MK-3475A-D77

Participants
Stage IV NSCLC newly diagnosed untreated

R 2:1 N=377

SC

Nonsquamous:
MK-3475A SC Q6W plus Pemetrexed 500 mg/m^2 IV + Cisplatin 75 mg/m^2 IV or Carboplatin AUC 5 mg/mL/min

Squamous:
MK-3475A SC Q6W plus either Carboplatin AUC 6 mg/mL/min or Cisplatin 75 mg/m^2 IV and either Paclitaxel 200 mg/m^2 IV or Nab-paclitaxel 100 mg/m^2 IV

IV

Nonsquamous:
IV Q6W plus Pemetrexed 500 mg/m^2 IV + Cisplatin 75 mg/m^2 IV or Carboplatin AUC 5 mg/mL/min

Squamous:
IV Q6W plus either Carboplatin AUC 6 mg/mL/min or Cisplatin 75 mg/m^2 IV and either Paclitaxel 200 mg/m^2 IV or Nab-paclitaxel 100 mg/m^2 IV

Safety, imaging, and survival follow-up

Second course retreatment if eligible

Primary Endpoints: $AUC_{0\text{-}6wks}$ [cycle 1] and C_{trough} at steady state

Secondary Endpoints: Additional PK parameters, descriptive efficacy measures including ORR, PFS, and OS, and safety

Chemotherapy Options

- Nonsquamous: Pemetrexed, Cisplatin/Carboplatin
- Squamous: Cisplatin/Carboplatin, Paclitaxel/Nabpaclitaxel

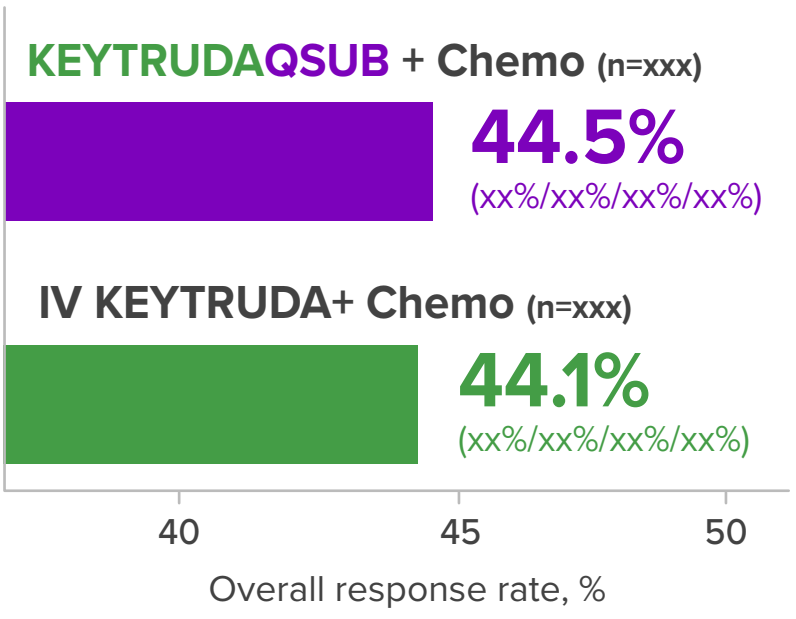
KEYTRUDAQSUB was studied in 1L NSCLC patients in combination with chemotherapy, in squamous and nonsquamous histology

Primary Endpoint: Pharmacokinetics

- Cycle 1 observed serum C_{trough} (ie, pre-dose Cycle 2) showed a geometric mean ratio (GMR) of 1.06 (90% CI, 0.90, 1.15)
- The GMR for Cycle 1 model-predicted AUC from 0 to 21 days (AUC 0-21 d) was .91 (90% CI, 0.82, 1.31)

- The comparability of KEYTRUDA QSUB and intravenous pembrolizumab was established in Study MK-3475A-D77
- Use of KEYTRUDA QSUB for the approved indications is supported by evidence from adequate and well-controlled studies conducted with intravenous pembrolizumab across tumor types and additional pharmacokinetic, efficacy, and safety data from MK-3475A-D77

Secondary Endpoints: Overall Response Rate and Progression-Free Survivial



No difference in progression-free survival was observed when compared to IV KEYTRUDA

- Efficacy observed with KEYTRUDA QSUB was consistent with IV KEYTRUDA
- Efficacy was a descriptive analysis and was not used to formally test for comparable efficacy to IV KEYTRUDA