Changes in peripheral and local tumor immunity after Cemiplimab treatment early describe clinical outcomes in patients with cutaneous squamous cell carcinoma

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INTRODUCTION AND METHODS

Cutaneous squamous cell carcinoma (cSCC) is the second most common skin tumor arising from malignant progression of keratinocytes (Que et al., 2018). It accounts for 20% of all deaths from skin cancer and its incidence its increasing worldwide.

Cemiplimab is a high-affinity, highly potent human monoclonal antibody directed against programmed death 1 (PD-1) (Burova et al., 2017) and the first immune checkpoint inhibitor approved by FDA for the treatment of cSCC not eligible for curative surgery or curative radiation. The absence of biomarkers able to predict response to the immune checkpoint inhibitors in cSCC highlights the need of defining predictive/prognostic molecules.

We collected tumor and liquid biopsies of 12 patients who underwent to cemiplimab before and after 3-weeks of treatment. We profiled RNA of pre- and post-cemiplimab tumor biopsies using the "PanCancer Immunoprofile Panel" (Nanostring). We determined cytokines released in blood by multiplex ELISA, and lymphocyte abundance by flow cytometry.

RESULTS

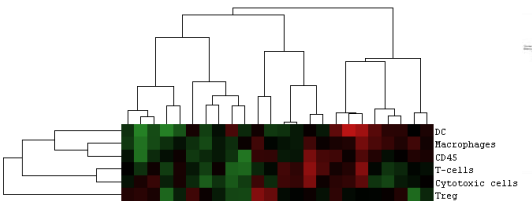

Fig. 1: Heatmap showing cell abundance scores for all samples in the experiments grouped by cell type.

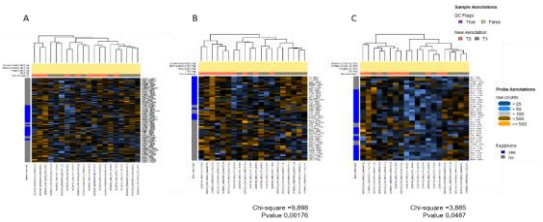

Fig. 2: Heatmap showing unsupervised hierarchical clustering of differentially expressed genes pre- and post- treatment biopsies (T0 and T1). A) Chemokines; B) Cytokines; C) Interleukins.

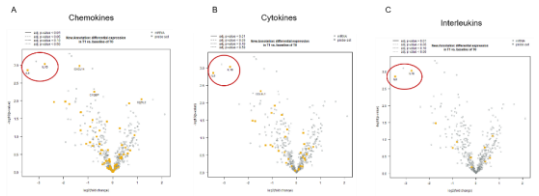

Fig. 3: Top down-modulated genes in the 3 groups of analysis are represented by IL1B and IL8.

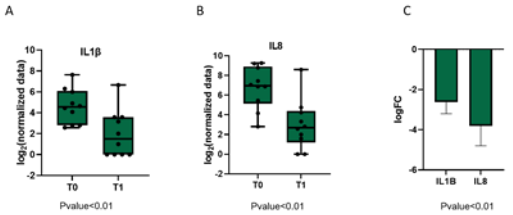

Fig. 4: Top down-modulated genes in the 3 groups of analysis are represented by IL1B and IL8.

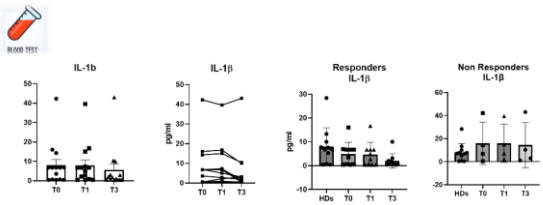

Fig. 5: IL-1β shows decreased level in the peripheral blood of responder patients treated with anti-PD-1.

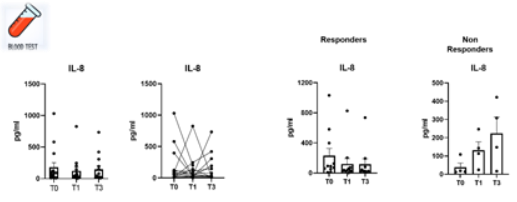

Fig. 6: IL-8 strongly decreases in the peripheral blood of responder patients treated with anti-PD-1.

CONCLUSIONS

- **Anti-PD-1 treatment decreased IL1B and IL8 levels in the tumor tissues;**
- **IL1B and IL8 decreased levels support anti-tumor activity;**
- **Our data reveal IL1B and IL-8 as potential early marker of good response to cemiplimab in the peripheral blood;**
- **Finally, PD-1 Treg cells in the peripheral blood could indicate the bona-fide of the treatment.**

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