15 May 2018

**Direct Healthcare Professional Communication**

**LYMPHOSEEK® ▼ (tilmanocept) 50 micrograms kit for radiopharmaceutical preparation: temporary extension of shelf life of Lot F03016002**

Dear Healthcare professional,

Norgine B.V., in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency, would like to inform you of the following:

## *Summary*

- **Due to manufacturing difficulties, no new supplies of LYMPHOSEEK will be available for the EU market until Q3 or Q4 of 2018.**
- **Currently there is only one LYMPHOSEEK batch on the EU market (Lot F03016002), which is due to expire on 31 May 2018.**
- **To allow continued use of LYMPHOSEEK, it has been exceptionally agreed with the EMA that lot F03016002 can be used until 30 September 2018.**
- **The 4-month extension of expiry date to 30 September 2018 is based on an analysis of the stability data for LYMPHOSEEK and applies to lot F03016002 only.**

### *Background on the safety concern*

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 **lot F03016002** for a **further 4 months after expiry date, until 30 September 2018**. 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 lot F03016002 until 30 September 2018.

This DHPC letter should be kept with the relevant LYMPHOSEEK lot F03016002 stock.

***Call for reporting***

▼ This medicinal product remains subject to additional monitoring because it is new to the EU market. This will allow quick identification of new safety information.

Healthcare professionals are reminded to continue to report any suspected adverse drug reactions (ADRs) associated with this product to the MHRA in accordance with the Yellow Card Scheme

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form

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

Adverse drug reactions should also be reported to Norgine on tel: +44 (0)1895 826 606 or by email at medinfo@norgine.com

***Company contact point***

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

Norgine Medical Information Department

Email: medinfo@norgine.com

Telephone: +44 (0)1895 826 606

Yours faithfully

Sangeeta Sharma

UK & IRE Medical Director