PDC*line Pharma presents first clinical results from Phase I/II trial with PDC*lung01 at ESMO 2022

Preliminary results with PDC*lung01 in monotherapy and at low dose with pembrolizumab evoke acceptable safety profile, immunological activity and promising tumor response in Non-Small Cell Lung Cancer

Combination of PDC*lung01 at low dose with pembrolizumab resulted in objective response rate and progression free survival at nine months of 66.7%

Liège, Belgium, and Grenoble, France, September 12, 2022 – PDC*line Pharma, a clinical stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, today announces the first results of its PDC-LUNG-101 phase I/II clinical trial (NCT03970746) with PDC*lung01, the company's therapeutic off-the shelf cancer vaccine candidate for Non-Small Cell Lung Cancer (NSCLC). The preliminary data was presented today at a poster discussion session at the 2022 European Society for Medical Oncology (ESMO) Annual Meeting. This showed that PDC*lung01, in monotherapy and combined with pembrolizumab, evokes an acceptable safety profile, immunological activity and a promising tumor response in Non-Small Cell Lung Cancer, with the caveat of low numbers at the present time.

The objectives of the phase I/II trial (PDC-LUNG-101) are to assess the safety, tolerability, immunogenicity and preliminary clinical activity of the drug candidate PDC*lung01, associated with, or not, anti-PD-1 treatment in NSCLC patients. It is planned to administer PDC*lung01 to 64 evaluable HLA-A*02:01 positive NSCLC patients at two dose levels in two different settings:

- As a single agent to patients in the adjuvant setting (A1: Low Dose, A2: High Dose)
- Or added to standard of care anti-PD-1 monotherapy to patients with first-line stage IV (metastatic) NSCLC disease with a PD-L1 tumor proportion score of ≥50% and no targetable driver mutation, (B1: Low Dose, B2: High Dose)

PDC*lung01 is a cell suspension of seven active agents - made of irradiated human Plasmacytoid Dendritic Cells (PDC*line), loaded with HLA-A*02:01-restricted peptides, derived from NY-ESO-1, MAGE-A3, MAGE-A4, Multi-MAGE-A, MUC1 and Survivin tumor antigens. PDC*line is a potent professional antigen-presenting cell that is able to prime and boost the patient's antitumor cytotoxic CD8+ T-cells and is synergistic with anti-Programmed Death-1 (PD-1) treatment. It is administered weekly by a subcutaneous and intravenous route, in six consecutive doses. Clinical activity is assessed only for B cohorts. Results are reported on the first three cohorts that have been completed (A1/A2/B1).

"With preliminary clinical data now available from patients in the first three enrolled cohorts, it is encouraging to see PDC*lung01 as safe, immunogenic and to have signs of clinical efficacy. Durability of response in all first-line stage IV (metastatic) NSCLC patients with partial response or stable disease is particularly encouraging and provides hope for this patient group where there is still a significant unmet need. I look forward to seeing further clinical results of this compound in NSCLC patients," said Prof Vansteenkiste, head of clinic – respiratory oncology unit and trial unit - department of respiratory diseases (KU Leuven / Belgium) and chair of the Data Safety Monitoring Board for the PDC-LUNG-101 trial.

"I am very pleased that we have been able to present this encouraging data from the PDC-LUNG-101 trial, evaluating PDC*lung01 in combination with a checkpoint blockade. This is a very encouraging step for the company and we are looking forward to sharing a more mature set of data when the B2 cohort is completed," said Dr. Channa Debruyne, medical director of PDC*line Pharma.

"These new results reinforce our differentiating data package for PDC*lung01.They support the potency of our platform to trigger anti-tumor specific and effector memory T-cells against lung antigens in a large proportion of subjects, with a dose effect and a combined effect with anti-PD-1," said Eric Halioua, CEO of PDC*line Pharma.

