

27 April 2022

Direct Healthcare Professional Communication

LYMPHOSEEK® (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation: temporary extension of shelf life

EU/1/14/955/001-002

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

Dear Healthcare professional,

In agreement with the European Medicines Agency, we would like to inform you of the following:

Summary

- **Due to manufacturing difficulties, a supply shortage of LYMPHOSEEK on the EU market is foreseen until Q4 2022.**
- **To allow continued use of LYMPHOSEEK, it has been exceptionally agreed with the EMA that the shelf life of the following lots can be extended until 30 Nov 2022:**

Lot numbers		
347446	349863	349878
347447	349864	349882
347448	349865	349883
347449	349866	349885
349046	349867	-

- **This information must be shared with those who will be administering the product.**
- **The 12-month extension of expiry date from 30 November 2021 to 30 Nov 2022 is based on an analysis of the stability data for LYMPHOSEEK and applies to the above lots only.**

Background

Navidea Biopharmaceuticals Europe Ltd has now replaced Norgine B.V. as the new 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 EMA and in view of ongoing manufacturing issues, it has been exceptionally agreed to allow use of **the above-mentioned lots** for **12 months after expiry date, until 30 Nov 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 lots until 30 Nov 2022.

Company contact point

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

Country	Navidea Biopharmaceuticals Europe Ltd contact details			
	Telephone	24hour Telephone	Fax	email
AT	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
BE	+32 (0) 11 31 26 16	+32 (0) 479 42 32 97	+32 (0) 11 59 15 12	safety@navidea.com
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SE	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com

Yours faithfully,

SIGNATURE TO BE ADDED WHEN AGREED

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	LYMPHOSEEK® (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation
Marketing authorisation holder(s)	Navidea Biopharmaceuticals Europe Ltd
Safety concern and purpose of the communication	The purpose of the communication is to inform healthcare professionals that the EMA has exceptionally agreed to the use of LYMPHOSEEK for 12 months after the expiry date stated on the packs for certain lots.
DHPC recipients	Due to the nature of the product and the controlled use of LYMPHOSEEK®, with the last step of manufacture, radiolabelling with ^{99m}Techetium, in radiopharmacies, the DHPC will only be sent to the specific recipients below. Navidea has the list and addresses of all customers that have received LYMPHOSEEK to date. The DHPC will also accompany every pack of LYMPHOSEEK distributed, according to the below timelines. Heads of Radiopharmacy - only in hospitals that currently stock/use LYMPHOSEEK® Heads of Nuclear Medicine - only in hospitals that currently stock/use LYMPHOSEEK® Heads of Surgery - only in hospitals that currently stock/use LYMPHOSEEK® Hospital Pharmacists - only in hospitals that currently stock/use LYMPHOSEEK®
Member States where the DHPC will be distributed	AT, BE, DE, DK, ES, FI, FR, IE, IS, IT, NL, NO, SE
Timetable	
DHPC and communication plan (in English) agreed by CHMP/CMDh	19/05/2022
Submission of translated DHPCs to the national competent authorities for review	24/05/2022
Agreement of translations by national competent authorities	27/05/2022
Dissemination of DHPC	30/05/2022