Doctor's Note — Clinical Trial Summary

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TRIAL

Study of IDE196 in Patients With Solid Tumors Harboring GNAQ/11 Mutations or PRKC Fusions

NCT ID: NCT03947385 Phase: PHASE1 / PHASE2 Sponsor: IDEAYA Biosciences Status: Recruiting

SUMMARY

This is a Phase 1/2, multi-center, open-label basket study designed to evaluate the safety and anti-tumor activity of IDE196 in patients with solid tumors harboring GNAQ or GNA11 (GNAQ/11) mutations or PRKC fusions, including metastatic uveal melanoma (MUM), cutaneous melanoma, colorectal cancer, and other solid tumors.

Phase 1 (dose escalation - monotherapy) will assess safety, tolerability and pharmacokinetics of IDE196 via standard dose escalation scheme and determine the recommended Phase 2 dose. Safety and anti-tumor activity will be assessed in the Phase 2 (dose expansion) part of the study.

Phase 1 (dose escalation - binimetib combination) will assess safety, tolerability and pharmacokinetics of IDE196 and binimetinib via standard dose escalation scheme and determine the recommended Phase 2 dose. Safety and anti-tumor activity will be assessed in the Phase 2 (dose expansion) part of the study.

Phase 1 (dose escalation - crizotinib combination) will assess safety, tolerability and pharmacokinetics of IDE196 and crizotinib via standard dose escalation scheme and determine the recommended Phase 2 dose. Safety and anti-tumor activity will be assessed in the Phase 2 (dose expansion) part of the study. Evaluation of safety and efficacy across multiple doses may be explored in the dose optimization part of the study.

Crizotinib monotherapy with crossover to combination cohort may be assessed for safety and to show the contribution of each study drug to anti-tumor activity.

As of Protocol Amendment 10, Phase 1, Phase 2 dose expansion in IDE196 monotherapy, and Phase 2 dose expansion of IDE196 in combination with binimetinib have been fully enrolled. There were no patients enrolled in the crizotinib monotherapy cohorts.

KEY ELIGIBILITY CRITERIA

- * Patient must be e18 years of age and able to provide written informed consent
- * Diagnosis of the following:
- o MUM: Uveal melanoma with histological or cytological confirmed metastatic disease. Metastatic disease may be treatment naïve or have progressed on or after most recent therapy. If the most recent therapy was an immune-oncology agent, PD must be confirmed.
- \- If a patient is treatment naïve and human leukocyte antigen (HLA)-A*02:01 positive***, documentation is required to provide rationale why treatment with tebentafusp is not the ideal firstline treatment approach or of the patient's intolerance to tebentafusp.

• ***To be enrolled in the HLA-A*02:01 positive cohort, HLA status must be documented by test results from a CAP/CLIA-certified laboratory.

• * Measurable disease per RECIST v1.1

• * Eastern Cooperative Oncology Group d1 and expected life expectancy of \> 3 months

• * Adequate organ function at screening

• * Adequate contraceptive measures for non-sterilized male and female patients of childbearing potential

• Crizotinib Combination Additional Inclusion Criteria:

ENROLLMENT CONTACT

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Total sites: 15 | 7 currently recruiting

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