25 September 2014
EMA/CHMP/525445/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lymphoseek

tilmanocept

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lymphoseek, 250 µg, kit for radiopharmaceutical preparation, intended for diagnostic use only. The applicant for this medicinal product is Navidea Biopharmaceuticals Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Lymphoseek is tilmanocept, a diagnostic radiopharmaceutical (V09IA09) that specifically binds to mannose binding receptor proteins (CD206) that reside on the surface of macrophages and dendritic cells present in the tumour draining lymph nodes (sentinel lymph nodes).

The benefits with Lymphoseek are its ability to detect sentinel lymph nodes. The incidence of adverse events related to Lymphoseek appears low, and the radiation exposure/ absorbed doses are within acceptable limits.

A pharmacovigilance plan for Lymphoseek will be implemented as part of the marketing authorisation.

The approved indication is: "This medicinal product is for diagnostic use only. Radiolabelled Lymphoseek 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. External imaging and intraoperative evaluation may be performed using a gamma detection device." It is proposed that this product should only be administered by trained healthcare professionals with technical expertise in performing and interpreting sentinel lymph node mapping procedures.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Lymphoseek and therefore recommends the granting of the marketing authorisation.