15 December 2021

Direct Healthcare Professional Communication

Lymphoseek® (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation: temporary 6 month extension of shelf life of LOT 347446

PLGB 53423/0002 (EU/1/14/955/001)

This DHPC letter should be kept with the relevant LYMPHOSEEK stock.

Dear Healthcare professional,

Navidea Biopharmaceuticals Ltd in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- **Due to manufacturing difficulties, a supply shortage of Lymphoseek on the UK market is foreseen until Q2 2022.**
- **To allow continued use of Lymphoseek, it has been agreed with the MHRA that the shelf life of LOT 347446 can be extended until 31 May 2022.**
- **The 6-month extension of expiry date from 30 November 2021 to 31 May 2022 is based on an analysis of the stability data for Lymphoseek and applies to the above lot only.**
- **Healthcare professionals should check the LOT numbers of Lymphoseek stock and use product from LOT 347446 until the extended expiry date of 31 May 2022.**
- **After 31 May 2022, healthcare professionals are asked to dispose of any remaining Lymphoseek stock from LOT 347446 that has expired as per usual procedure.**
- **This information must be shared with those who will be administering the product.**

Background

Navidea Biopharmaceuticals Ltd has now replaced Norgine B.V. as the Marketing Authorisation Holder for Lymphoseek.

Lymphoseek (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation is indicated for imaging and intraoperative detection of sentinel lymph nodes draining a primary tumour in adult patients with breast cancer, melanoma, or localised squamous cell carcinoma of the oral cavity.

Stability data for Lymphoseek have been submitted to the MHRA and in view of ongoing manufacturing issues, it has exceptionally agreed to allow use of **LOT 347446** for a

further 6 months after expiry date, until 31 May 2022. After this date any remaining stock should be disposed of as per usual procedure.

No safety concerns were identified during the data review which led to a decision to permit use of the above identified lot until 31 May 2022.

Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically.

Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have further questions or require further information, please contact:

Country	**Navidea Biopharmaceuticals Ltd contact details**		
	Telephone	24hour Telephone	email
UK	+353 (0)86 8112397	+353 (0)86 8112397	safety@navidea.com

Yours faithfully,

Ms. Sarah Bailey
Director/EU QPPV for Navidea Biopharmaceuticals Europe Ltd