



Sanofi and Translate Bio mRNA COVID-19 Vaccine Candidate Induced High Antibody Levels in Preclinical Studies

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- mRNA-based vaccine candidate MRT5500 induced potent neutralizing antibodies against SARS-CoV-2 in preclinical studies --
- Two doses of MRT5500 induced neutralizing antibody levels significantly higher than those observed in COVID-19 patients --
- Phase 1/2 clinical trial anticipated to begin in the fourth quarter of 2020 --

PARIS and LEXINGTON, Mass., Oct. 15, 2020 (GLOBE NEWSWIRE) -- Sanofi Pasteur, the vaccines global business unit of Sanofi, and Translate Bio (NASDAQ: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company, today announced the preclinical results for MRT5500, a mRNA-based vaccine candidate against SARS-CoV-2, the virus that causes COVID-19 disease.

Preclinical evaluation of MRT5500, importantly, demonstrated a favorable immune response profile against SARS-CoV-2. These data support the selection of MRT5500 for clinical development. A Phase 1/2 clinical trial is anticipated to begin in the fourth quarter of 2020. Full results are available [here](#). MRT5500 is being developed under a collaboration agreement between Sanofi Pasteur and Translate Bio.

"To tackle this global pandemic, we must look to both the strong knowledge we have from years of infectious disease expertise and the promise of new, innovative technologies," said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. "Today's presentation of these positive results is another development milestone for providing a safe and effective potential vaccine against SARS-CoV2 and shows how promising this technology is. We are looking forward to working on next steps with our partner Translate Bio to bring this technology to people worldwide."

"The rapid development of effective vaccines to address the COVID-19 pandemic continues to be an urgent global public health need and I am encouraged by the progress we've made to date with our partner Sanofi Pasteur toward the development of a promising mRNA vaccine candidate," said Ronald Renaud, Chief Executive Officer at Translate Bio. "The preclinical results we report in this paper demonstrate the ability of MRT5500 to elicit a favorable immune response in both mice and non-human primates. Importantly, these results provide additional support for using our mRNA platform to potentially expedite the development of alternative approaches to traditional vaccines."

Key preclinical findings

The main findings of the preclinical studies demonstrate the potential of MRT5500 to elicit neutralizing antibodies against SARS-CoV-2.

In mice, four dose levels were assessed at 0.2, 1, 5 and 10 µg per dose using a two-dose vaccination schedule, administered three weeks apart. MRT5500 induced dose-dependent levels of binding antibodies and neutralizing antibodies specific to the SARS-CoV-2 spike protein. 100% seroconversion was observed at all dose levels after one administration, and a further increase in titers was observed following a second administration. Neutralizing antibody titers were observed across all dose levels after receiving the two-dose-administration regimen. In the higher dose groups (5 µg, 10 µg), titers were detected after one administration of MRT5500 and were more pronounced after the second administration.

In non-human primates (NHPs), three dose levels were assessed at 15, 45 and 135 µg per dose using a two-administration vaccination schedule, three weeks apart. The potency of MRT5500 was assessed by two types of neutralization assays: pseudovirus neutralization and micro-neutralization. After the first administration, the majority of NHPs developed neutralizing antibodies reactive to the SARS-CoV-2 spike protein and those antibody titers were further enhanced after a second administration with 100% of NHPs reaching levels significantly higher than those from human convalescent sera by day 35.

It was also demonstrated that MRT5500-immunized mice and non-human primates exhibited a Th1-biased T cell response against SARS-CoV-2.

The preprint publication, "Immunogenicity of novel mRNA COVID-19 vaccine MRT5500 in mice and non-human primates," is available [here](#).

About mRNA vaccines

Vaccines work by mimicking disease agents to stimulate the immune system, building up a defense mechanism that remains active in the body to fight future infections. mRNA vaccines offer an innovative approach by delivering a nucleotide sequence encoding the antigen or antigens 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, ability to initiate protein production without the need for nuclear entry, capacity for rapid development and potential for low-cost manufacture and safe administration using non-viral delivery. 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.

About the Sanofi Pasteur and Translate Bio collaboration

In 2018, Translate Bio entered into a collaboration and exclusive license agreement with Sanofi Pasteur Inc., the vaccines global business unit of Sanofi, to develop mRNA vaccines for up to five infectious disease pathogens. The agreement was first expanded in March 2020 to include development of a novel mRNA vaccine for COVID-19. In June 2020, the two Companies built upon the existing collaboration to pursue novel mRNA vaccines to broadly address current and future infectious diseases.

This collaboration brings together Sanofi Pasteur's leadership in vaccines and Translate Bio's mRNA research and development expertise. Under the agreement, the companies are jointly conducting 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.

About Translate Bio

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, or to prevent infectious diseases by generating protective immunity. 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 pulmonary candidate is being evaluated as an inhaled treatment for cystic fibrosis (CF) in a Phase 1/2 clinical trial. Additional pulmonary diseases are being evaluated in discovery-stage research programs that utilize a proprietary lung delivery platform. Translate Bio believes that mRNA can be delivered to target tissues via multiple routes of administration and, consequently, its technology may apply broadly to a wide range of diseases, including diseases that affect the liver. Translate Bio is also pursuing the development of mRNA vaccines for infectious diseases under a collaboration with Sanofi Pasteur.

About Sanofi

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

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Translate Bio Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, those regarding: the goal to initiate a Phase 1/2 clinical trial of MRT5500 in the fourth quarter of 2020; the potential for MRT5500 to be a promising candidate for clinical development; the development of an mRNA vaccine candidate; the potential for MRT5500 to elicit a robust immune response; Translate Bio's beliefs regarding the broad applicability of its MRT platform; and Translate Bio's plans, strategies and prospects for its business, including its lead development programs and continued development of mRNA vaccines for the treatment of infectious diseases. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "forward," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to: the current and potential future impacts of the COVID-19 pandemic on Translate Bio's business, financial condition, operations and liquidity; Translate Bio's ability to advance the development of its platform and programs, including without limitation its vaccine development program generally and MRT5500 specifically, under the timelines it projects, demonstrate the requisite safety and efficacy of its product candidates and replicate in clinical trials any positive findings from preclinical studies; the successful advancement of the collaboration agreement between Translate Bio and Sanofi; uncertainties relating to the discovery and development of vaccine candidates based on mRNA, and specifically as it relates to the novel coronavirus, COVID-19; the content and timing of decisions made by the U.S. Food and Drug Administration, other regulatory authorities and investigational review boards at clinical trial sites, including decisions as it relates to ongoing and planned clinical trials; Translate Bio's ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the availability of significant cash required to fund operations; competitive factors; general economic and market conditions and other important risk factors set forth under the caption "Risk Factors" in Translate Bio's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2020 filed with the Securities and Exchange Commission on August 6, 2020 and in any other subsequent filings made by Translate Bio. Any forward-looking statements contained in this press release speak only as of the date hereof, and Translate Bio specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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