Activity of a novel immunotherapy combination of intralesional Coxackievirus A21 and systemic ipilimumab in advanced melanoma patients previously treated with anti-PD1 blockade therapy

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Introduction

Coxackievirus A21 is a small RNA virus and putative oncoimmunotherapeutic class of Coxackievirus A21; it is naturally non-lethal to the host, but has been shown to be replication-competent in vitro. In a previous study, we investigated the efficacy and safety of treatment with Coxackievirus A21 in patients with advanced melanoma. The primary endpoint of the study was overall survival (OS). In a phase I trial, the overall response rate was 6% at 24 weeks, with a median OS of 13 weeks. The study also demonstrated that this combination has the potential to induce a robust immune response in patients with advanced melanoma. In this study, we aimed to further evaluate the efficacy and safety of Coxackievirus A21 in patients with advanced melanoma. The study was conducted in two phases: Phase I and Phase II. The Phase I trial was designed to determine the maximum tolerated dose (MTD) and to assess the safety of Coxackievirus A21 in patients with advanced melanoma. The Phase II trial was designed to further evaluate the safety and efficacy of Coxackievirus A21 in patients with advanced melanoma.

Patient Characteristics

Prior anti-PD1 therapy

Prior anti-CTLA-4 therapy

Prior anti-PD1 and anti-CTLA-4 therapies

Results

Tumor Response

Best Overall Response (BOR) (Preliminary data, investigator assessed)

Prior anti-PD1 therapy

Prior anti-CTLA-4 therapy

Prior anti-PD1 and anti-CTLA-4 therapies

Conclusions

The Coxackievirus A21 (CVA21) combination immunotherapy treatment is generally well tolerated and has demonstrated durable anti-tumor activity in both, original and relapsed disease.

Future Directions

A focus on an oral clinical trial in advanced melanoma patients refractory to prior PD1 and PD-L1 therapies is suggested.

Additional tables and figures are available in the full manuscript.

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