PDC*line Pharma opens last cohort of PDC-LUNG-101 clinical trial

B2 cohort (high dose added to anti-PD-1) of the PDC-LUNG-101 trial with PDC*lung01 therapeutic cancer vaccine candidate for non-small cell lung cancer has been opened and first patients were dosed

Liège, Belgium and Grenoble, France, November 4, 2021 – PDC*line Pharma, a clinical stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, today announces that the last cohort of patients has been opened and the first patients were dosed, in the 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).

PDC*lung01 is a cell suspension of a mix, in the same proportion, of seven active agents - made of irradiated human plasmacytoïd dendritic cells (PDC*line), loaded separately with a distinct synthetic human leukocyte antigen serotype-restricted peptide - (HLA-A*02:01), encoded by a tumor antigen. PDC*line is a potent professional antigen-presenting cell that is able to prime and boost the antitumor cytotoxic CD8+ T-cells in the patient's immune system.

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 62 evaluable HLA-A*02:01 positive NSCLC patients at two dose levels in two different settings: as a single agent to adjuvant patients (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 (B1: Low Dose, B2: High Dose).

Following the completion of the first three cohorts (A1, A2 and B1), the Data and Safety Monitoring Board (DSMB) assessed all safety parameters. As no dose-limiting toxicity or other safety signals were observed, it allowed the opening of the last cohort, B2.

This cohort of 42 evaluable patients will assess PDC*lung01 at 'High Dose' added to pembrolizumab in monotherapy in a first line Stage IV setting.

The first patient dosed in the B2 cohort is under the supervision of Dr Kristof Cuppens, medical oncologist at the Jessa Ziekenhuis Hospital in Hasselt (Belgium). Currently, there are clinical sites open in France, Belgium and Germany.

"This is a very interesting trial with PDC*lung01 vaccine, especially thanks to the potential to administer it in combination with anti-PD1 immunotherapy. Early data from the first three cohorts show a very mild safety profile and good patient acceptance," said Prof Vansteenkiste, head of clinic – respiratory oncology unit and trial unit - department of respiratory diseases (KU Leuven / Belgium) and chair of the DSMB.

"We are delighted to have achieved this new milestone in our NSCLC clinical trial, which is progressing well - despite the Covid-19 pandemic. We look forward to completing the B2 cohort, in order to assess the preliminary clinical activity of our vaccine in association with anti-PD1 immunotherapy in the target NSCLC population," said Eric Halioua, CEO of PDC*line Pharma.

"I would like to thank both the investigators and patients for their continued participation in the study. We are encouraged by the favorable safety profile, also in combination with anti-PD1. We are looking forward to opening new clinical centers in The Netherlands and Poland; ensuring a continued smooth enrolment for this target trial population," said Dr. Channa Debruyne, medical director of PDC*line Pharma.

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, new candidates can be validated for new cancer indications within a few weeks, 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 25, with an experienced management team. 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 (€143.3M), plus tiered royalties on net sales in Asia.
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