19 September 2024
EMA/CHMP/417097/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Theralugand

lutetium (^{177}Lu) chloride

On 19 September 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Theralugand, a radiopharmaceutical precursor. Theralugand is not intended for direct use in patients and must be used only for the radiolabelling of carrier medicines that have been specifically developed and authorised for radiolabelling with lutetium (^{177}Lu) chloride.

The applicant for this medicinal product is Eckert & Ziegler Radiopharma GmbH.

Theralugand will be available as a solution containing 40 GBq/ml radiopharmaceutical precursor. The active substance of Theralugand is lutetium (^{177}Lu) chloride, a radioactive isotope of lutetium that emits beta-minus and gamma radiation (ATC code: V10X). The effect of Theralugand depends on the nature of the carrier medicine radiolabelled with the product.

The clinical utility of lutetium (^{177}Lu) when attached to relevant carrier medicines was demonstrated based on an extensive review of the literature, for example in the treatment of patients with neuroendocrine tumours or prostate cancer. Unfavourable effects relating to radiation exposure can occur with Theralugand, as is the case with all radionuclides in clinical use. These effects, which include carcinogenicity and mutagenicity, will depend both on the radiation characteristics of lutetium (^{177}Lu) in Theralugand and on the carrier medicine radiolabelled with lutetium (^{177}Lu) (Theralugand).

In addition to radiation exposure for the patient, there is also a risk of radiation exposure for individuals in close proximity to the patient. A judgement on whether these risks are acceptable in any particular case can only be made in subsequent applications for carrier medicines intending to use Theralugand as a radiolabel.

The full indication is:

> Theralugand 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 (^{177}Lu) chloride.

[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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Theralugand should only be used by specialists experienced with in vitro radiolabelling.

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.