PDC*line pharma
ADVANCED CANCER VACCINES

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

PDC*line Pharma (www.pdc-line-pharma.com) is a clinical-stage biotech company developing a new class of potent, off-the-shelf therapeutic cancer vaccines based on a proprietary cell line of Plasmacytoid Dendritic Cells (PDC*line). Born from the innovative research at the French Blood Bank (EFS), we reported promising Phase I/II results in lung cancer (PDC*lung) in 2024. Preparations are now underway for a randomized Phase II trial in lung cancer and a Phase Ib trial in colorectal cancer with neoantigens (PDC*neo). The company has raised €61M and signed a €108M licensing deal in Asia with a Korean pharmaceutical company, LG Chem Life Science.

Immune-checkpoint inhibitors such as anti-PD-(L)1 offer unprecedent hope to cancer patients , but around 70% of patients do not respond , often due to a lack of pre-existing anti-tumor immunity. Therefore, combining immune checkpoint inhibitors with therapeutic vaccines is expected to improve responses (Mellman I. et al., Cancer Immunology Research, 2016).

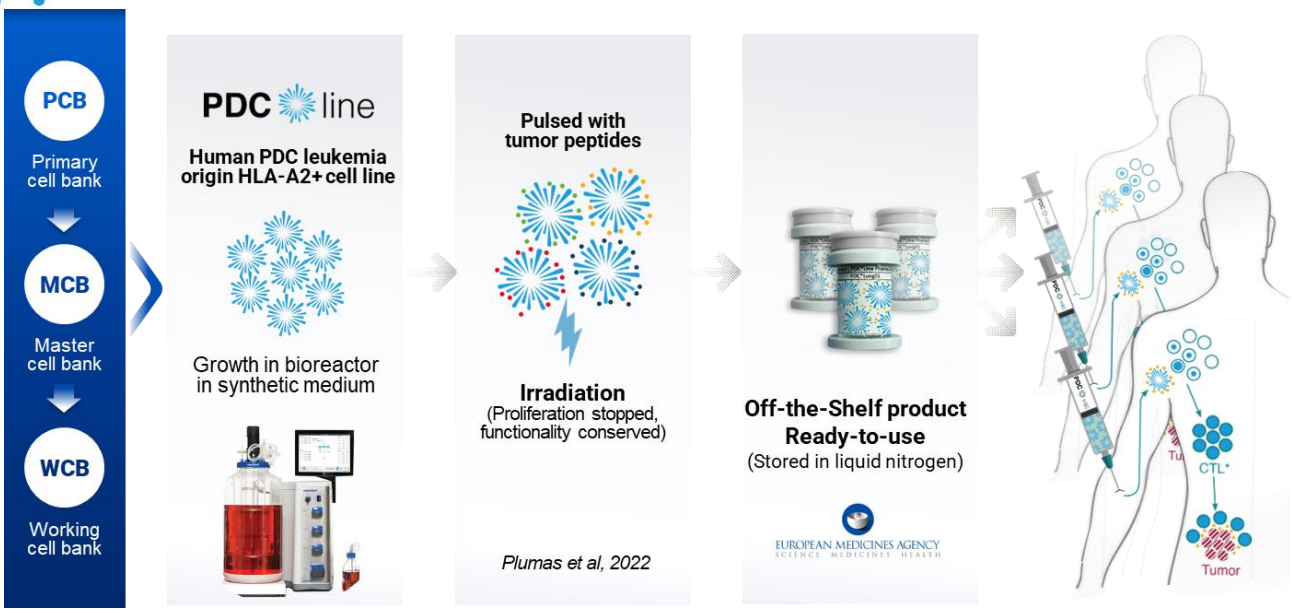
For decades, researchers have been working to develop therapeutic vaccines to promote a potent anti-tumor immune response in cancer patients. **The most potent approach is based on dendritic cells (DC)** thanks to their unique antigen-presenting properties. However, most DC-based vaccines are developed from the patient's own cells (autologous), resulting in complex and costly logistic and production processes, and only modest clinical efficacy thus far.

What sets us apart is our unique PDC*line technology. It's the only ready-to-use cell line of Dendritic Cells available for therapeutic use. With our exclusive cell line of Plasmacytoid Dendritic Cells (PDC*line), we are offering a groundbreaking solution that addresses the scalability and potency challenges faced by conventional DC-based vaccines. PDC*line is much more potent than conventional DCs in priming and boosting fully functional anti-tumor CD8+ T cells displaying a strong cytotoxic activity against tumor cells. Loaded with synthetic peptides derived from tumor antigens, it can be stored frozen for years, ready to be thawed and injected when needed. In addition, it is highly versatile and synergetic with anti-PD-1 immune checkpoint inhibitors.

TECHNOLOGY & COMPETITIVE ADVANTAGES

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

- PDC*line is a professional antigen-presenting cell, **much more potent** than conventional DCs in priming and expanding antitumor-specific cytotoxic CD8+ T cells (for both conventional shared tumor antigens and neoantigens).
- While allogeneic, **PDC*line** can be injected several times to boost the immune response.
- PDC*line-based vaccines can be **produced on a large industrial scale**, with a straightforward, fully mastered and simple manufacturing process (use of bioreactors with synthetic medium, no growth, differentiation or activation factors required).
- PDC*line-based vaccines are easy to use: after thawing, the **off-the-shelf product** can be used to treat any patient with a specific cancer type that express the target antigens.
- PDC*line is **highly versatile**: tumor antigens can be provided by peptide loading, mRNA transfection or retroviral transduction. 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 quickly validated for new cancer indications, through *ex vivo* testing with human PBMC.
- PDC*line **synergizes with anti-PD-1** inhibitors to boost antitumor CD8+ T cells.



