Sanofi and Translate Bio Initiate Phase 1 Clinical Trial of mRNA Influenza Vaccine

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-- Trial will evaluate potential of next generation of influenza vaccines with combined mRNA technology and flu vaccine development expertise --

-- Positive preclinical safety and immunogenicity data for mRNA influenza vaccine candidates support initiation of Phase 1 clinical trial --

-- Interim data anticipated by the end of 2021; outcomes from this clinical trial will inform next steps of our mRNA-based influenza vaccine program and strategy --

LEXINGTON, Mass., June 22, 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, have initiated a Phase 1 clinical trial evaluating an mRNA-based investigational vaccine against seasonal influenza.

The trial will evaluate the safety and immunogenicity of a monovalent flu vaccine candidate coding for the hemagglutinin protein of the A/H3N2 strain of the influenza virus. Flu seasons that are dominated by A/H3N2 strain circulation activity tend to be more severe, especially among those considered at-risk such as older adults and younger children.

"*The first clinical trial of a seasonal mRNA flu vaccine candidate is an exciting milestone in our quest for the next generation of influenza vaccines. We've all witnessed the promise of mRNA technology during this pandemic and are now looking to extend that promise to select annual vaccines,*" said Jean-François Toussaint, Global Head of Research and Development, Sanofi Pasteur. *"In line with our global leadership and our 70-year history of protecting people with influenza vaccines, we will always focus on developing products that demonstrate protection beyond flu, as we believe it is critical to demonstrate protecting patients from hospitalizations due to cardiovascular events and pneumonia. We look forward to sharing initial results by year-end."*

"We are pleased to have this second mRNA vaccine program underway with our partner Sanofi Pasteur," said Ronald Renaud, chief executive officer, Translate Bio. *"We believe that mRNA technology could have several advantages for a seasonal flu application including the potential ability to demonstrate robust immune responses based on preclinical data to date, enable antigen specificity within a short timeframe from seasonal virus strain selection, and deploy agile manufacturing capacity. We look forward to evaluating the potential of these mRNA influenza vaccine candidates in this Phase 1 clinical trial."*

Sanofi and Translate Bio have developed and will evaluate two formulations of the vaccine (MRT5400 and MRT5401) in the Phase 1 influenza mRNA vaccine clinical trial. The two formulations differ in the lipid nanoparticle (LNP) that contains the mRNA.

The trial follows successful preclinical research which demonstrated promising safety and immunogenicity. Preclinical results were shared previously at the 8th annual mRNA Healthcare Conference in November 2020.

About the Phase 1 trial
The US-based Phase 1 clinical trial will assess the safety and immunogenicity (immune response) of the monovalent (single-strain) mRNA-based flu vaccine candidate in up to 280 participants. The trial will evaluate several dose levels of both vaccine formulations given to healthy adults 18 - 49 years of age.

About the Sanofi Pasteur and Translate Bio collaboration
In June 2018, Translate Bio entered into a collaboration and exclusive license agreement with Sanofi Pasteur, 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 agreement to pursue novel mRNA vaccines to broadly address current and future infectious diseases. There are two ongoing mRNA vaccine clinical trials under the collaboration, one for COVID-19 and one for influenza.

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.

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 evaluation of the next generation of influenza vaccines; the potential for MRT5400 and MRT5401 to be promising influenza vaccine candidates; the plans to share interim clinical data from the trial evaluating MRT5400 and MRT5401 by year-end 2021; the anticipated enrollment of participants in the clinical trial of MRT5400 and MRT5401; the extension of mRNA technology to influenza vaccines; the role of Translate Bio's platform in developing seasonal influenza vaccines and the advantages of the application of its technology for seasonal flu vaccine; the next steps of the broader mRNA-based influenza vaccine program and strategy; 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, 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 influenza; 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 Quarterly Report on Form 10-Q for the three months ended March 31, 2021 filed with the Securities and Exchange Commission ("SEC") on May 6, 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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