PDC*line pharma
ADVANCED CANCER VACCINES

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

PDC*line Pharma (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 is completing Phase I/II study in lung cancer (PDC*lung) in 2024 and will initiate a new Phase Ib trial with neoantigens (PDC*neo) in 2025. The company has raised €61M and signed a €108M licensing deal in Asia with the pharma company, LG Chem Life Science.

Immune-checkpoint inhibitors such as anti-PD-(L)1 offer unprecedent hope to cancer patients and are becoming a backbone treatment in several indications. It represents a of tens of billions of euros. 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, most DC-based vaccines are developed from the patient's own cells (autologous), and therefore face complex and costly logistic and production processes. Moreover, their clinical efficacy is still to be convincingly demonstrated.

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

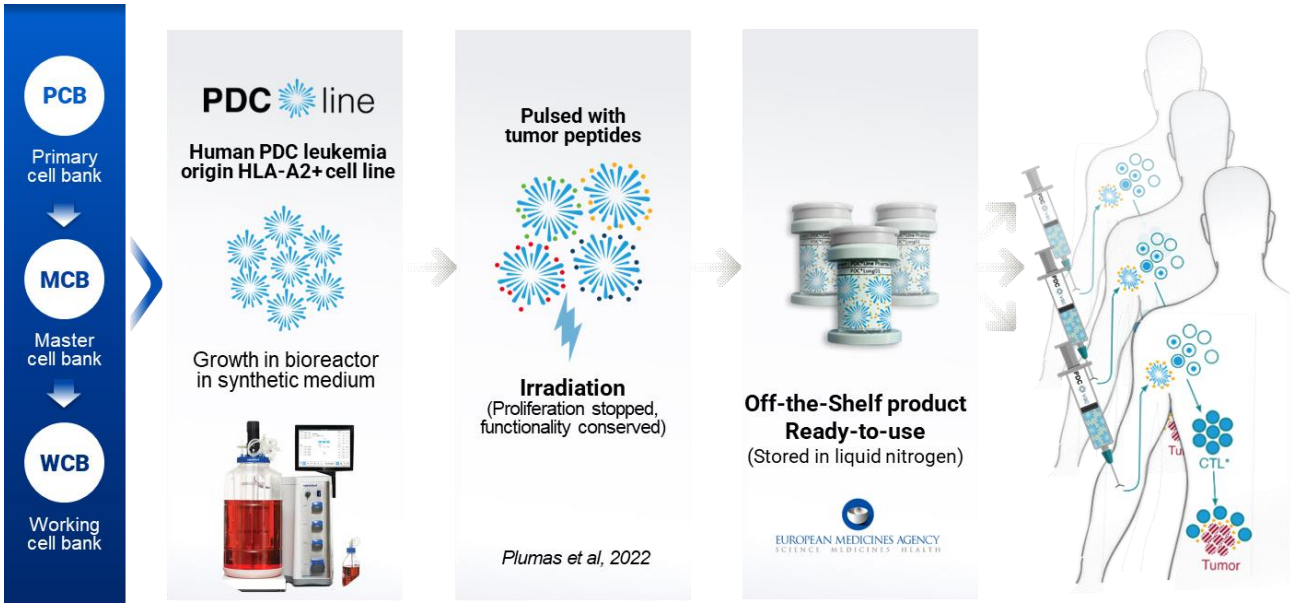
PDC*line is the **only cell line of ready-to-use Dendritic Cells for therapeutic use**. It is loaded with synthetic peptides derived from tumor antigens, irradiated, and can be stored frozen for years. After thawing, it is injected to activate *in vivo* a potent cytotoxic anti-tumor CD8+ T-cell response. The product is classified as an ATMP (Advanced-Therapy Medicinal Product) by the EMA (European Medicines Agency). It currently comes in the form of 5 candidates:

- **PDC*mel**: our first investigational drug for melanoma. PDC*mel completed a first-in-human phase Ib feasibility trial in 2017, to assess the safety of the product, the absence of rejection and its biological activity. The results of the study have been published in Oncoimmunology journal.
- **PDC* lung:** our leading candidate for non-small-cell lung cancer (NSCLC). This targets widely expressed shared tumor antigens. A phase Ib/II trial evaluating its safety and biological and clinical activity, with and without anti-PD1 will be completed in 2024.
- **PDC*neo**: our next candidate for colorectal cancer (CRC) patients as monotherapy post adjuvant chemotherapy, targeting patient-specific neoantigens. A Phase Ib trial is planned in mid-2025.

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** can be injected several times to boost the immune response.

- PDC*line-based vaccines 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-based vaccines are 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 cells.



IP Position

PDC*line Pharma 's Intellectual Property relies 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 for biological safety. This Master Cell Bank represents one of the main assets and protection for PDC*line Pharma as it is impossible to reproduce.
- A family of **international patents** (co-invented by Joel PLUMAS, under license from EFS) protect the therapeutic use of any DC Plasmacytoid line (WO 2009/138489). A **patent filed in 2018** protects genetic optimizations of the PDC*line. **Three new patents** were filed in 2023.
- **Strong expertise** and a large set of data accumulated over more than 20 years in the fields of preclinical 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, 36% of US, and 20% of Asian population) – with extension possibilities to other HLAs. Our leading candidate **PDC*lung for advanced non-small cell lung cancer** represents a significant market: 584,000 new lung cancer patients with HLA-A2 phenotype per year, leading cause of cancer deaths, and potential sales of about €3.1B in the peak year. This drug candidate may also be used for other cancers that express the same antigens.