Pipeline

- **PDC* lung:** our leading candidate for non-small-cell lung cancer (NSCLC) targeting widely expressed shared tumor antigens. Phase I/II clinical trial results presented at ESMO-IO in Dec. 2024 were promising, and a randomized phase IIb is planned for early 2026.
- **PDC*neo**: our next candidate for colorectal cancer (CRC) as monotherapy, targeting patient-specific neoantigens, with a Phase Ib trial anticipated in 2026.
- **PDC*mel**: completed a first-in-human phase Ib feasibility trial (investigator driven) in 2017 for melanoma, confirming safety, the absence of rejection and biological activity. Results were published in the Oncoimmunology journal.
- Additional developments have also been initiated for **breast, liver and bladder cancer**.

IP Position

PDC*line Pharma 's Intellectual Property strategy is built on 4 pillars:

- **Proprietary PDC*line**: PDC*line has unique features and remains the only known cell line of human DCs for therapeutic use. A Master Cell Bank manufactured under GMP has been fully characterized and validated for biological safety, making it the main assets and protection for PDC*line Pharma as it is impossible to replicate.
- A family of **international patents** protects the therapeutic use of any Plasmacytoid DC line (WO 2009/138489). A **patent filed in 2018** protects genetic optimizations of the PDC*line. **Three more patents** were filed in 2023.
- **Strong expertise** and **a large set of data** resulting from 20+ years of preclinical research, manufacturing process, Quality Control and immuno-monitoring *in vitro* assay developments.
- **Orphan Drug Designation (ODD) strategy for the US.**

Market Opportunity

The PDC*line technology platform can treat virtually all cancer patients expressing HLA-A2 (around 50% in the EU, 36% in the US, and 20% in Asia) – 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. Potential peak-year sales are estimated at about €3.1B.

TEAM

PDC*line Pharma comprises 41 team members across 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 €170M over the course of his career and led numerous deals between pharma and biotechnology companies. He achieved together with his 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. Ex-CFO and Development Director of a leading French Cancer Cluster, he managed an oncology focused fund and co-founded PDC*line Pharma, winning several awards.

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, where he invented the technology. He coordinated its development up to clinical trial including manufacturing, regulatory and IP aspects. 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 35-year experience in bioproduction and cell therapy.

Dr. Beatrice De Vos (MD, PhD), Chief Medical Officer, has more than 30 years in executive positions of clinical research and medical affairs departments of major international pharmaceutical companies, including GSK Biologicals, Sanofi Pasteur, and several Biotechnology companies (Novadip, Promethera…). She succeeded developing, from bench to bed, a pediatric rotavirus vaccine 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), Leen Limbourg (MD, Noshaq), François Fontaine (SPFI) and Sangwoo Lee (Korean Investment Partners).

FINANCING AND INDUSTRIAL DEAL

The company has raised **€61M** (€31.3M in equity and €30M in non-dilutive money). Last rounds were led by KIP (Korean Investment Partners), a leading Asian VC.

In March 2019, PDC*line Pharma granted **LG Chem** Life Sciences Company an exclusive license in South Korea (plus an exclusive option in other Asian countries), for the development and commercialization of PDC*lung for lung cancer. The total deal value is **€108M (US$123M)** plus significant tiered royalties on net sales in Asia.

KEY ACHIEVEMENTS OVER THE LAST 4 YEARS

- 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 (with or without an anti-PD-1) at 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 (clean rooms).
- 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.
- Decembre 2024: presentation of promising primary results of PDC-LUNG-101 at the ESMO IO conference.

INVESTMENT OPPORTUNITY

Primary results presented at ESMO-IO 2024 demonstrate that PDC*lung01 in combination with anti-PD1 has the potential to provide a **meaningful clinical activity** compared to anti-PD1 alone in stage IV NSCLC, with a favorable safety profile:

- **15% increase in ORR** for design per protocol population (55% vs 39% in Keynote-042).
- **36% relative improvement in median PFS** for design per protocol population (a 2.4 month increase versus pembrolizumab alone in Keynote-042).
- **Other clinical endpoints are encouraging**: DCR of 76%, CBR of 62%, and favorable trend on OS compared to Keynote-042 (not yet mature).
- **Mild safety profile** (typical of cancer vaccines): mostly Grade 1-2 Treatment-related AEs, and only 2% of TRAEs leading to discontinuation (vs 9.1% for Pembrolizumab alone in KEYNOTE-042)
- **Significant antigen-specific CD8+ T-cell response**: detected in 56% of patients, with remarkable expansions up to 2.3% of total CD8+T-cells
- **Significant correlation between the amplitude of antigen-specific CD8+ T-cell response and the PFS**.

PDC*line Pharma is preparing a 55 M€ Series C to fund:

- A randomized Phase IIb clinical trial on 120 patients in NSCLC,
- A phase Ib clinical trial with PDC*neo (with neoantigens) in colorectal cancer,
- New generations of technology, including additional HLA such as HLA-A24, and
- New vaccines candidates for additional indications.

By completing these activities, PDC*line Pharma aims to secure **a major industrial deal in 2029** and pursue a potential IPO.

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