

LNP Technology & samRNA Platform

An innovative lipid nanoparticle (LNP) delivery technology leveraging an extensive self-amplifying mRNA (SamRNA) platform to advance mRNA medicines on oncology, vaccines, autoimmune diseases and rare diseases, maximizing the potential for transformative medical breakthroughs.

Background

This proprietary lipid nanoparticle (LNP) technology held by SunVax leverages their extensive self-amplifying mRNA (samRNA) platform and creates powerful possibilities for the advancement of immuno-oncology (IO) including chimeric antigen receptors (CAR) T cell therapy, vaccines, rare and autoimmune diseases.

The potential use of samRNA in IO involves delivery of RNA molecules, using the LNP system, encoding for tumor antigens or immunomodulators to prime an immune response against cancer cells. The direct delivery of samRNA by LNP into host cells allows for targeted delivery of the RNA molecule encoding therapeutic payloads or tumor associated antigens to enhance the immune response against cancer cells and improve patient outcomes.

SamRNA therapy offers an adaptable platform to build for the future of precision medicine and has the potential to improve the efficacy of cancer treatments and ultimately benefit patients. Comprehensive research is ongoing to determine the toxicological profiles and therapeutic efficacy of samRNA in immuno-oncology applications.

Tech Overview

The mRNA therapeutic has emerged as a promising approach for a variety of biological and therapeutic purposes, such as protein replacement therapy, cancer immunotherapy, vaccinations and genome editing. Self-amplifying mRNA (samRNA) represents a subtype of mRNA capable of self-replication and amplification of cargo gene expression, such as a gene of interest in a cell. However, significant challenges persist in achieving integrity of samRNA molecules and managing interferon responses due to its large size and immunogenicity. Additionally, it's not trivial to deliver mRNA encoding therapeutic payloads given the negative charges of mRNA. Although lipid nanoparticles (LNPs) have shown remarkable efficacy in mRNA delivery, as evidenced by the highly successful COVID-19 vaccines, delivering samRNA remains challenging due to its large size and instability.

To tackle these challenges, SunVax has developed both samRNA and LNP patented platforms. In comparison to commercially available samRNA, **SunVax's synthesized samRNA demonstrates higher yield (up to 40% increase), reduced cytopathic effects, longer half-life (up to 35 days), and enhanced integrity (up to 90%).**

Ionizable lipids, a crucial component of LNPs, are believed to play a pivotal role in both the uptake of LNPs by cells and the release of LNPs from the endosome. SunVax has undertaken the task of designing a vast library containing over 100,000 ionizable lipids and has developed a high-throughput screening system to identify those ionizable lipids has potentials to deliver samRNA effectively. To date, SunVax has screened more than 50,000 ionizable lipids and has successfully identified over 700 efficient candidates. Simultaneously, **SunVax has devised a three-component LNP system that demonstrates effective delivery of samRNA both *in vitro* and *in vivo*.**

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Seeking

Development partners
Out-licensing

IP Status

LNP platform: WO2023196527A2, PCT/US2023/085919
samRNA platform: WO2023220693A1

2 provisional patents: US63/563,062, US63/512,154,

Benefits

- Extensive library of ionizable lipids to optimize LNP formulations for enhanced cellular uptake and endosomal release.
- Sophisticated three-component LNP platform for efficient and targeted delivery of therapeutic payloads, ensuring superior efficacy.
- High-yield samRNA technology that facilitates the production of ample quantities of therapeutic RNA for various applications.
- High-integrity samRNA platform that maintains the structural integrity of RNA molecules, preserving their functionality and therapeutic potential.
- samRNA that exhibits a longer half-life and reduced cytopathic effects, enhancing safety and efficacy profiles for therapeutic interventions.
- 66 variants of samRNA developed with each tailored to address specific therapeutic targets and applications, offering a diverse portfolio of therapeutic options.

Applications

- Developing innovative vaccines for infectious diseases that leverages the advanced LNP and samRNA platforms to create effective and targeted immunization solutions.
- Utilizing cutting-edge technology at the forefront of anticancer vaccine research to engineer vaccines that stimulate the immune system to recognize and combat cancer cells, offering hope for improved treatment outcomes.
- Tackling autoimmune diseases by harnessing the power of LNP and samRNA platforms to develop precision therapies that modulate the immune response and restore immune balance, seeking relief for patients suffering from autoimmune conditions.
- Employing state-of-the-art technology to develop tailored treatments that target the underlying genetic or molecular causes of rare diseases, offering new hope for patients with rare and often overlooked disorders.

Stage of Development

The LNP and samRNA platforms developed by SunVax have been extensively validated across vaccine and immuno-oncology applications.

- SunVax's fully developed respiratory syncytial virus (RSV) vaccine incorporates one of the identified ionizable lipids and has demonstrated comparable performance to mimic both Moderna's RSV vaccine (mRNA-1345) and GSK's FDA-approved RSV vaccine (Arexvy), as evidenced by neutralization antibody titers (Figure 1).
- LNP-samRNA engagement can explore mRNA screening and toxicity testing across various immuno-oncology applications. In *in vivo* studies across various animal models, SunVax's LNP-samRNA therapy has shown remarkable efficacy, achieving tumor-free rates ranging from 80% B16F10 melanoma mice to 100% MC38 colon cancer mice (Figure 2).
- Early discovery stage for targeted delivery of mRNA to competent Balb/c, where SunVax's LNP has shown ~30% delivery efficacy, in both CD4 and CD8 T cells (Figure 3) for application in *in vivo* CAR-T cell therapy.

