PDC*line Pharma presents first immunological results from phase I/II trial with PDC*lung01 at ESMO-IO 2022

Treatment with PDC*lung01 induces anti-tumor immune response in significant number of patients which appears to be enhanced by combination with pembrolizumab

Liège, Belgium, and Grenoble, France, December 8, 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 immunological 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 display session at the ESMO Immuno-Oncology Congress 2022 (ESMO-IO) in Geneva (Switzerland). Results showed that in a large proportion of subjects PDC*lung01, in monotherapy and combined with pembrolizumab, induces a significant expansion of effector memory CD8+ T-cells specific to the tumor peptides carried by PDC*lung01.

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 or not with anti-PD-1 treatment in NSCLC patients. PDC*lung01 will be administered to a total of 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)
- 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 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. It is administered weekly by a subcutaneous and intravenous route, in six consecutive doses. Safety and clinical activity of the product were presented at ESMO 2022 in September 2022 in Paris (France). PDC*line is a potent professional antigen-presenting cell line that is able to prime and boost the patient's antitumor cytotoxic CD8+ T-cells and is synergistic *in vitro* with anti-Programmed Death-1 (PD-1) treatment. The poster presented the analysis of the immune responses of the first three cohorts of patients.

"We are very pleased that PDC*lung01 is found to be biologically active to trigger an antitumor immune response, detectable without any *in vitro* restimulation, in a significant number of patients in our NSCLC clinical trial. The first signal of correlation between immune and clinical responses in six metastatic patients from the B1 cohort is encouraging," **said Dr. Joël Plumas, co-founder and chief scientific officer of PDC*line Pharma.**

"Presenting the first immunological data set from our lead candidate, PDC*lung01, for the treatment of NSCLC at ESMO-IO, a major immuno-oncology conference, is an important milestone for the company," added **Eric Halioua, CEO of PDC*line Pharma.** "We are very pleased to demonstrate that our innovative immunotherapy platform can induce a strong immune response in humans. These first results illustrate the potential targeted

mechanism of action of PDC*lung01 to prime naive anti-tumor specific T-Cells and trigger effector memory T-cells in humans."

Key highlights from the poster display
Poster title: *The therapeutic cancer vaccine PDC*lung01 induces immune responses with or without anti-PD-1 treatment in patients with non-small cell lung cancer.*

- **Several circulating immune parameters were monitored at different times before and after PDC*lung01 administrations using assays developed by PDC*line Pharma**
  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. Assays allow evaluation of circulating antitumor specific CD8+ T-cells pre and post treatment, *ex vivo* with an LOQ of 0.003%, without prior *in vitro* restimulation

- **PDC*lung01 is found to be biologically active to trigger an antitumor immune response in a significant number of patients**
  23 of the 25 patients included received at least four doses and were evaluable. No major changes in circulating lymphocyte frequencies (B cells, NK cells, CD4+, CD8+, or Treg T-cells) were observed during treatment. In contrast, a specific and memory CD8+ T-cell response was induced against the antigens from which are derived the peptides loaded on PDC*lung01 in 33%, 45% and 67% of evaluable patients in, respectively, A1 (six patients), A2 (eleven patients) and B1 (six patients) cohorts

- **First signal of correlation observed between immune and best overall clinical responses in metastatic patients treated with pembrolizumab**
  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. CD8+ T-cells for at least one of the six lung antigens were observed in the majority of the partial and stable disease patients. In contrast, no immune response was detected in the progressive disease patient

The poster 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 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 32, with an experienced management team. It has raised more than €56M 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 €108M, plus tiered royalties on net sales in Asia.
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