

1st August 2022

Direct Healthcare Professional Communication

Shortage of Caprelsa® [vandetanib®] 100 mg and 300 mg film-coated tablets

Dear Healthcare Professional,

Sanofi in agreement with the European Medicines Agency and the Medicines Authority would like to inform you of the following:

Summary

- **In Malta a temporary shortage of Caprelsa® (vandetanib) 100 mg and 300 mg film-coated tablets is expected to start in July 2022. The shortage is expected to last until Q4 2022.**
- **The shortage is due to an unexpected change of supplier of the active ingredient, as well as an increase in the demand globally.**
- **There is no additional risk for patients with Caprelsa® batches currently on the market, which can continue to be used.**
- If Caprelsa® is not available, healthcare professionals are encouraged to consider treatment alternatives.
- Caprelsa® 100 mg film-coated tablets should not be used during this shortage period for patients treated with Caprelsa 300mg per day. Caprelsa 100 mg film-coated tablets should be reserved for pediatric patients and patients with renal failure or QT prolongation. As Caprelsa 300 mg film-coated tablets cannot be broken, every effort should be made to save Caprelsa® 100 mg film-coated tablets for these patients.
- In case of a shortage of 300 mg film-coated tablets or if 300 mg film-coated tablets are not marketed in your country, please reach out to Sanofi in your country to assess the possibility to provide 300 mg film-coated tablets from another country. The importation of Caprelsa 100mg film-coated tablets may also be possible on a case-by-case basis.

Product information and background on the supply shortage

- Caprelsa® (vandetanib) is a potent inhibitor of vascular endothelial growth factor receptor-2 (VEGFR-2), epidermal growth factor receptor (EGFR) and re-arranged during transfection (RET) tyrosine kinases.
- Caprelsa® is indicated for the treatment of patients with aggressive, symptomatic, medullary thyroid cancer which is locally advanced or metastatic and unresectable.
- There is no generic of Caprelsa®. Potential treatment alternatives are limited and not available everywhere. Alternatives include cabozantinib and RET-targeted (REarranged during Transfection) agents (only for patients who have a known RET mutation)

The purpose of this communication is to inform you about a supply shortage for Caprelsa® and to provide options to be considered to mitigate any potential risk to the patients during this supply constraint:

- Patients' health and safety is Sanofi's number one priority. We are making every effort to mitigate the impact of the supply situation for Caprelsa® (INN: Vandetanib) 100 mg

and 300 mg film-coated tablets at patient level and to return to a routine supply situation as soon as possible.

- We have initiated measures to minimize the impact of limited supplies in the best interest of patients and healthcare professionals. We are managing and allocating stocks very carefully and are liaising with health authorities as needed.

Call for reporting

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Caprelsa according to national reporting requirements. Please report suspected adverse events to the Medicines Authority; ADR report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to postlicensing.medicinesauthority@gov.mt or sent to ADR to Medicines Authority Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta or to the Marketing Authorisation Holder, Sanofi via the following email address: pharmacovigilancemalta@sanofi.com

▼ This medicine is under additional monitoring, meaning that it is monitored even more intensively.

Sanofi is making every effort to mitigate the impact of the supply situation for Caprelsa® 100 mg and 300 mg film-coated tablets at patient level and to return to a routine supply situation as soon as possible.

Patients' health and safety is Sanofi's number one priority, and we are committed to ensure timely patient access to our products.

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