TEAM

A team of 42 persons based in Belgium (Liège, headquarters), France (Grenoble) and South Korea (Seoul).

Eric HALIOUA (MS, MBA), President & CEO, is a successful serial entrepreneur with a 30-year experience, co-founder of Myosix (sold to Genzyme/Sanofi), Murigenetics, HairClone and Digital Orthopaedics He raised more than €160M over the course of his career and led numerous deals between pharma and biotechnology companies. He achieved together with its different teams to bring four drug candidates from research to the clinics (up to phase III).

Laurent LEVY (MS, MBA), Co-founder, Board member & COO/CFO has a 30-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 20 years.

M. Claude Dedry (Industrial Pharmacist), Vice-President of Pharmaceutical operations & Quality, is the owner of CMDL Consulting (Belgium) and a QP (Qualified Person). He is the former COO of Promethera, QA director of GSK vaccines and has an over 33-year experience in bioproduction and cell therapy.

Dr. Beatrice De Vos (MD, PhD), Chief Medical Officer, has for more than 30 years in executive positions of clinical research and medical affairs departments of major international pharmaceutical companies, including GSK Biologicals and Sanofi Pasteur and several Biotechnology companies (Novadip, Promethera…). She succeeded developing a paediatric rotavirus vaccine, from bench to bed, that is currently globally used.

Other board members: Dr. Mondher Mahjoubi (MD, independent president of the board, Chief Medical Officer of GSK),), Dr. Alain HERRERA (MD, independent board member), Dr. Jean-Paul PRIEELS (Ph.D., shareholder), Patrick Stragier (Noshaq), François Fontaine (SPFI) and Sangwoo Lee (Korean Investment Partners).

FINANCING AND CORPORATE DEAL

The company has raised nearly **€61** (31.3 M€ in equity and 30 M€ of non-dilutive money). The last rounds have 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.

KEY ACHIEVEMENTS OVER THE LAST 4 YEARS

- February 2021: publication in *Vaccines* an article describing the capabilities of our "Engineered PDC*line to Prime and Expand Multispecific Viral and Tumor Antigen-Specific T-Cells".
- November 2021: closing of a 17.5M€ B2-Round of financing led by the multi-billion Asian VC, Korea Investment Partners (B1-Round of 20M€ was closed in December 2019, also led by KIP).
- December 2022: 90% success rate for the release of the 11 clinical batches of PDC*lung01 manufactured for the Phase I/II trial.
- September, December 2022 and February 2023: Presentation of first immunological and clinical results of the first three cohorts of patients treated with PDC*lung (in combination or not with an anti-PD-1) in three prestigious conferences in Medical Oncology (ESMO, ESMO-IO and CIMT).
- February and June 2023: filing of 3 new patents.
- June 2023: presentation of PDC*lung research at the International Session of the Korean Cancer Society and winning the International Abstract Award.
- June 2023: relocation of the headquarter in a brand-new facility in Liège (Belgium) including a 330m^2 GMP manufacturing Unit.
- August 2023: mild safety profile and promising clinical activity observed in the B2 interim results (high dose PDC*lung01 in combination with pembrolizumab).
- October 2023: completion of patient enrolment (inclusion of the last patient in the last cohort).
- January 2024: 8.1M€ grant from the Walloon region to develop PDC*neo for colorectal cancer.
- April 2024: presentation of promising interim results of PDC-LUNG-101 at the AACR conference.

Investment Opportunity

The phase I/II clinical trial with PDC*lung in combination with anti-PD-1 in patients for Stage IV Non-Small-Cell Lung Cancer (NSCLC) generated promising preliminary clinical data presented at the prestigious conference AACR 2024.

- Of 19 evaluated patients, 12 had a confirmed partial response (63.2%) and 7 had stable disease (36.8%), resulting in **an objective response rate (ORR) of 63.2% (80% CI 45.9 - 78.2).**
- When compared with the Pembrolizumab Phase III study (Keynote-042), the ORR for PDC*lung combined with Pembrolizumab is 24% higher. The tumor shrinkage reaches more than 50% in 7 out of 12 patients presenting a partial response.
- Furthermore, the median progression-free survival (mPFS**) reaches 10.9 months (95% CI 5.6 – Not Reached), 68% higher than Keynote-042 study** which was 6.1 months.
- High dose of PDC*lung01 **showed an acceptable safety profile,** consistent with other vaccines.

PDC*line Pharma is preparing a Round-C of funding of 70 à 90 M€ to finance:

- A randomized Phase IIb clinical trial on 200 patients in NSCLC patients
- A phase Ib clinical trial with PDC*neo (néoantigènes) in colorectal cancer,
- The development of new generations of technology, such as the addition of additional HLA within the PDC*line such as HLA-A24,
- The preparation of new vaccines candidates for new indications.

This funding is expected to position PDC*line Pharma for **a significant industrial deal in 2027/2028** and an IPO.

Contacts Investisseurs et Partenaires Industriels

Eric Halioua, President & CEO
@: e.halioua@pdc-line-pharma.com
M: +32 474 05 78 66

Laurent Levy, Co-fondateur & COO/CFO
@: l.levy@pdc-line-pharma.com
M: +33 634 36 77