Opportunity

SunVax is actively seeking collaborations with researchers and biotechnology companies interested in leveraging our extensive expertise in immuno-oncology and biologics engineering.

We offer opportunities for partnership to explore LNP optimization for specific payloads or access to our cutting-edge platforms and technologies for research and development purposes. Through collaboration, we aim to accelerate the advancement of novel therapeutics and contribute to the collective effort in combating cancer and other diseases. Interested parties are encouraged to reach out to explore potential collaborations and synergies with SunVax.

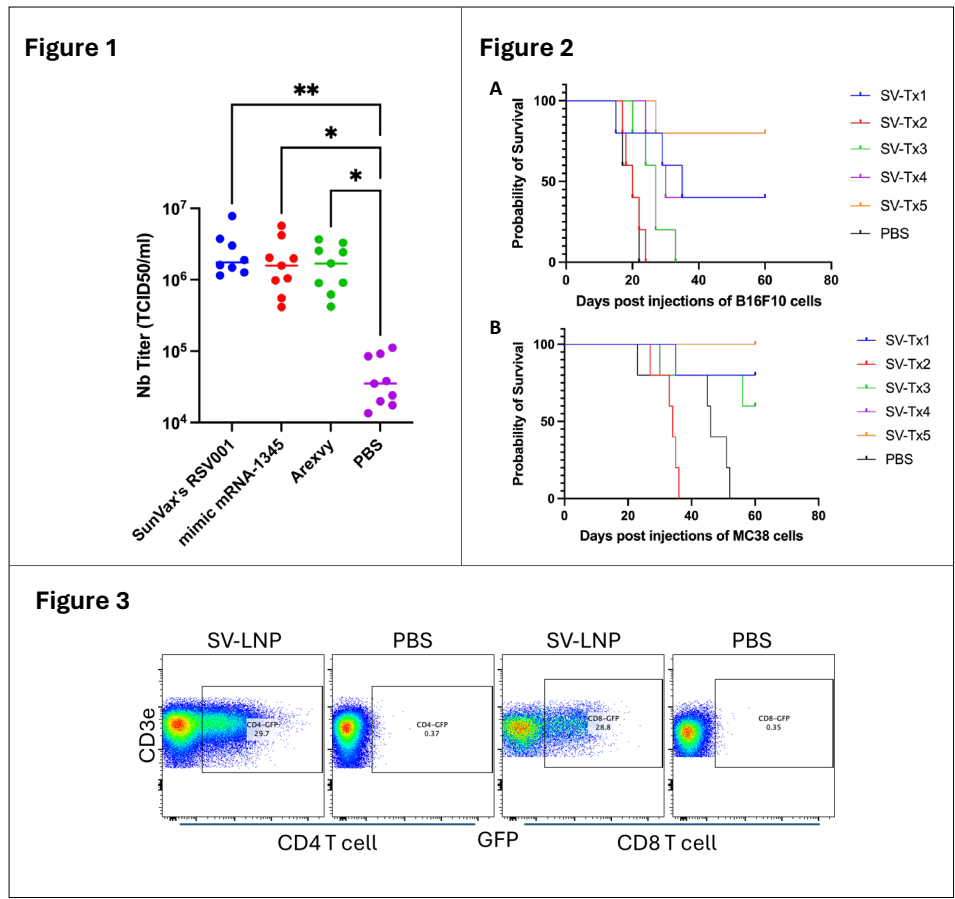


Figure 1 neutralization antibody titers of SunVax's RSV vaccine which incorporates one of the identified ionizable lipids and has demonstrated comparable performance to mimic both Moderna's RSV vaccine (mRNA-1345) and GSK's FDA-approved RSV vaccine (Arexvy)

Figure 2 LNP-samRNA therapy has shown remarkable efficacy, achieving tumor-free rates ranging from 80% B16F10 melanoma mice to 100% MC38 colon cancer mice

Figure 3 SunVax's LNP has showing ~30% delivery efficacy, in both splenic CD4 and CD8 T cells of competent mice for applications of in vivo CAR-T cell therapy

About SunVax

SunVax is a pioneering biotechnology company headquartered in the Greater Boston area, dedicated to revolutionizing the field of immunotherapy and vaccine development. Established in November 2021, SunVax has quickly emerged as a leader in the development of innovative therapeutic solutions, leveraging its proprietary state-of-the-art lipid nanoparticle (LNP) and self-amplifying mRNA (samRNA) platforms employing rigorous criteria to select the most potent and effective options. The company's strategic focus lies in harnessing the power of these advanced platforms to address critical unmet needs in various therapeutic areas, including immuno-oncology, infectious diseases, autoimmune diseases and rare diseases.

About Xentria

Xentria is a Venture Studio partnering with early-stage biopharmaceutical companies. Since the company was formed in 2020 we have established authentic partnerships, advancing challenging drug development that addresses unmet needs where greater levels of collaboration, tenacity, and partnership are demanded. Our goal is to provide capital and insight into breakthrough science that aligns with our core therapeutic areas to improve the lives of patients and their families. Based in Chicago, Xentria is committed to supporting partners such as SunVax in pursuing strategic opportunities for collaboration. www.xentria.com