1 design for treatment with sotorasib at 960 mg PO daily or 240 mg PO daily, stratified by STK11m
- Study treatment until disease progression, unacceptable toxicity, withdrawal of informed consent, or death

In select cases, subjects may continue on treatment following radiologic progression if they are continuing to:

- Last dose
- LTFU visits (in clinic or via telephone) every 12 weeks starting from date of last dose

Primary and secondary endpoints

Primary: Objective Response (OR = CR + PR)
Secondary: Disease control (CR + PR + SD); DOR; TTR; PFS; OS; TEAEs; TRAEs; Changes in vital signs, ECGs, and clinical laboratory tests