Key highlights from the poster presentation
Poster title: *Open-label, dose escalation, Phase I/II study to assess safety, tolerability, immunogenicity and preliminary clinical activity of the therapeutic cancer vaccine PDC*lung01 with or without anti-Programmed Death-1 (PD-1) treatment in patients with non-small cell lung cancer (NSCLC).*

- ***PDC*lung01 treatment was feasible with an acceptable safety profile***
  Of the 25 patients (6 in A1, 12 in A2 and 7 in B1) that started treatment, 22 received at least five doses and were evaluable. Treatment-related adverse events were all Grade 1-2 and one Grade 3 with no dose-limiting toxicity (DLT) was observed. Six patients experienced a Serious Adverse Event (SAE), of which only one was considered possibly related to PDC*lung01, occurring six months post-treatment
- ***PDC*lung01 is found to be biologically active to trigger an antitumor immune response in a significant number of patients***
  A peptide-specific and memory CD8+ T-cell response was induced against the lung antigens of PDC*lung01 in 33%, 45% and 67% of evaluable patients in, respectively, A1, A2 and B1 cohorts
- ***PDC*lung01 is associated with a promising objective response rate and progression free survival in combination with pembrolizumab in first line setting stage IV patients***
  The best overall response in six evaluable patients of the B1 cohort, according to RECIST criteria, included four partial responses, one stable disease and one progressive disease, leading to an objective response rate of 66.7% (80% CI 33.3% - 90.7%). Progression free survival at nine months for the same patient population is 66.7% (80% CI 36.4% - 85%)

The abstract is available here.

About PDC*line Pharma's technology

PDC*line's biological features provide unique advantages:
- A professional antigen-presenting cell line, much more potent than conventional dendritic cells in priming and expanding antitumor-specific cytotoxic CD8+ T-cells (conventional tumor antigens and neoantigens)
- While allogeneic, PDC*line is not rejected by the host immune system; it can be injected several times to boost the immune response
- Easily produced on a large scale, with a fully mastered and simple manufacturing process (via use of bioreactors with a synthetic medium without growth, differentiation or activation factors)

- Easy to use: after thawing, the same off-the-shelf product is used to treat the whole target population with a cancer type expressing the target antigens
- Very versatile: tumor antigens can be provided by peptide loading, mRNA transfection or retrovirus transduction of PDC*line and the target population can be extended beyond HLA-A2, (currently used as it is expressed by 50% of the Caucasian population), by using other HLAs, either already expressed by PDC*line or added by genetic modification. Moreover, within a few weeks new candidates can be validated for new cancer indications, with *ex vivo* testing using human Peripheral Blood Mononuclear Cells (PBMC)
- Synergizes with anti-PD-1 to activate antitumor CD8 T-cells

About PDC*line Pharma

Founded in 2014 as a spin-off of the French Blood Bank (EFS), PDC*line Pharma is a Belgian-French clinical-stage biotech company that develops an innovative class of active immunotherapies for cancers, based on a GMP-grade allogeneic therapeutic cell line of Plasmacytoid Dendritic Cells (PDC*line). PDC*line is much more potent than conventional dendritic cell-based vaccines in priming and boosting antitumor antigen-specific cytotoxic T-cells, including the T-cells specific for neoantigens, and is synergistic with checkpoint inhibitors. The technology can potentially be applied to any type of cancer. Following a first-in-human phase I feasibility study in melanoma, PDC*line Pharma focuses on the development of PDC*lung01, a candidate for Non-Small-Cell Lung Cancer (NSCLC) currently in phase I/II trials, and PDC*neo with neoantigens in preclinical development. The company has a staff of 30, with an experienced management team. It has raised more than €52M in equity and non-dilutive funding. In March 2019, PDC*line Pharma granted an exclusive license to the LG Chem Life Sciences company in South Korea and an exclusive option in other Asian countries, for the development and commercialization of the PDC*lung01 cancer vaccine for lung cancer. The total deal is worth $123M, plus tiered royalties on net sales in Asia.
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