Doctor's Note — Clinical Trial Summary

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TRIAL

A Study to Assess a PI3K´Inhibitor (IOA-244) in Patients With Metastatic Cancers

NCT ID: NCT04328844 Phase: PHASE1 Sponsor: iOnctura Status: Active Not Recruiting

SUMMARY

The objective of study IOA-244-101 is to determine whether IOA-244 is safe and tolerable in cancer patients (Part A). In addition, the study will assess whether IOA-244 can increase the anti-tumour immune response in patients both as monotherapy and in combination pemetrexed/cisplatin/avelumab (Part B Mesothelioma and NSCLC 1st line), in combination with avelumab (Part B Cutaneous Melanoma and NSCLC 2nd/3rd line) and ruxolitinib (Part B Primary Myelofibrosis)

KEY ELIGIBILITY CRITERIA

- 1. e18 years of age inclusive, at the time of signing the informed consent.
- 2. Capable of giving signed informed consent, which includes compliance with the requirements of this protocol.
- 3. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. For patients with NHL, ECOG 2 will be allowed.
- 4. Patients with histologically or cytologically confirmed advanced or metastatic malignancies (including histologically confirmed, unresectable Stage III or IV melanoma); see following details for each malignancy:
- For Patients with cutaneous and mucosal melanoma:
- 1. Baseline lactate dehydrogenase levels are available.
- 2. Disease progression is confirmed and they are eligible for second- or third-line treatment:
- * After first-line treatment and progression on approved programmed cell death-1 (PD-1) or cytotoxic T lymphocyte antigen-4 (CTLA-4) or combination of PD-1 and CTLA-4-pathway targeted agent.
- * After second-line treatment and progression on prior BRAF V600 mutation targeted agent followed by PD-1 or CTLA-4-pathway targeted agent (Note: There is no mandatory sequence of these approved treatments).
- 3. No clinically significant tumour-related symptoms.

Total sites: 3 | 0 currently recruiting