



**PDC\*line**  
**pharma**  
ADVANCED CANCER  
VACCINES

Executive Summary  
(09/06/2020)



*« We are developing a novel class of potent and off-the-shelf cancer immunotherapies to treat cancer patients »*

**PDC\*line Pharma ([www.pdc-line-pharma.com](http://www.pdc-line-pharma.com)) is a clinical-stage spin-off of the French Blood Bank (EFS) that develops a new class of potent and off-the-shelf therapeutic cancer vaccines based on a proprietary cell line of Plasmacytoid Dendritic Cells (PDC\*line). Based on a robust preclinical package and a first-in-human phase Ib in melanoma, PDC\*line Pharma has initiated a clinical development in lung cancer with a new candidate (PDC\*lung) and neoantigens (PDC\*Neo).**

Immune-checkpoint inhibitors such as anti-PD-(L)1 offer unprecedented hope to cancer patients and are becoming a backbone treatment in several indications. It represents a market potential of tens of billions of euros by 2021. However, around 70% patients don't respond to anti-PD-(L)1. Non-responders often lack pre-existing anti-tumor immunity. Therefore, a combination with therapeutic vaccines is expected to improve the response to anti-PD-(L)1 immune checkpoint inhibitors (Mellman I. et al., Cancer Immunology Research, 2016).

For decades, researchers have been trying to develop therapeutic vaccines to promote a potent anti-tumor immune-response in cancer patients. **The most potent therapeutic vaccines approach is considered to be based on dendritic cells (DC)** due to their unique antigen-presenting properties. However, DC-based vaccines are autologous cell therapies which face complex

and costly logistic and production processes and still lack convincing clinical efficacy.

**Thanks to its exclusive cell line of Plasmacytoid Dendritic Cells (PDC\*line), PDC\*line Pharma is developing a ground-breaking solution to address the scalability and potency challenges faced by conventional DC-based vaccines. PDC\*line is much more potent than conventional DC in priming and boosting fully functional antitumor CD8+ T cells displaying a strong cytotoxic activity against tumor cells.** Contrary to autologous DC-based vaccines, it is an **off-the-shelf approach, easily scalable at industrial scale.** In addition, it is **highly versatile**, and it is **synergetic with anti-PD-1** immune checkpoint inhibitors.

