PDC*line Pharma obtains authorization to launch phase I/II trial of its cancer vaccine (PDC*lung01) in non-small cell lung cancer

PDC*line is a potent, scalable and versatile professional antigen-presenting T-cell with great potential for treating a range of cancers

Liège, Belgium, and Grenoble, France, May 7, 2019 - PDC*line Pharma, a clinical stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, announces today that the Belgian Federal Agency for Medicines Health Product (FAMHP), together with the designated Ethics Committee, have authorized the initiation of an open-label, dose-escalation, phase I/II trial with its cancer vaccine candidate (PDC*lung01) for non-small-cell lung cancer (NSCLC).

The objectives of this phase I/II study (PDC-LUNG-101) are to assess safety, tolerability, immunogenicity and preliminary clinical activity of the drug candidate, PDC*lung01, associated or not with anti-PD-1 treatment in non-small cell lung cancer. A total of 66 evaluable, HLA-A*02:01 positive NSCLC patients will be included in the study. The multicenter trial will be launched at three clinical centers in Belgium at the end of Q2 2019 and as well as at six additional sites in France, pending the approval of French authorities.

PDC*lung01 is a cell suspension of a mixture of seven active agents in equal proportions made of irradiated human plasmacytoid dendritic cells (PDC*line). Each is loaded with a different synthetic human leukocyte antigen serotype-restricted peptide (HLA-A*02:01) derived from lung tumor antigens. 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 Cell Therapy Unit of EFS Rhone-Alpes in Saint Ismier (France), a GMP-accredited facility and partner of PDC*line Pharma, manufactures the PDC*lung01 drug product. Quality control and release of the drug product is ensured by PDC*line Pharma's GMP laboratory, located at the LabHotel of GIGA (Liège, Belgium).

"PDC*line Pharma has developed an innovative and potent immunotherapy that appears particularly suitable for the treatment of NSCLC patients," said Johan Vansteenkiste, Professor of Internal Medicine at the Catholic University of Leuven, Belgium, who is also Head of Clinic at the Respiratory Oncology and Clinical Trial Unit at the University Hospital KU Leuven and global principal investigator for the PDC-LUNG-101 study.

"The launch of this clinical trial with our lead cancer vaccine product is a major milestone for PDC*line Pharma and recognition by the regulatory authorities of the quality of the data generated by our team and our partners," said Eric Halioua, president & CEO of PDC*line Pharma.

About lung cancer

Lung cancer is the most common malignancy worldwide for male patients and for both sexes combined (2.1 million new cases per year), and the third most common for female patients (after breast and colorectal cancers). Deaths from lung cancer exceed those from any other malignancy globally, with the number of lung-cancer-related deaths worldwide for 2018 estimated at 1.8 million[1], representing 18.4% for both sexes. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, representing 80% of cases.

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 T-cells specific for neoantigens, and is synergistic with checkpoint inhibitors. The technology can 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) and neoantigens (PDC*Neo). The company has a staff of 20 people, with an experienced management team. The company has so far raised €17M ($19.3M) including €7.6M ($8.6M) in equity and loans from Belgian investors (MeusInvest, Innodem3, InvestSud and SFPI) and several business angels, in addition to €9.3M ($10.5M) of non-dilutive funding (including grants from the Walloon region, Belgium, French entities and the European Commission).
In March 2019, the company granted an exclusive license to 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 value is €108M ($123M) plus tiered royalties on net sales in Asia.

www.pdc-line-pharma.com

About PDC*line Pharma's technology

PDC*line's biological features provide **unique advantages**:

- PDC*line is a professional antigen-presenting cell, **much more potent** than conventional DC 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 and can be injected several times to boost the immune response
- PDC*line can easily be **produced on a large scale**, with a fully mastered and simple manufacturing process (use of bioreactors with a synthetic medium without growth, differentiation or activation factors)
- PDC*line is 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
- PDC*line is **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 in a few weeks, with *ex vivo* testing using human PBMC
- PDC*line **synergizes with anti-PD-1** to activate antitumor CD8 T cells

[1] https://www.iarc.fr/wp-content/uploads/2018/09/pr263_E.pdf GLOBOCAN 2018

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