



Sanofi and Translate Bio Expand Collaboration to Develop mRNA Vaccines Across All Infectious Disease Areas

June 23, 2020

- The two companies will build upon their existing collaboration to pursue novel mRNA vaccines aimed at broadly 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 --

PARIS and LEXINGTON, Mass., June 23, 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, have agreed to expand their existing 2018 collaboration and license agreement to develop mRNA vaccines for infectious diseases.

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 representing a 50 percent premium to the 20-day moving average share price prior to signing. 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. Under this agreement Sanofi Pasteur will receive exclusive worldwide rights for infectious disease vaccines.

"As all eyes are on prevention of infectious disease through vaccines, this is a pointed moment in time where we are called upon to seek innovative ways to protect public health," said Thomas Triomphe, Executive Vice President, Sanofi Pasteur. *"We are excited by the novel technology and expertise Translate Bio brings, and we believe that adding this mRNA platform to our vaccines development capabilities will help us advance prevention against current and future infectious diseases."*

"The expansion of our collaboration with Sanofi Pasteur validates the progress we've made in the development of mRNA vaccines for infectious diseases since our work together began in 2018 and also speaks to the potential of our mRNA platform. We are excited to work with Sanofi in this broadened capacity with the goal of ultimately delivering vaccines on a global scale, a need underscored by the current pandemic," said Ronald Renaud, Chief Executive Officer of Translate Bio. *"Translate Bio will also be well positioned financially to continue to build upon our internal capabilities with a focus on advancing innovations in platform discovery and on the development of ongoing and additional preclinical therapeutic programs as we aim to bring multiple programs towards clinical development."*

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.

The transactions, including the equity sale, are subject to customary closing conditions, including termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act. For more information regarding the financial and other terms of the agreement, please refer to the Current Report on Form 8-K which will be filed by Translate Bio with the U.S. Securities & Exchange Commission on June 23, 2020.

Evercore acted as financial advisor to Translate Bio for the expansion of the collaboration agreement.

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. This agreement was first expanded in March 2020 to include the collaborative development of a novel mRNA vaccine for COVID-19. 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. 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.

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

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. 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. For more information about the Company, please visit www.translate.bio or on Twitter at @TranslateBio.

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: Translate Bio's expectations with respect to the benefits of its collaboration with Sanofi; the potential of Translate Bio's mRNA platform; Translate Bio's expectations regarding its financial positioning after giving effect to the amended transaction with Sanofi; and the anticipated initiation of clinical trials for the COVID-19 vaccine in the fourth quarter of 2020 and for the flu vaccine in mid-year 2021; the timing and amount of future potential milestone and royalty payments under its collaboration with Sanofi; 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 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; the content and timing of decisions made by the 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 fiscal quarter ended March 31, 2020 filed with the Securities and Exchange Commission on May 7, 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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