



Sanofi and Translate Bio Initiate Phase 1/2 Clinical Trial of mRNA COVID-19 Vaccine Candidate

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-- Clinical trial to assess safety, immune response and reactogenicity, after preclinical data showed high neutralizing antibody levels --

-- Expected to enroll 415 participants; interim results expected in Q3 2021 --

-- Translate Bio to receive \$25 million payment upon initiation of the Phase 1/2 clinical trial --

-- In parallel, preclinical studies are underway to evaluate additional mRNA candidates against emerging SARS-CoV-2 variants --

PARIS and LEXINGTON, Mass., March 12, 2021 (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 start of the Phase 1/2 clinical trial for MRT5500, an mRNA vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. Translate Bio will receive a \$25 million payment based on achievement of this milestone. The Companies expect interim results from this trial in the third quarter of 2021.

"Our mRNA vaccine candidate is the result of our expertise in infectious diseases coupled with the innovative technologies of our partner," said Thomas Triomphe, Executive Vice President and Global Head of Sanofi Pasteur. "Initiating the Phase 1/2 trial represents an important step forward in our goal of bringing another effective vaccine to the ongoing fight against the COVID-19 pandemic."

"We have made important progress toward developing mRNA vaccine candidates for infectious diseases through our collaboration with our partner Sanofi Pasteur," said Ronald Renaud, Chief Executive Officer of Translate Bio. "With the impact of mRNA vaccines demonstrated during the pandemic, our joint development team remains steadfast in our commitment to advancing MRT5500 as part of the collaborative effort to overcome this global health crisis."

Preclinical studies are ongoing and will continue over the next several months to evaluate whether MRT5500, as well as additional mRNA vaccine candidates, will induce neutralizing antibodies against the emerging SARS-CoV-2 variants, with the potential to inform current and future clinical development.

The joint development team is working on improving the temperature stability of the mRNA vaccine candidate and targeting a -20°C storage temperature for late-stage clinical trials and at launch. Efforts are also underway to enable the product to be stable at routine refrigerator temperature (2-8°C).

MRT5500 is being developed under a collaboration and license agreement between Sanofi Pasteur and Translate Bio.

About the Phase 1/2 clinical trial

The Phase 1/2 clinical trial is a randomized, double blind and placebo-controlled trial designed to evaluate the safety, reactogenicity (tolerability) and immunogenicity (immune response) of MRT5500, a COVID-19 vaccine candidate. A total of 415 healthy adults 18 years of age and older are expected to be enrolled in the trial across 13 investigational sites. Clinical trial participants will receive one dose of MRT5500, or two doses 21 days apart. Three different dose levels will be investigated (15µg, 45µg or 135µg).

About previously-published preclinical results

Preclinical data [showed](#) that two immunizations of the mRNA vaccine induced high neutralizing antibody levels that are comparable to the upper range of those observed in infected humans.

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 infectious disease vaccine candidates 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 with a lead pulmonary candidate 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 also believes its technology may apply broadly to a wide 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 protein degradation. 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

Translate Bio Cautionary Note Regarding 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 expected number of participants to be enrolled in the Phase 1/2 clinical trial of MRT5500; the plans to report interim results from the Phase 1/2 clinical trial of MRT5500 in the third quarter of 2021; plans and strategies to further advance MRT5500, including improvements to the temperature stability; the potential for MRT5500 to be a promising COVID-19 vaccine candidate; the potential for mRNA vaccine approaches to effectively address COVID-19 and any new SARS-CoV-2 variants; the expected benefits of Translate Bio's collaboration with Sanofi; Translate Bio's beliefs regarding the broad applicability of its technology; 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 COVID-19; the content and timing of decisions made by the U.S. Food and Drug Administration ("FDA"), 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 Annual Report on Form 10-K for the full year ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC") on March 1, 2021 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.

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, 2020. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements

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