A randomized phase 3 comparison of IMO-2125 with ipilimumab versus ipilimumab alone in subjects with anti-PD-1 refractory melanoma

OBJECTIVES

- Primary objective: To compare the efficacy, measured survival benefit and overall survival duration, of the study treatments in combination with ipilimumab vs ipilimumab alone

- Secondary objectives: To assess the safety and tolerability of the study treatments, including clinically significant laboratory test abnormalities, adverse drug reactions, and serious adverse events

- Exploratory objectives: To evaluate biomarkers of interest and the incidence of antitumor antibodies

STUDY DESIGN

- Study population: Subjects with unresectable or metastatic melanoma who have failed prior anti-PD-1 therapy and who have no evidence of central nervous system, meningeal, or epidural metastases

- Study treatment: Subjects will be randomized 1:1 to either study treatment Arm A (ipilimumab 3 mg/kg, 4 doses: wk 1, 4, 7, 10) or Arm B (IMO-2125 plus ipilimumab 3 mg/kg, 4 doses: wk 2, 5, 8, 11)

- Study duration: Treatment will continue for 12 weeks in each arm and will be followed by 48 weeks of observation

- Disease assessment: Disease progression will be assessed at baseline and every 8 weeks during the first year, then every 4 months for 12 months after study treatment completion

- Secondary endpoints: Durability of response, survival, and quality of life

- Primary endpoints: Overall survival (HR, 0.63)

- Secondary endpoints: Disease control rate, progression-free survival, and overall response rate

- Safety: Assessing adverse events, laboratory abnormalities, and any other safety events

STUDY ENROLLMENT

- Eligibility criteria: Subjects must have unresectable or metastatic melanoma with confirmed radiologic progression during or after prior anti-PD-1 therapy who are not candidates for standard systemic therapy and who have no evidence of central nervous system, meningeal, or epidural metastases

- Inclusion criteria: Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1, adequate organ function, no prior treatment with T-cell costimulator antibody, no brain metastases, and no ongoing systemic therapy within 6 months before enrollment

- Exclusion criteria: Previous or current treatment with T-cell costimulator antibodies, prior treatment within 6 months before enrollment, and no evidence of central nervous system, meningeal, or epidural metastases

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