THERANOSTICS INSIGHTS

^{177}Lu-AKIR001

Radioisotope

Lu-177, lutetium-177
Transition metals
T ½ : 6.71 days

Production

In nuclear reactor:
^{176}Yb (n, γ)^{177}Yb (β-)^{177}Lu

Radiation

Beta particles (β-)
Gamma photons (γ)

Use

In clinical trial for multiple cancer types: certain thyroid cancers; head and neck cancer; non-small cell lung cancer; vulvar squamous cell carcinoma; and cervical squamous cell carcinoma

Target/Mechanism

^{177}Lu-AKIR001 is an antibody-based radiopharmaceutical targeting cancers with high expression of CD44v6.^{177}Lu- AKIR001 internalization in the tumour cell induces DNA breakage, by Lu-177 β- radiation, causing cell death.

Insight

A Phase 1 Prospective, Open-label, first-in-human study to evaluate the safety, tolerability and biodistribution of ^{177}Lu-AKIR001 and its anti-tumour effect in adult patients with cd44v6 expressing Solid Tumours.

N patients: 15 participants

OBJECTIVE: evaluate safety and tolerability of increasing doses of ^{177}Lu-AKIR001, both in relation to tolerable activity of Lu-177 and the absorbed protein mass dose of AKIR-001 in patients with irresectable or metastatic CD44v6-expressing solid malignancies for whom no reasonable systemic treatment options are be available. The main question it aims to answer is:

DESIGN: Participants will receive one ^{177}Lu -AKIR001 infusion followed by a 6-week safety follow-up period, which can be extended up to 12 weeks. Possible additional infusions, up to a maximum number of four, can be given when clinical benefit is noted and toxicity is acceptable.