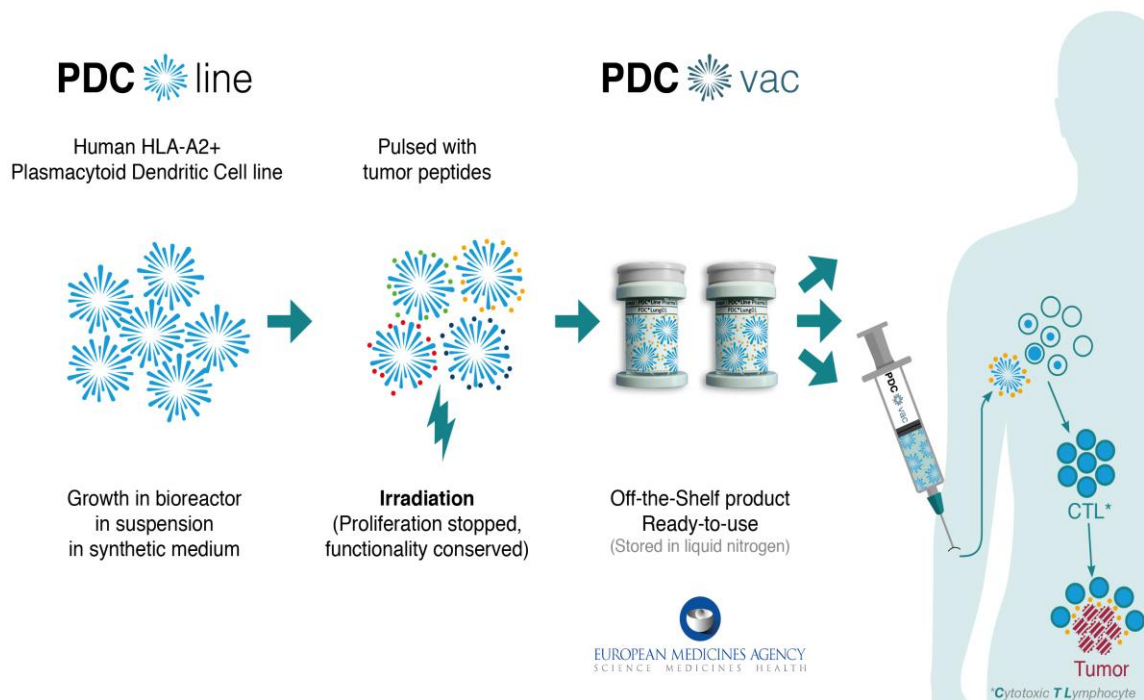
## TECHNOLOGY & COMPETITIVE ADVANTAGES

PDC\*line is the **only cell line of Dendritic Cells for therapeutic use**. It is exposed *in vitro* to tumor antigens, irradiated, and can be stored frozen for years. After thawing, it is injected to activate *in vivo* a potent cytotoxic anti-tumor CD8+ T-cell response. The product is classified as an ATMP (Advanced-Therapy Medicinal Product) by the EMA (European Medicines Agency). It currently comes in the form of 3 candidates:

- **PDC\*mel:** our first candidate for melanoma completed a first-in-human phase Ib trial in 2017, demonstrating the safety of the product, the absence of allogeneic rejection and its biological activity. The results of the trial have been published and the study is not active anymore.
- **PDC\*lung:** our leading candidate for non-small-cell lung cancer (NSCLC) targets widely expressed shared antigens (including cancer/testis antigens). A phase Ib/II trial evaluating its safety and biological activity, with and without anti-PD1, is currently on-going.
- **PDC\*neo:** is currently being developed at the pre-clinical stage.

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 neo-antigens).
- While allogeneic, **PDC\*line is not rejected** 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 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 boost anti-tumor CD8+ T cells



Description of the PDC\*line Pharma manufacturing process

In addition, the safety of PDC\*line and its ability to prime and boost antitumor T cells in vivo have been demonstrated in humanized mice and melanoma patients.

## IP POSITION

PDC\*line Pharma's Intellectual Property rests on three pillars:

- **Proprietary PDC\*line:** PDC\*line is unique and is the only cell line of human DCs for therapeutic use. A Master Cell Bank manufactured under GMP procedures has been fully characterized and validated in terms of biological safety.
- **Two** granted international **patent** families (co-invented by Joel PLUMAS, licensed from EFS) protecting PDC\*line generation (WO 2004/061089) and the therapeutic use of any Plasmacytoid DC lines (WO 2009/138489). **One patent filed in 2018** protecting genetic optimizations of PDC\*line.
- **Strong expertise** and a large set of data accumulated over more than 15 years in the fields of pre-clinical data, manufacturing process, Quality Control and immuno-monitoring *in vitro* assays.

## MARKET OPPORTUNITY

The PDC\*line technology is a platform that can be used for the treatment of virtually all cancer patients expressing HLA-A2 (50% of EU population, and 36% of US) – with extension possibilities to other HLAs. The revenue potential is in the range of € 3 BN to € 4.5 BN in the US and EU. Our leading candidate **PDC\*lung for ad-**

**vanced non-small cell lung cancer** represents a significant market in the US and EU: 380,000 new cases per year, leading cause of cancer deaths, and potential sales of about € 1.6 BN. This drug candidate may also be used for other cancers that express the same antigens.

## TEAM

PDC\*line Pharma comprises a team of 25 persons based in Belgium (Liège, headquarters) and France (Grenoble).

