28 April 2016
EMA/CHMP/230649/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

EndolucinBeta

lutetium (177 Lu) chloride

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product EndolucinBeta, a radiopharmaceutical precursor. EndolucinBeta is not intended for direct use in patients and must be used only for radiolabelling carrier molecules specifically developed to be used with EndolucinBeta. The applicant for this medicinal product is ITG Isotope Technologies Garching GmbH.

EndolucinBeta will be available as a solution of 3 - 150 GBq Lutetium (^{177}Lu). The active substance of EndolucinBeta is lutetium (^{177}Lu) chloride, a radioactive isotope of lutetium that emits beta and gamma radiation. The effect of EndolucinBeta will depend on the nature of the medicine that is radiolabelled with it.

Since EndolucinBeta is only intended for administration after conjugation to carrier molecules, no clinical data with the use of EndolucinBeta alone have been submitted. However, the clinical utility of EndolucinBeta when attached to relevant carrier molecules has been demonstrated, for example, in the molecular imaging and treatment of neuroendocrine tumours.

Unfavourable effects relating to radiation exposure of the patient and other individuals in close proximity can occur with EndolucinBeta, as is the case with all radionuclides in clinical use. These effects, which include carcinogenicity and mutagenicity, will depend on the radiation characteristics of lutetium (^{177}Lu) chloride in EndolucinBeta and on the carrier molecule to which EndolucinBeta is labelled. A judgement on whether the risk is acceptable in any particular case can only be made in subsequent applications for carrier molecules intending to use EndolucinBeta as a radiolabel.

The full indication is:

"EndolucinBeta is a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with Lutetium (177Lu) chloride."

It is recommended that EndolucinBeta only be used by specialists experienced with in-vitro radiolabelling.

[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

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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.