

Sanofi and Translate Bio expand collaboration to develop mRNA vaccines

Sanofi Pasteur and Translate Bio have agreed to expand their existing 2018 collaboration and licensing agreement to develop mRNA vaccines for infectious diseases. The companies announced plans to develop an mRNA vaccine for Covid-19 in March.

- Sanofi and Translate will build upon their existing collaboration to pursue novel mRNA vaccines aimed at addressing current and future infectious diseases
- Translate Bio to receive \$425 million in upfront payment and common stock equity investment and overall is eligible to receive up to \$1.9 billion of potential milestones/payments as well as tiered royalties on worldwide sales of developed vaccines
- Sanofi to receive exclusive worldwide rights to develop, manufacture and commercialize infectious disease vaccines using Translate Bio technology
- The expanded collaboration brings together Translate Bio's leading mRNA technology and manufacturing with Sanofi's world class vaccine development and distribution



The Deal

- The expansion of this agreement will further unite Translate Bio's expertise and knowledge from more than 10 years of mRNA research and development with Sanofi's leadership in vaccine research and development.
- Under the expansion agreement, Translate Bio will receive a total upfront payment of \$425 million, consisting of a \$300 million cash payment and a private placement common stock investment of \$125 million at \$25.59 per share
- Translate Bio will also be eligible for potential future milestones and other payments up to \$1.9 billion, including \$450 million of milestones under the 2018 agreement. Of these potential milestones and other payments, approximately \$360 million are anticipated over the next several years, inclusive of COVID-19 vaccine development milestones. In addition, Translate Bio is also eligible to receive tiered royalty payments based upon worldwide sales of the developed vaccines.
- Sanofi Pasteur will pay for all costs during the collaboration term and under this agreement will receive exclusive worldwide rights for infectious disease vaccines.

mRNA Platform



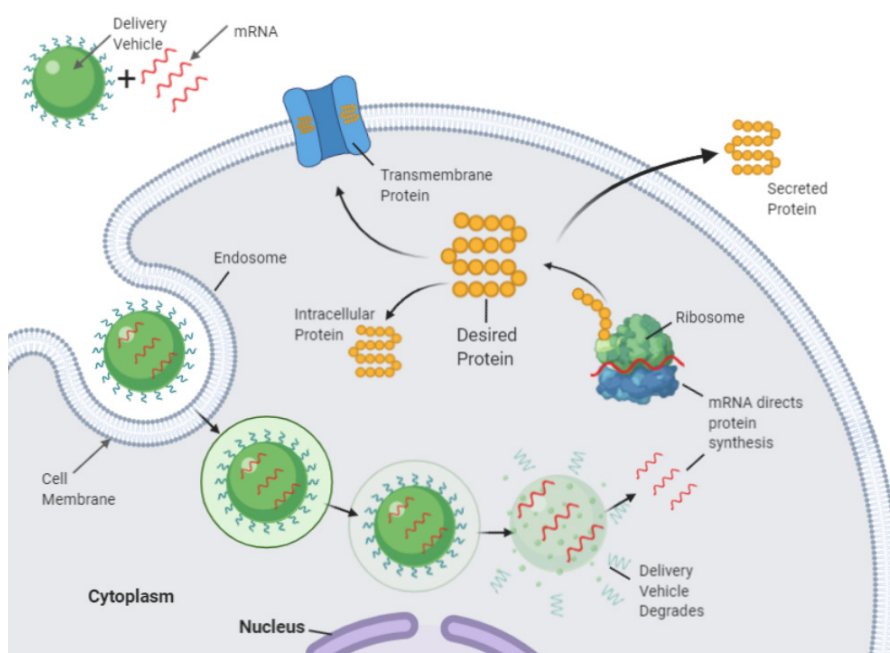
Under the collaboration, Translate Bio is using its mRNA platform to discover, design and manufacture vaccine candidates and Sanofi Pasteur is providing its deep vaccine expertise to advance vaccine candidates into and through further development. Translate Bio will also transfer technology and processes to allow Sanofi Pasteur to develop and manufacture mRNA vaccines for infectious diseases.

The teams are currently evaluating multiple COVID-19 vaccine candidates in vivo for immunogenicity and neutralizing antibody activity to support lead candidate selection and the companies have the goal of initiating a first-in-human clinical trial in the fourth quarter of 2020. The companies are also advancing an mRNA vaccine development candidate against influenza through preclinical studies with clinical trial initiation anticipated in mid-year 2021. Additional mRNA vaccine development programs under the collaboration include another viral pathogen and a bacterial pathogen.

