#202P The therapeutic cancer vaccine PDC*lung01 induces immune responses with or without anti-PD-1 treatment in patients with non-small cell lung cancer

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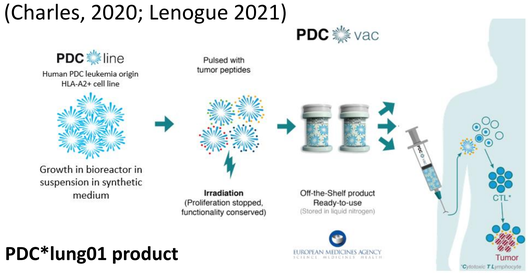
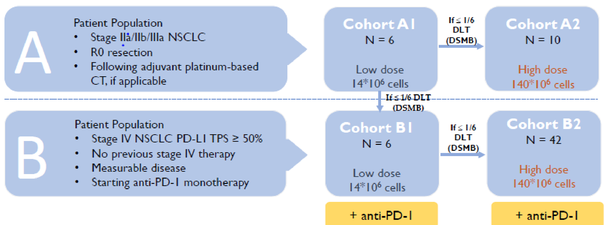
PDC*lung01 Off-the-shelf plasmacytoid dendritic cell-based product

- PDC*lung01 (IMP) is a therapeutic cancer vaccine based on an irradiated plasmacytoid dendritic cell line loaded with HLA-A*02:01 restricted peptides (NY-ESO-1, MAGE-A3, MAGE-A4, Multi-MAGE-A, MUC1, Survivin and Melan-A) able to prime and expand peptide-specific CD8+ T cells *in vitro* and *in vivo*, and is synergistic with anti-Programmed Death (PD)-1 (Charles, 2020; Lenogue 2021)



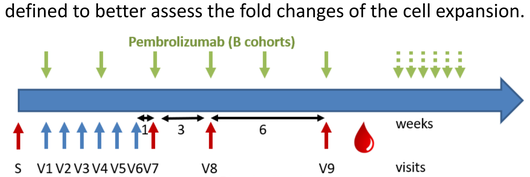
PDC*lung01 product

PDC-LUNG-101 study design

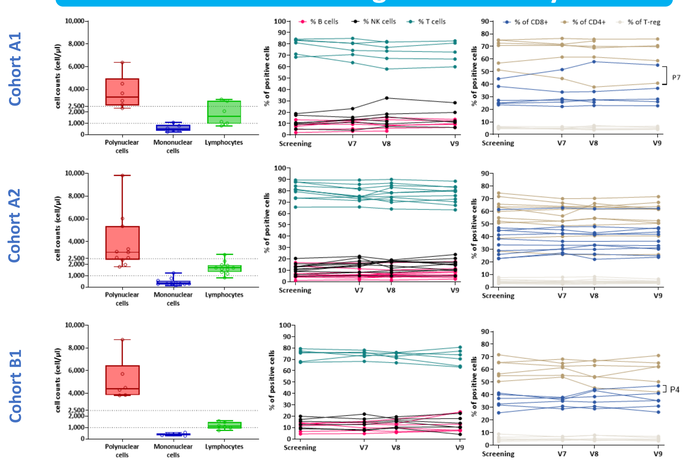


Immunomonitoring assays

- Several circulating immune parameters were monitored at different times before and after vaccination using different assays developed by the sponsor: leukocyte count and determination of peptide-specific CD8+ T cells, for which a limit of quantification (LOQ) was defined to better assess the fold changes of the cell expansion.

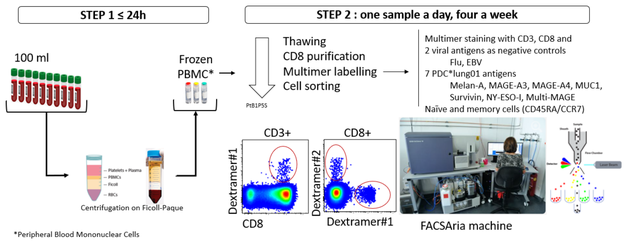


Kinetic of circulating main leukocytes



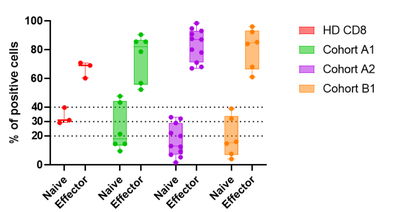
- Lymphocytes, polynuclear & mononuclear cell concentrations at Screening (left) and kinetic of % of circulating NK, B, T, (middle) and CD8+, CD4+ and T-reg (right) at Screening, V7, V8 and V9.

