

Update from Sanofi regarding Kevzara® (sarilumab): Supply constraints anticipated until early 2022

October 12, 2021

Sanofi is currently experiencing an increase in worldwide demand for sarilumab (Kevzara®) due to an increase in the global demand for IL-6 receptor blockers and the temporary tocilizumab shortage.¹

Due to this exceptional demand, supply for all four formats of sarilumab (150mg or 200mg pre-filled syringe or auto-injector) is expected to be constrained until early 2022 based on current forecasts.

Various country and global health authorities have recommended IL-6 receptor blockers for the treatment of patients with severe or critical COVID-19. Sarilumab is not approved or authorized for emergency use for the treatment of COVID-19 anywhere in the world, and Sanofi will continue to prioritize access for indicated patients with rheumatoid arthritis.

Sanofi is working diligently to manage supply to minimize the impact of this increase in demand, and we are committed to proactive and timely communication as the situation evolves.

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 signaling. 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.

¹ European Medicines Agency. (2021, September 3, 2021). *RoActemra (tocilizumab)*

Temporary supply shortage for 162 mg solution for subcutaneous injection and RoActemra 20 mg/mL

concentrate for solution for infusion (IV) & recommendations to manage potential risk of disease flare in patient.

<https://www.ema.europa.eu/en/medicines/dhpc/roactemra-tocilizumab-temporary-supply-shortage#about-section> (referenced October 12, 2021).

The use of sarilumab to treat patients with COVID-19 is investigational and has not been approved or authorized for emergency use by any regulatory authority. Randomized controlled studies conducted by Sanofi and our collaboration partner, Regeneron, did not show a benefit and development of sarilumab for COVID-19 was discontinued.

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