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 Q1 2023.**
- **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 31 March 2023:**

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 16-month extension of expiry date from 30 November 2021 to 31 March 2023 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 **16 months after expiry date, until 31 March 2023**. 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 31 March 2023.

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
DE	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
DK	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
ES	+34 93 169 65 51	+34 610 53 03 72	+34 93 169 65 52	safety@navidea.com
FI	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
FR	+33 411 93 21 10	+33 642 05 16 53	N/A	safety@navidea.com
IE	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
IS	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
IT	+30 210 8047 709	+30 697 2093 996	N/A	safety@navidea.com
NL	+32 (0) 11 31 26 16	+32 (0) 479 42 32 97	+32 (0) 11 59 15 12	safety@navidea.com
NO	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com
SE	+353 (0)86 8112397	+353 (0)86 8112397	N/A	safety@navidea.com

Yours faithfully,

Ms. Sarah Bailey

Director/EU QPPV for Navidea Biopharmaceuticals Europe Ltd

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 **16 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}Technetium, 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	Date
DHPC and communication plan (in English) updated	22/12/2022 Comms plan updated accordingly
Submission of updated DHPCs to the national competent authorities for review	Week commencing 18 January 2023
Agreement by national competent authorities	Estimated by 27 January 2023
Dissemination of DHPC	31 January 2023