Overview of the immunomonitoring workflow



- Calculation of % of ASTC (Antigen-specific T cells) on CD8+ T-cells as a mean of two determinations Dex#1/Dex#2 & Dex#1:Dex#3

Naïve and Memory circulating CD8+ T-cells

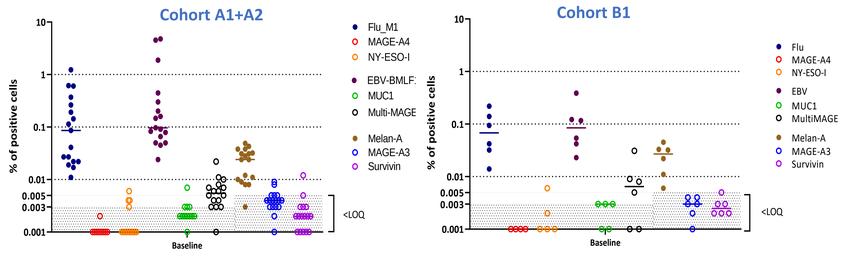


- Compared to healthy donors (HD), at baseline, patients from the different cohorts displayed less naïve cells with a more heterogenous pattern

>>> Conclusion <<<<

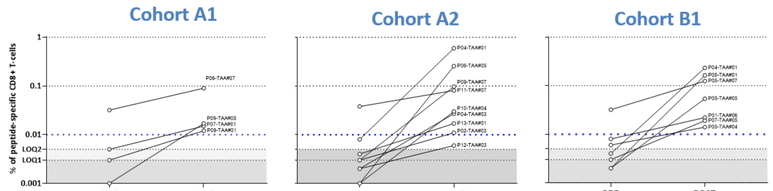
- PDC*lung01 is biologically active to induce an antitumor immune response in a significant number of patients, synergistic with pembrolizumab and associated with clinical responses

Basal circulating frequencies of antigen-specific CD8+ T-cells (ASTC)

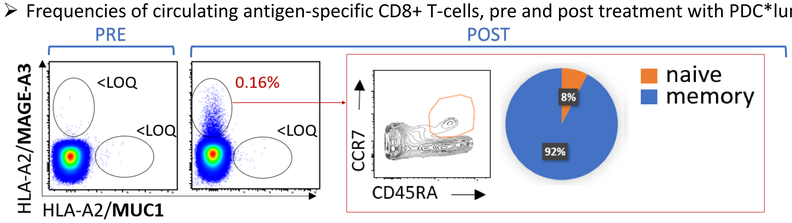


- The basal frequencies of antigen-specific CD8+ T-cells for A (left) and B (right) cohorts were similar. The proportions of tumor antigen-specific T cells targeted were generally under the Limit of Quantification (LOQ, grey zone). By contrast control viral-specific T-cells (EBV or Flu) were well detected.

Expansion of circulating antitumor-specific CD8+ T-cells following PDC*lung01 treatment

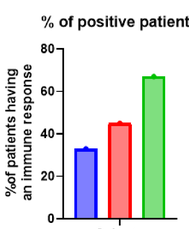


- Frequencies of circulating antigen-specific CD8+ T-cells, pre and post treatment with PDC*lung01



- Expanded antigen-specific CD8+ T-cells displayed a memory phenotype

Correlation between Best Overall Response and immunological response in B1 patients



Best Overall Response		Partial Response	Stable Disease	Progressive Disease
Immunological Response	Specific CD8+ T cells for at least 1/6 lung antigen	3	1	0
	No Immune response detected	1	0	1

A positive patient is defined when a change of at least 2 in the percentage of circulating peptide-specific CD8+ T cells for any of the PDC*lung01 peptides between baseline and V7, V8 or V9.

Protocol Nb: PDC-LUNG-101, Status: Recruiting, Clinical Trial Identification: NCT03970746; Acknowledgements: This study is sponsored by PDC*line Pharma SAS. ; Disclosure Statement: Dr. Anne Sibille declares no conflict of interest
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