PDC*line Pharma completes enrolment of four cohorts of patients in PDC-LUNG-101 phase I/II clinical trial

Total of 67 patients dosed in four cohorts in PDC-LUNG-101 trial with PDC*lung01 therapeutic cancer vaccine candidate for non-small cell lung cancer

Liège, Belgium and Grenoble, France, December 6, 2023 – PDC*line Pharma, a clinical stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, today announces the completion of enrolment of the fourth cohort of patients in its PDC-LUNG-101 phase I/II clinical trial (NCT03970746) with PDC*lung01, the company's therapeutic cancer vaccine candidate for Non-Small Cell Lung Cancer (NSCLC). This cohort, B2, was designed to assess PDC*lung01 at 'high dose', added to pembrolizumab in monotherapy in a first-line stage IV setting. It includes 45 patients.

The objectives of the phase I/II trial (PDC-LUNG-101) were 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. The trial was conducted at 17 clinical sites in France, Belgium, Germany, the Netherlands and Poland. PDC*lung01 has been administered to a total of 67 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)

Safety and clinical activity results of the first three cohorts of patients (A1, A2 and B1), which included a total of 22 patients, were presented at ESMO 2022 in September 2022 in Paris (France) and ESMO-IO in December 2022 in Geneva (Switzerland). Preliminary results with PDC*lung01 in monotherapy and at low dose with pembrolizumab show a mild safety profile, immunological activity and promising tumor response in Non-Small Cell Lung Cancer.

"It is a privilege to be the global principal investigator in the PDC*lung01 cancer vaccine program. I am thrilled that we have reached this significant milestone in its development. Most advanced stage NSCLC patients eligible for pembrolizumab as a monotherapy in the first line of treatment still show high unmet need. It makes sense to combine anti-PD-1, which works to unleash anti-tumor cytotoxic T cells, with PDC*line, to prime and boost T-cells. PDC*lung01 is the only therapeutic vaccine currently in development in this setting, providing great hope for patients," said Prof Johan Vansteenkiste, emeritus professor in respiratory oncology at KU Leuven in Belgium and chair of the Data and Safety Monitoring Board (DSMB).

"We are pleased to have achieved full patient enrolment in the PDC-LUNG-101 clinical trial, a key step in the product's clinical development and another important milestone for PDC*line Pharma. We look forward to presenting our interim report on the clinical trial at international conferences next year including the promising safety, immunological and clinical results we have observed in the first 19 evaluable patients of the B2 cohort," said Eric Halioua, CEO of PDC*line Pharma.

"I would like to extend my gratitude to the investigators and patients across the five countries included in our clinical trial. Their commitment has been invaluable. We eagerly anticipate the next steps in our development process and look forward to continuing our collaboration with all the trial sites," said Dr. Beatrice De Vos, chief medical director at PDC*line Pharma.

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. PDC*line is a potent professional antigen-presenting cell line that primes and boosts the patient's antitumor cytotoxic CD8+ T-cells and is synergistic *in vitro* with anti-Programmed Death-1 (PD-1) treatment.

In October 2023, the Data and Safety Monitoring Board (DSMB) confirmed the mild safety profile of PDC*lung01 at high dose in association with pembrolizumab in the B2 cohort.

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 is now focused on the development of PDC*lung01, its 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 close to €56M in equity and non-dilutive funding. In March 2019, PDC*line Pharma granted the LG Chem Life Sciences company an exclusive license 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.
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
@ALA_Group