Translate Bio mRNA platform

Translate's MRTTM platform enables development of product candidates designed to deliver mRNA that can carry instructions to produce intracellular, transmembrane and secreted proteins. The platform is designed to be flexible and scalable by allowing for the development of MRTTM product candidates that vary only in the mRNA sequence and the tissue-specific delivery vehicle. This modular nature of the platform may allow rapid advancements into new indications after successful establishment of delivery vehicles for specific tissues. This is an advanced platform for developing product candidates that deliver mRNA encoding functional proteins for therapeutic uses.

Figure 1:- mRNA therapeutic platform



mRNA is encapsulated in a lipid nanoparticle and delivered to the target cell where the cell's own machinery recognizes it and translates it, restoring or augmenting protein function to treat or prevent disease.

About mRNA Vaccines

mRNA vaccines offer an innovative approach by delivering a nucleotide sequence encoding the antigen(s) selected for their high potential to induce a protective immune response. mRNA vaccines also represent a potentially innovative alternative to conventional vaccine approaches for several reasons: their high potency, their ability to initiate protein production without the need for nuclear entry, their capacity for rapid development and their potential for low-cost manufacturing, as well as their potential for safe administration using non-viral delivery.

Sanofi/Translate are among several companies using the approach:

Table 1:- mRNA Vaccines

Company	Vaccine	Type	Target
Moderna/ Lonza	mRNA-1273	mRNA vaccine	Sars-CoV-2 spike protein
Arcturus Therapeutics / Catalent	LUNAR-COV19	mRNA vaccine	SARS-CoV-2 coronavirus
Inovio Pharma/Richter-Helm Biologics	INO-4800	DNA Vaccine	coronavirus SARS-CoV-2
Biontech/ Pfizer/Fosun	BNT162a1, b1, b2 & c2	mRNA vaccine	Large spike sequence, or 2 smaller receptor-binding domains
Johnson & Johnson	AdVac® and PER.C6® technology	Adenovirus type 26 vaccine	Sars-CoV-2 spike protein
Sanofi/ Glaxosmithkline	Spike (S) protein COVID-19 antigen (Sanofi)/ AS03 adjuvant technology (GSK)	DNA vaccine	Sars-CoV-2 spike protein
Translate Bio/ Sanofi	MRT platform	mRNA vaccine	SARS-CoV-2 coronavirus
CanSino Biologics	Ad5-nCoV	Adenovirus Type 5 Vector	SARS-CoV-2 spike protein
Shenzhen Geno-Immune Medical Institute	LV-SMENP-DC and pathogen-specific aAPC	lentivirus (disabled HIV) used to deliver viral proteins	SARS-CoV-2 spike protein



Summary

In 2018, Translate Bio entered into a collaboration and exclusive licensing agreement with Sanofi Pasteur Inc., the vaccines global business unit of Sanofi, to develop mRNA vaccines for up to five infectious disease pathogens. This agreement was first expanded in March 2020 to include the collaborative development of a novel mRNA vaccine for COVID-19. This collaboration combines the leadership of Sanofi Pasteur in vaccines and the mRNA research and development expertise of Translate Bio. Under the agreement, the companies are to jointly conduct research and development activities to advance mRNA vaccines and mRNA vaccine platform development during a research term of at least four years after the original signing in 2018. Translate Bio and Sanofi Pasteur have advanced the preclinical development vaccine programs including screening, optimization and production of mRNA and LNP formulations across multiple targets.

This approach potentially enables the development of vaccines for disease areas where vaccination is not a viable option today. Additionally, a desired antigen or multiple antigens can be expressed from mRNA without the need to adjust the production process offering maximum flexibility and efficiency in development.



Translate Bio is a clinical-stage mRNA therapeutics company developing a new class of potentially transformative medicines to treat diseases caused by protein or gene dysfunction. Translate Bio is primarily focused on applying its technology to treat pulmonary diseases caused by insufficient protein production or where the reduction of proteins can modify disease. Translate Bio's lead mRNA therapeutic program is being developed as a treatment for cystic fibrosis (CF) and is in a Phase 1/2 clinical trial. The Company also believes its technology is applicable to a broad range of diseases, including diseases that affect the liver. Additionally, the platform may be applied to various classes of treatments, such as therapeutic antibodies or vaccines in areas such as infectious disease and oncology.



Sanofi is dedicated to supporting people through their health challenges. Sanofi are a global biopharmaceutical company focused on human health. Sanofi prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. Sanofi stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.



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Sources

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