



PDC*line Pharma announces the administration of a first patient with its therapeutic cancer vaccine candidate (PDC*lung01) targeting non-small cell lung cancer

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

Liège, Belgium and Grenoble, France, March 2, 2020 – PDC*line Pharma, a clinical stage biotech company developing a new class of potent and scalable active immunotherapies for cancers, announces today that the first patient was dosed with its innovative medicinal product candidate PDC*lung01 in a phase I/II trial in non-small cell lung cancer (NSCLC). This patient is under the supervision of Dr. Anne Sibille, principal investigator for the Liege University Hospital (Belgium).

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. A total of 62 evaluable HLA-A*02:01 positive NSCLC patients are expected in three clinical centers in Belgium and six in France.

PDC*lung01 is a cell suspension of a mix, in the same proportion, of seven active agents made of irradiated human plasmacytoid dendritic cells (PDC*line) loaded separately with a distinct synthetic human leukocyte antigen serotype-restricted peptide (HLA-A*02:01) encoded by a tumour 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.

"We are delighted to have achieved this first important milestone in the clinical development of PDC*line Pharma with our lead cancer vaccine candidate," said Eric Halioua, president and CEO of PDC*line Pharma. "Based on preclinical studies there is a strong rationale for developing PDC*lung01 in this indication and we are currently exploring a number of additional indications, where our technology may provide potential benefit for patients."

"PDC*lung01 is an innovation in the field of cancer vaccines that appears particularly suitable for the treatment of NSCLC patients, an area where there is still a high unmet medical need," said Dr. Channa Debruyne, medical director of PDC*line Pharma.

About lung cancer

Worldwide, lung cancer is the most common malignancy 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). Globally, deaths from lung cancer exceed those from any other cancer, with the number of lung-cancer-related deaths for [2018 estimated at 18.1 million](#); 18.4% of total cancer deaths. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, representing 80% of cases.

About PDC*line Pharma's technology

PDC*line's biological features provide unique advantages:



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- 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 and can be injected several times to boost the immune response
- Easily 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)
- 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 in 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 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 22, 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 €108M (\$120M), plus tiered royalties on net sales in Asia.
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