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POSTER PRESENTATION Open Access

A multi-center study of high dose Aldesleukin (Proleukin®(HD IL-2) + Vemurafenib Zelboraf®) therapy in patients with BRAF^{V600} mutation positive metastatic melanoma (proclivity 01)

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Purpose

To investigate whether the Vemurafenib-induced increased tumor antigen expression, T lymphocyte infiltration and tumor debulking improve the complete response rate induced by HD IL-2 in metastatic melanoma and if there is synergistic toxicity using the drugs in close approximation.

Schema

Adult patients with measurable metastatic or unresectable Stage III melanoma with no prior therapy and a BRAF^{V600} mutation who are candidates for HD IL-2 are eligible for entry into the first cohort of 135 patients (figure 1). Six weeks of Vemurafenib therapy per package insert precedes

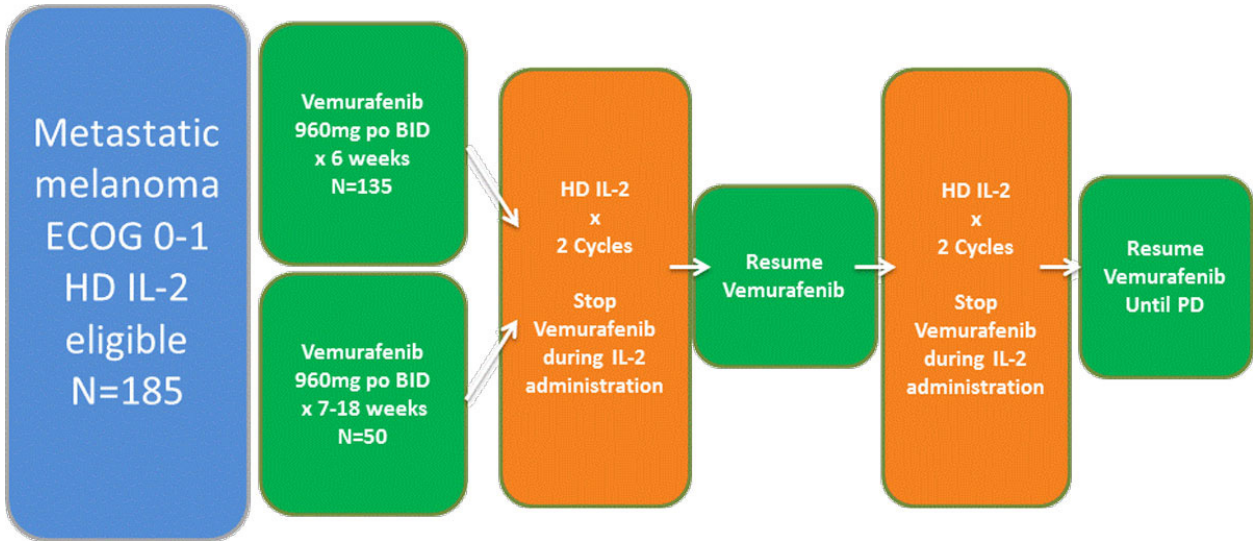

Figure 1 Treatment of metastatic melanoma with HD IL-2 immunotherapy and targeted agent vemurafenib.

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up to 2 courses of HD IL-2. Vemurafenib is administered during the outpatient intervals between cycles of HD IL-2 and following completion. A second cohort of up to 50 similar patients already responding or stable with < 18 weeks of Vemurafenib therapy will also be accrued. The study was amended to permit prior anti-PD-1 therapy. The primary endpoint is Complete Response (CR) and near CR at 6 months of therapy.

Current status

Sixteen sites have enrolled patients. 41 patients have been enrolled to date, 27 in Cohort 1 and 14 in cohort 2. The Data Safety and Monitoring Board performed an initial safety analysis after the initial 8 patients which demonstrated no unexpected safety signal. An analysis of the effect of the combination on Progression Free Survival in both cohorts will be performed after the first 20% of patients in Cohort 1 have received at least one course of HD IL-2. The results of this analysis should be available at the time of the SITC meeting.

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