SANOFI

Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

Sanofi announces positive Phase 1/2 study interim results for its first mRNA-based vaccine candidate

- High seroconversion across the three dosages tested and comparable tolerability to other unmodified mRNA COVID-19 vaccines
- Now accelerating transformation of acquired platform to modified mRNA and targeting a modified quadrivalent flu mRNA vaccine in the clinic in 2022

PARIS – September 28, 2021 – Positive interim results from a Phase 1/2 study[1] of Sanofi's mRNA-based COVID-19 vaccine candidate confirm the potential of recently-acquired Translate Bio's messenger RNA (mRNA) and lipid nanoparticle (LNP) platform and support Sanofi's mRNA strategy.

The initial data from Phase 1/2 showed neutralizing antibody seroconversion (defined as 4-fold increase vs baseline) in 91% to 100% of study participants, two weeks after a second injection, across all 3 dosages tested. No safety concern has been observed and the tolerability profile is comparable to that of other unmodified mRNA COVID-19 vaccines. Further data from this first study of Sanofi's mRNA platform will be presented at a later date.

> *"We are happy to see those positive initial results. We have made an impressive move just 9 months after the worldwide proof of concept of mRNA vaccines and only 17 since we started this first mRNA vaccine project", says Jean-Francois Toussaint, Global Head of Research and Development, Sanofi Pasteur. "These results will clearly help inform the path forward for our mRNA development programs. Today, we have a promising mRNA platform, which we're taking to the next level in development, including moving to modified mRNA, and against other diseases, including flu."*

Targeting 2022 initiation of its clinical studies for an influenza vaccine with modified mRNA, Sanofi launched a Phase 1 clinical trial in June 2021 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 across two formulations (MRT5400 and MRT5401) with different lipid nanoparticles.

At the same time, Sanofi continues its efforts in the fight against the COVID-19 pandemic with its adjuvanted recombinant protein candidate vaccine, developed in partnership with GSK. In parallel to its ongoing Phase 3[2] efficacy and safety study, Sanofi has expanded its development program to include a study of the vaccine as a potentially broadly

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[1] Study of mRNA Vaccine Formulation Against COVID-19 in Healthy Adults 18 Years of Age and Older - Full Text View - ClinicalTrials.gov

[2] https://clinicaltrials.gov/ct2/show/NCT04904549

protective booster to address evolving public health needs. Recently published preclinical data[3] indicated the candidate has the potential to strongly boost immune responses following primary vaccination across multiple vaccine technology platforms and against a broad spectrum of variants of concern. The booster studies[4] began this summer in the U.S., Australia, France, and the UK. First results are expected by the end of Q4 2021.

Sanofi also keeps its commitment to making a strong contribution to current global public health priorities, with the supply of half a billion doses of authorized vaccines. Sanofi is the only company leveraging its worldwide manufacturing capacity and expertise for the supply of three different authorized COVID-19 vaccines from BioNTech / Pfizer, Moderna, and Johnson & Johnson. Manufacturing teams on three industrial sites of the company in France, Germany and the U.S. are mobilized, with 30 million doses released so far.

About the Sanofi and GSK partnership
In the partnership between the two Companies, Sanofi provides its recombinant antigen and GSK contributes its pandemic adjuvant, both established vaccine platforms that have proven successful against influenza. The recombinant technology combined with GSK's adjuvant is designed to offer the advantages of stability at temperatures used for routine vaccines, making it easily implementable and easier to distribute at a global scale through existing infrastructures where vaccines are stored at normal refrigerator temperature. It is also designed to offer the potential to generate high and sustained immune responses, and the potential to prevent virus transmission.

This effort is supported by federal funds from the Biomedical Advanced Research and Development Authority, part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services in collaboration with the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense under Contract # W15QKN-16-9-1002.

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.

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[3] SARS-CoV-2 preS dTM vaccine booster candidates increase functional antibody responses and crossneutralization against SARS-CoV-2 variants of concern in non-human primates. https://assets.researchsquare.com/files/rs-871537/v1/1d418160-97ed-45c4-b13d-067194a124db.pdf?c=1632254127
and https://www.biorxiv.org/content/10.1101/2021.09.20.461023v1
4 https://clinicaltrials.gov/ct2/show/NCT04762680

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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.