**Eric HALIOUA (MS, MBA), President & CEO**, is a successful serial entrepreneur, co-founder of Myosix (sold to Genzyme/Sanofi), Murigenetics, HairClone and Digital Orthopaedics and former CEO of Promethera Biosciences. He raised more than 130 M€ over the course of his career and had numerous successes in the sale and IPO of biotechnology companies.

**Laurent LEVY (MS, MBA), Co-founder, Board member & COO/CFO** has a 25-year experience in finance and business development in Life Sciences. He has worked with over 100 companies at the regional and international levels. As CFO and Development director of a leading French Cancer Cluster, he managed an oncology focused fund (30 projects, €36 M budget). He co-founded PDC\*line Pharma and won several prizes.

**Dr. Joel PLUMAS (Ph.D.), Co-founder, Board member & CSO**, is a former director of the "Immunobiology and Immunotherapy of cancer" R&D lab of the French blood bank (EFS), Grenoble University and INSERM that invented the technology. He coordinated its development up to clinical trial including manufacturing, regulatory and IP issues. Joel has developed the technology for more than 15 years.

**M. Claude Dedry (Industrial Pharmacist), Vice-President of Pharmaceutical operations & Quality**, is the owner of CMDL Consulting (Belgium). He is the former COO of Promethera Biosciences, QA director of GSK vaccines and has an over 25-year experience in bioproduction and cell therapy.

**Dr. Channa Debruyne (MD), Medical Director**, has more than 25-year experience in the clinical development of chemotherapeutic products and immunotherapeutic vaccines. She led the clinical team for the GSK MAGE-A3 Cancer Immunotherapeutic registration trials. She had a successful career at EORTC (European Organisation for Research and Treatment of Cancer), EMA (European Medicines Agency), GSK Vaccines and University Hospital Leuven.

**Other board members:** Dr. Mondher Mahjoubi (MD, independent president of the board), Dr. Alain HERRERA (MD, independent board member), Dr. Jean-Paul PRIEELS (Ph.D., shareholder), Hugues Wallemacq (MBA, Noshag), François Fontaine (SPFI) and Sangwoo Lee (Korean Investment Partners).

## FINANCING AND CORPORATE DEAL

The company has raised nearly **€31.5 M** (19,5 M€ in equity and 12 M€ of non-dilutive money). The last round has been led by the Asian leading VC KIP (Korean Investment Partners).

In March 2019, PDC\*line Pharma granted an exclusive license in South Korea and exclusive option in other

Asian countries to **LG Chem** Life Sciences Company, for the development and commercialization of PDC\*lung cancer vaccine for lung cancer. The total deal value is **€108M (123M\$)** plus significant tiered royalties on net sales in Asia.

## ACHIEVEMENTS OVER THE LAST 18 MONTHS

- January 2019: GMP accreditation by the Belgian Federal Agency for Medicines and Health Products (FAMHP) for its Quality Control & Release Activities for PDC\*lung.
- June 2019: authorization to launch an open-label, dose-escalation, phase I/II trial with the cancer vaccine candidate (PDC\*lung01) in non-small cell lung cancer in Belgium and France (with and without anti-PD-1).
- August 2019: the arrival of a new Medical Director (Dr. Channa Debruyne) that has led the clinical team for GSK vaccines MAGE-A3 Cancer Immunotherapeutic registration trials in lung and melanoma indications.
- December 2019: closing of a 20M€ B-Round of financing led by the multi-billion Asian VC KIP (Korea Investment Partners).
- February 2020: First PDC\*lung01 administration dosed in patient with non-small cell lung cancer.
- June 2020: strengthening of board of directors with an industry leader in the field of immuno-oncology (Mondher Mahjoubi)
- September 2020: doses first patient with high dose in the cancer vaccine candidate (PDC\*lung01)

## CONTACTS FOR INVESTORS AND INDUSTRIAL PARTNERS

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