

## PDS Biotechnology Corp gets U.S. and European patents for Versamune

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**A portion of the work leading to this invention was carried out with support from the United States Government provided under the National Institutes of Health CRADA No. 2644.**



PDS Biotechnology Corporation, a clinical-stage immuno-oncology company pioneering the development of novel multifunctional immunotherapeutic products, today announced that the United States Patent and Trademark Office and the European Patent Office have granted U.S. Patent No. 10,286,064 and European Patent Publication No. 2861245 respectively. The patent includes claims that cover compositions of the immunologically active enantiomer of the cationic lipid R-1,2-dioleoyl-3-trimethyl-ammonium-propane (DOTAP) or its racemic mixture with Granulocyte-macrophage colony-stimulating factor (GM-CSF) to reduce the population of myeloid derived suppressor cells within the tumor microenvironment.

Dr. Frank Bedu-Addo, PDS Biotechnology's President and Chief Executive Officer, said: "The award of this patent is a significant milestone for PDS as it provides further protections for our Versamune platform technology and pipeline of Versamune-powered therapeutic candidates, including our lead candidate, PDS0101. The patent adds to our robust portfolio of exclusively-owned international patents that cover the compositions and use of cationic lipids to activate key immunological pathways that facilitate T-cell priming and activation of antigen specific CD8+ T-cells while also reducing the population of immune suppressive regulatory T-cells. A major limitation of T-cell activating immunotherapies in the treatment of cancer is the need to overcome the tumor's immune-suppressive environment. However, we believe that through our work with the National Cancer Institute we have received additional validation for the use of cationic lipids to activate key immunological signaling pathways that are essential to prime the right phenotype of tumor targeting T-cells *in-vivo*, while simultaneously making the tumor cells much more susceptible to killing by the primed T-cells."

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**About the Versamune Cationic Lipid Platform Technology**

Versamune is a proprietary, clinical stage, synthetic lipid-based immunotherapy platform. PDS Biotechnology's pipeline of Versamune-based products, which are administered by subcutaneous injection, provides strong activation of type I interferon genes. The Versamune mechanism of action also involves effective presentation of tumor antigens via the MHC Class I and Class II pathways. These mechanisms together promote strong in-vivo induction of polyfunctional tumor-targeting CD8+ T-cells. This result, as well as a high degree of safety, was confirmed in the PDS0101 monotherapy Phase 1/2a human clinical trial.

Versamune-based immunotherapies have been demonstrated to alter the tumor micro-environment in preclinical mechanism of action studies, thus further enhancing the ability of Versamune-induced T-cells to effectively kill tumor cells. Versamune is now being applied to the development of multiple clinical-stage cancer products, including those intended to address both early and late-stage cancer indications as monotherapies, as well as combinations with other successful immuno-oncology approaches such as checkpoint inhibitors.