

31 January 2023

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