AACR 2024: PDC*line Pharma presents interim clinical results from last cohort of patients in phase I/II trial with PDC*lung01 cancer vaccine

Intermediary results of high dose PDC*lung01 combined with pembrolizumab show mild safety profile, immunological activity and promising tumor response in Non-Small Cell Lung Cancer patients

Combination of high dose PDC*lung01 with pembrolizumab in 19 evaluable patients resulted in objective response rate of 63.2% and median progression-free survival of 10.9 months

Liège, Belgium, and Grenoble, France, April 8, 2024 – PDC*line Pharma, a clinical-stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, today announces the interim results from the last cohort of patients in its phase I/II clinical trial (PDC-LUNG-101, NCT03970746) with PDC*lung01.

PDC*lung01 is the company's off-the shelf therapeutic cancer vaccine candidate for Non-Small Cell Lung Cancer (NSCLC). The preliminary data on the last cohort of patients was presented today through both an oral presentation and a poster at the American Association for Cancer Research (AACR) Annual Meeting 2024. This data revealed that the high dose PDC*lung01 combined with pembrolizumab shows an immunological activity in a majority of patients and a promising antitumor response in stage IV NSCLC with a mild safety profile.

The phase I/II trial (PDC-LUNG-101) aimed to assess the safety, tolerability, immunogenicity and preliminary clinical activity of PDC*lung01 in NSCLC patients, alone or in combination with anti-PD-1 treatment. PDC*lung01 was administered weekly through both subcutaneous and intravenous routes, in six consecutive doses. The trial was conducted across 17 clinical sites in France, Belgium, Germany, the Netherlands and Poland. PDC*lung01 was administered to a total of 67 evaluable HLA-A*02:01 positive NSCLC patients, at two dose levels and settings:

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

Clinical activity parameters such as Objective Response Rate (ORR) and Progression-Free Survival (PFS) were assessed only in cohorts B1 and B2. The B2 cohort included 45 patients. PDC*Line is reporting preliminary efficacy results for 19 evaluable patients in the B2 cohort that reached the 9-month PFS mark.

Key highlights from the oral presentation
Title: *Preliminary clinical results of a therapeutic cancer vaccine PDC*lung01 in combination with anti-PD-1 in patients with Stage IV NSCLC*

- ***PDC*lung01 treatment at high dose with pembrolizumab exhibited a mild safety profile***
  At database cut-off, 38 patients started treatment. Out of the 21 patients in the B2 cohort who started treatment and reached the 9-month follow-up, 19 received at least 5 doses of PDC*lung01 and had 1 post-baseline radiological evaluation, qualifying them

as evaluable per protocol. Overall, the high dose of PDC*lung01 showed an acceptable safety profile. Most of the treatment-related Adverse Events (AEs) were consistent with AEs associated with SC/IV injections of other vaccines, or with AEs already observed in clinical trials of anti-cancer vaccines. The evaluation of the SAEs reported did not identify any safety concerns.

- ***PDC*lung01 demonstrated biological activity in triggering an antitumor immune response in the majority of patients***
  A peptide-specific and effector memory CD8+ T-cell response was induced against the lung antigens of PDC*lung01 in 68.4% of patients. Immune responses with remarkable expanded anti-tumor CD8+ T-cells were observed in both Partial Response and Stable Disease patients. More immune response results will be available in the final analysis of the 45 patients in cohort B2.

- ***PDC*lung01, in combination with pembrolizumab, is associated with a promising objective response rate and progression free survival in first line setting stage IV NSCLC patients***
  With the 19 evaluable patients, the median follow-up at the database lock was 12.5 months (95% CI: 9.9, 14.2). The Best Objective Response (BOR) included 12 Partial Response (63.2%) and 7 Stable Disease (36.8%) with ORR of 63.2% (80% CI 45.9 - 78.2) and a Disease Control Rate (DCR) of 94.7% (80% CI: 81, 99.4). The 9-month PFS according to the Kaplan-Meier estimate was 52.1% (80% CI 36.5 - 65.56). The median PFS was 10.9 months (95% CI 5.6 – Not Reached). The median duration of response was 9.49 months (95% CI: 4.4, -).

The safety, immunological and clinical activity results from the B2 cohort are consistent with the data from the first three cohorts of patients (A1, A2 and B1) that were presented at ESMO 2022 in September 2022 in Paris (France) and ESMO-IO in December 2022 in Geneva (Switzerland).

The final analysis of the clinical trial including the 45 patients from the B2 cohort will be conducted in Q3, 2024.

The oral presentation is available here.
The poster presentation is available here.

"PDC*lung01 in combination with anti-PD-1 showed very promising signals suggesting that this combination could offer a clinically meaningful tumor response in stage IV NSCLC patients, along with an interesting mild safety profile," said Prof Johan Vansteenkiste, emeritus professor in respiratory oncology at KU Leuven in Belgium and chair of the Data and Safety Monitoring Board (DSMB).

"These interim results have real potential; this is a very encouraging step for the company. We are looking forward to sharing the complete set of data when the B2 cohort is complete," said Dr. Beatrice De Vos, chief medical officer at PDC*line Pharma.

"We are excited to share these very favourable results for our innovative cancer vaccine. The objective response rate of 63.2% and the median progression free survival of 10.9 months along with a mild safety profile are in line with our targets. We're also encouraged by the evidence of immune response observed in patients, which supports the mechanism of action of PDC*lung01 in relation to clinical activity," said Eric Halioua, CEO of PDC*line Pharma.

About PDC*lung01

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, Survivin and Melan-A 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.

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 42, with an experienced management team. It has raised more than €62M 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.
www.pdc-line-pharma.com

Media and analysts contact
Andrew Lloyd & Associates
Saffiyah Khalique – Juliette Schmitt
saffiyah@ala.associates / juliette@ala.associates
UK: +44 1273 952 481