Doctor's Note — Clinical Trial Summary

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TRIAL

A Study of APG-115 in as a Monotherapy or Combination With Pembrolizumab in Patients With Metastatic Melanomas or Advanced Solid Tumors

NCT ID: NCT03611868 Phase: PHASE1 / PHASE2 Sponsor: Ascentage Pharma Group Inc. Status: Active Not Recruiting

SUMMARY

This study aims to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of APG-115, an MDM2 inhibitor, either alone or in combination with pembrolizumab, a programmed cell death protein-1 (PD-1) inhibitor, in patients with metastatic melanomas or advanced solid tumors. Our hypothesis is that restoration of the immune response concomitant to inhibition of the MDM2 pathway (which restores p53 functions) may promote cancer cell death, leading to effective anticancer therapy.

KEY ELIGIBILITY CRITERIA

- * Male or non-pregnant, non-lactating female patients age e18 years, an exception for MPNST cohort: adolescents e12 years old (who weigh at least 40 kg) is allowed
- 1. Measurable disease according to RECIST 1.1. Lesions situated in a previously irradiated area, or an area subject to other loco-regional therapy (e.g., intralesional injections) should be considered non-measurable
- 2. ECOG performance status 0-2
- 3. Cohort A: Histologically confirmed, unresectable or metastatic melanoma, and refractory or relapse after PD-1 antibody treatment and ineligible for other standard of care therapy per NCCN guideline (previous PD-1/PD-L1 antibody treatment not required for uveal melanoma)
- 4. Cohort F: Histologically confirmed, metastatic or unresectable MPNST
- * Life expectancy e 3 months
- * Continuance of treatment related toxicities (except alopecia) due to prior radiotherapy or chemotherapy agents or biological therapy (including PD-1/PD-L1 antibodies) must be d grade 1 at the time of dosing
- * Adequate bone marrow and organ function without continuous supportive treatment
- * QTcF interval (mean of 3, 1-3 minutes between tests) d450 ms in males and d470 ms in females
- * Left ventricular ejection fraction (LVEF) e lower limit of institutional normal (LLN) as assessed by echocardiogram (ECHO) or multigated acquisition (MUGA) scan

Total sites: 21 | 0 currently recruiting

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