Supply Constraint of Sarilumab [Kevzara®]

Dear Healthcare professional,

Sanofi in agreement with the AIFA 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 Italy, the supply constraint of Kevzara® (sarilumab) is expected to constrained until March 2022**
- **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.
- 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.

[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).

- 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: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse