SANOFI

Press Release

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

Sanofi provides update on Kevzara® (sarilumab) Phase 3 trial in severe and critically ill COVID-19 patients outside the U.S.

PARIS – September 1, 2020 – Sanofi today announced that the global Phase 3 trial investigating intravenously administered Kevzara® (sarilumab) at a dose of 200 mg or 400 mg[a] in severely or critically ill[b] patients hospitalized with COVID-19 did not meet its primary endpoint and key secondary endpoint[c] when Kevzara was compared to placebo added to usual hospital care. The 420-patient randomized trial was conducted outside the U.S. in Argentina, Brazil, Canada, Chile, France, Germany, Israel, Italy, Japan, Russia and Spain (86 in placebo, 161 in 200 mg, and 173 in 400 mg arms).

> *"Although this trial did not yield the results we hoped for, we are proud of the work that was achieved by the team to further our understanding of the potential use of Kevzara for the treatment of COVID-19,"* said John Reed, M.D., Ph.D., Global Head of Research and Development, Sanofi. *"In times like these, commitment to properly designed, controlled clinical trials, provides the information and understanding the scientific community needs for fact-based decision making. At Sanofi, we are committed to help combat the global COVID-19 pandemic, including developing vaccine candidates that can be manufactured at large-scale."*

Although not statistically significant, numerical trends were observed toward a decrease in duration of hospital stay as well as an acceleration in time to improve clinical outcomes, as measured by a 2-point improvement from baseline on the 7-point scale. Further, a trend was observed towards reduced mortality in the critical patient group which was not seen in the severe patient group. Finally, the time to discharge was shortened by 2-3 days (statistically non-significant) in the patients treated with Kevzara within the first two weeks of treatment.

Serious adverse events were experienced by 26-29% of Kevzara patients and 24% of placebo patients. The incidence of adverse events leading to death was approximately 10% in all three treatment arms. Serious infections (including COVID-19 pneumonia) were observed in 11-13% of Kevzara patients and 12% of placebo patients.

Detailed results will be submitted to a peer-reviewed publication later this year. At this time, Sanofi and Regeneron do not anticipate conducting further clinical studies for Kevzara in COVID-19.

About Kevzara® (sarilumab) Injection

Kevzara is currently approved in multiple countries to treat adults with moderately to severely active rheumatoid arthritis who have not responded to or tolerated previous therapy.

Kevzara binds specifically to the IL-6 receptor and has been shown to inhibit IL-6 mediated signalling. IL-6 is an immune system protein produced in increased quantities in patients with rheumatoid arthritis and has been associated with disease activity, joint destruction and other systemic problems.

[a] The protocol initially prescribed a single infusion, and subsequently amended to allow a second infusion of the randomly assigned treatment 24-48 hours after the initial infusion if clinical deterioration or no improvement was observed according to protocol-defined criteria.
[b] Severe disease: requires oxygen by nasal cannula, simple face mask, or other similar oxygen delivery device. Critical disease: requires oxygen by non-rebreather mask or high-flow nasal cannula, or use of invasive or non-invasive ventilation, or treatment in an intensive care unit.
[c] The primary endpoint was time to improvement of 2 points or greater on a 7-point clinical scale (where 1=death; 2=hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation;3=hospitalized, on non-invasive ventilation or high flow oxygen devices; 4=hospitalized, requiring supplemental oxygen; 5=hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6=hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7=not hospitalized). The key secondary endpoint was percentage of patients alive at Day 29.

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

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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 regarding the marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the fact that product may not be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, 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.