Press release

PDC*line Pharma receives Advanced-Therapy Medicinal Product (ATMP) classification from the European Medicines Agency (EMA) for its new class of therapeutic cancer vaccines (PDC*vac)

June 15th 2015 - The Philadelphia 2015 BIO International Convention (US) and Grenoble (France) - PDC*line Pharma, a clinical-stage biotech company, announces that PDC*vac, its new class of therapeutic cancer vaccines based on a line of Plasmacytoid Dendritic Cells (PDC*line), was granted Advanced-Therapy Medicinal Product (ATMP) classification by the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA), in consultation with the European Commission. The EMA / CAT considers that PDC*vac fulfills the definition of an Advanced-Therapy Medicinal Product (ATMP), within the Somatic-Cell Therapy Medicinal Product category.

Laurent LEVY, co-founder & CEO of PDC*line Pharma, commented: *"The granting of ATMP classification for PDC*vac is a key milestone in the development of our new class of therapeutic cancer vaccines. This classification enables us to receive centralized scientific advice and guidance from the EMA / CAT and to file for the Marketing Authorization* at the European level*. In addition, PDC*line Pharma is now eligible to benefit from incentives for Small and Medium size Enterprises (SME) developing an ATMP."*

About ATMPs and the European Regulation on ATMPs

The ATMP classification aims at regulating cell and gene therapy and tissue-engineered medicinal products by providing the pharmaceutical industry with quality compliance guidelines and best practices, including for non-clinical developments, manufacturing and quality testing. The regulation also offers incentives to companies involved in developing ATMPs in the European Union, including fee reductions for scientific advice, scientific recommendations on ATMP classification, and evaluation and certification of quality and non-clinical data.

About PDC*vac technology

PDC*vac technology is the only therapeutic cancer vaccines based on a line of Dendritic Cells (DC) and the only one based on DCs of Plasmacytoid type. PDC*line is fully qualified, safe, easy to expand and manipulate. It is loaded with synthetic peptides derived from a combination of tumor antigens relevant for the targeted cancer type. The off-the-shelf vaccine can be stored frozen for years. Once injected to patient, it induces a potent and targeted cytotoxic T cell response against the tumor cells. The same product can be used to treat all patients with a cancer type expressing the selected antigens and expressing HLA-A2 (about 50% of the European and 36% of the US population).

About PDC*line Pharma

Founded in April 2014 in Grenoble (France) as a spin-off of the French Blood Bank (EFS), PDC*line Pharma is a clinical-stage biotech company that develops a new class of therapeutic cancer vaccines based on a line of Plasmacytoid Dendritic cells (PDC*line). Its breakthrough technology, PDC*vac, is more potent than conventional Dendritic Cell-based vaccines, scalable, versatile to any cancer type, and synergistic with checkpoint inhibitors such as anti-PD-1. The market potential for PDC*vac is estimated in the range of €3BN to €4.5BN. PDC*line Pharma's leading candidate is in clinical phase 1 studies for the treatment of melanoma (PDC*mel). Its next-in-line candidate is in preclinical stage for the treatment of lung cancer (PDC*lung). The company won several awards, including the 2015 Life Sciences Grand Prize of the French start-up competition Tremplin Entreprises, and is collecting €2.7M in pre/seed financing. For information, visit our web site: www.pdc-line-pharma.com)

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