LONG-TERM ANALYSIS OF MASTERKEY-265 PHASE 1B
TRIAL OF TALIMOGENE LAHERPAREPVEC (T-VEC) PLUS
PEMBROLIZUMAB IN PATIENTS WITH UNRESECTABLE
STAGE IIIB-IVM1C MELANOMA

Background Previous findings from the MASTERKEY-265 phase 1b study showed that the combination of T-VEC and pembrolizumab was well tolerated and produced a high complete response (CR) rate of 43% in patients with advanced melanoma. The 3-year progression-free survival (PFS) and overall survival (OS) rates at that time were 53.6% and 71%, respectively. Here, we report the results of the long-term follow-up efficacy analyses.

Methods The MASTERKEY-265 study was approved by the institutional review board at each participating center and conformed to the principles of the Declaration of Helsinki with Good Clinical Practice guidelines as defined by the International Conference on Harmonization. All patients provided written informed consent before enrollment.

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A PHASE II STUDY OF NIVOLUMAB + BMS-986016
(RELATILIMAB) IN PATIENTS WITH METASTATIC UVEAL
MELANOMA(UM) (CA224-094)

Background Fifty percent of patients with uveal melanoma (UM) develop metastatic disease, surviving 6–12 months from metastatic diagnosis. Liver-directed therapies, immunotherapy, targeted therapy, and chemo-therapy have limited activity. Lymphocyte activation gene 3 (LAG-3) is an immune checkpoint receptor associated with decreased T-cell effector function and tumor escape. Preclinical models have shown that dual inhibition of LAG-3 and PD-1 blockade generates synergic anti-tumor activity. In uveal melanoma, CD8+ T cells express the checkpoint receptor LAG3 to a greater extent than PD1 or CTLA4. This recent discovery nominates LAG3 as a potential candidate for checkpoint inhibitor immunotherapy in UM.

Methods This is an open-label, single-arm, single site investigator-initiated phase II study. Based on Simon two-stage min-max design, 13 patients will be enrolled in Stage 1. If at least one response is noted, the study will proceed to Stage 2 and enroll additional 14 patients. The null hypothesis will be rejected if 4 or more responses are observed among 27 patients. This design achieves 5% type I error and 80% power when the true ORR is 20%. Main eligibility criteria includes patients with biopsy proven metastatic uveal melanoma, previously untreated with PD-1, CTLA4 and/or LAG-3 blocking antibodies and in good performance status. Enrolled patients will be treated in the outpatient setting. Nivolumab 480 mg will be mixed in the same bag with relatilimab 160 mg and administered intravenously over 60 minutes every 4 weeks until disease progression or intolerable toxicity for up to 24 months. The primary endpoint is best objective response rate (ORR). Secondary endpoints include disease control rate (DCR), progression-free survival (PFS), overall survival (OS), median duration of response (mDOR), and adverse events.

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