European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 October 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
SCINTIMUN

International Nonproprietary Name (INN): ***besilesomab***

On 22 October 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Scintimun 1 mg, kit for radiopharmaceutical preparation, intended for scintigraphic imaging, in conjunction with other appropriate imaging modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. The applicant for this medicinal product is CIS bio international.

The active substance of Scintimun is besilesomab, a monoclonal antibody that specifically binds to NCA-95 (non specific cross-reacting antigen 95), an epitope expressed at the cell membrane of granulocytes and granulocyte precursors (V09HA03).

The benefits with Scintimun are *in vivo* labelling of granulocytes, which avoids the risks of *ex vivo* blood cells labelling and re-administration (^{99m}Tc white blood cells), the satisfactory agreement rate between the two methods and also the good quality of images achieved (technical performance). The most common side effect is the development of Human Anti-Mouse Antibodies (HAMA). Patients who are HAMA positive may have a greater risk for hypersensitivity reactions and therefore should not be administered Scintimun.
A pharmacovigilance plan for Scintimun, as for all medicinal products, will be implemented as part of the marketing authorisation.

This medicinal product is for diagnostic use only and the approved indication is scintigraphic imaging, in conjunction with other appropriate imaging modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. Scintimun should not be used for the diagnosis of diabetic foot infection.
It is proposed that Scintimun is prescribed by physicians, used in designated nuclear medicine facilities only, and only handled by authorised personnel.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Scintimun for scintigraphic imaging, in conjunction with other appropriate imaging modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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