KEYNOTE-029: Phase 1/2 Study of Pembrolizumab (MK-3475) in Combination With Pegylated Interferon Alfa-2b or Ipilimumab in Patients With Advanced Melanoma or Renal Cell Carcinoma

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Study Design

- Key eligibility criteria: Patients with histologically confirmed advanced or metastatic melanoma or RCC (≥1 prior therapy)

- Randomize 1:1:1

- N = 150

- Phase 2 Dose

- Pembro 2 mg/kg Q3W + IP-IFN or IP-IFN alone

- Phase 3 Dose

- Pembro 2 mg/kg Q3W + PEG-IFN or PEG-IFN alone

- Key patient eligibility criteria are shown in Table 1

Methods

- Study will have 3 parts (Phase 1/2/3)

- Duration of therapy: Up to 2 years of therapy

- Treatment will continue until disease progression, intolerable toxicity, investigator decision, or 2 years of therapy

- Efficacy analyses will be based on independent central review

- OS and PFS curves will be estimated using the Kaplan-Meier method

- All other terminologies will be assessed by the stratified Miettinen and Nurminen method

- Key Eligibility Criteria

- ADEs (Adverse Events): including serious AEs, fatal AEs, and immune-related events of clinical interest

- All other terminologies will be assessed by the stratified Miettinen and Nurminen method

- **References**

- **Current Status**

- **CONTACT INFORMATION**

- **Acknowledgments**

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