<Date>

Supply Constraint of Sarilumab [Kevzara®]

Dear Healthcare professional,

Sanofi in agreement with the <National Competent Authority> would like to inform you of the following important information about sarilumab.

Summary

- **Supply for Kevzara (sarilumab) is expected to be temporarily constrained. All pharmaceutical presentations may be impacted:**
  - **150mg pre-filled syringe**
  - **150mg auto injector**
  - **200mg pre-filled syringe**
  - **200mg auto injector**
- **In <INSERT COUNTRY>, the supply constraint of Kevzara® (sarilumab) is expected to begin on <INSERT DATE AND MONTH AS PER INDIVIDUAL COUNTRY>. [Each country to adapt according to specific supply situation, the pre-filled syringe may be more constrained]**
- **The shortage is due to an increase in demand and is expected to last until early 2022.**
- **If Kevzara is not available, you should consider a suitable alternative based on availability. Depending on the alternative, patients may need to be re-trained regarding self-administration.**

Background on the supply concern

- Kevzara® is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- Sanofi is currently experiencing an increase in demand worldwide for Kevzara® (sarilumab) (This is 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 presentations of Kevzara® (150mg or 200mg pre-filled syringe or auto-injector) is expected to be constrained until early 2022 based on current forecasts.
- Various countries and global health authorities have recommended use of IL-6 receptor blockers for the treatment of patients with severe or critical COVID-19. Kevzara® 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 patients with rheumatoid arthritis.

[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-hortage#about-section (referenced October 15th, 2021).

- 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.
- We suggest that you take the supply constraint into consideration when making treatment decisions.

Call for reporting

Healthcare professionals should report any off-label use with or without adverse reactions associated with the use of sarilumab, in accordance with the national spontaneous reporting system. <via the national reporting system: if applicable: details on the national reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Kevzara ®/Sarilumab
Marketing authorisation holder(s)	Sanofi
Safety concern and purpose of the communication	Supply Constraint of Sarilumab [Kevzara®]
DHPC recipients	Rheumatologists, Immunologists, hospital pharmacists and specialized nurses
Member States where the DHPC will be distributed	In all EEA member states where Kevzara shortage has been identified

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	19 October 2021
Submission of translated DHPCs to the national competent authorities for review	Within 5 working days after EMA approval
Agreement of translations by national competent authorities	Within 10 working days after submission to the national competent authorities
Dissemination of DHPC	15 working day after adoption or later dependent on individual situation in affected countries