IO102-IO103 in Combination With Pembrolizumab Versus Pembrolizumab Alone in Advanced Melanoma (IOB-013 / KN-D18)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Histologically or cytologically confirmed stage III (unresectable) or stage IV melanoma, as per American Joint Committee on Cancer 8th edition guidelines not amenable to local therapy 2. Patients are treatment naive, that is, no previous systemic anticancer therapy for unresectable or metastatic melanoma. For clarification, the following patients are eligible: 1. Patients with proto-oncogene B-Raf (BRAFV600) mutation-positive melanoma are eligible if treatment naive and without rapidly progressive disease as per investigator assessment. 2. Patients who have received previous adjuvant and/or neoadjuvant therapy with targeted therapy or immune therapy are eligible if administered the last dose at least 6 months before inclusion in this trial (randomization), and if relapse did not occur during active treatment or within 6 months of treatment discontinuation. 3. At least 1 measurable lesion (not a cutaneous lesion) according to response evaluation criteria for solid tumors (RECIST v1.1) and confirmed by IRC. 4. Provision of archival (obtained within 3 months), or newly acquired biopsy tissue not previously irradiated, and blood at screening for biomarker assessments. Formalin-fixed, paraffin embedded (FFPE) tissue blocks are preferred to slides. Newly obtained biopsies are preferred to archived tissue.

Exclusion Criteria:

1. Patients with known or suspected central nervous system (CNS) metastases or with the CNS as the only site of active disease are excluded with the following exception: • Patients with controlled (stable) brain metastases will be allowed to enroll (subject to baseline magnetic resonance imaging (MRI) confirmation). Controlled (stable) brain metastases are defined as those with no radiographic progression for at least 4 weeks after radiation and/or surgical treatment at the time of signed informed consent. Patients must have been off steroids for at least 2 weeks before signed informed consent and have no new or progressive neurological signs and symptoms. 2. Patient has received previous radiotherapy within 2 weeks of start of trial treatment (visit 2). Patients must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis. A 1-week washout is permitted for palliative radiation (≤2 weeks of radiotherapy) to non-CNS disease. 3. Patients with BRAFV600-positive disease who are experiencing rapidly progressing disease and/or have received standard first-line therapy with BRAF and/or MEK inhibitor for unresectable or metastatic disease. Other protocol defined inclusion/exclusion criteria may apply.

Conditions & Interventions

Interventions:
Drug: IO102-IO103, Drug: Pembrolizumab
Conditions:
Metastatic Melanoma, Unresectable Melanoma
Keywords:
Metastatic melanoma, Unresectable melanoma, Immunotherapy, Progression free survival, IO102-IO103, Pembrolizumab

More Information

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