# T-2

## KinLET: Phase I Trial for Dose Determination and Pharmacokinetics Evaluation of [177Lu]Lu-edotreotide Radiopharmaceutical Therapy in Pediatric Participants with SSTR+ Tumors

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### BACKGROUND

Current therapy options for pediatric patients with SSTR-positive solid tumors/lymphoma are limited. Considering the rarity of SSTR-positive tumors in the pediatric population, a broad patient screening effort is critical for this trial. Target tumors include neuroendocrine tumors, central nervous system tumors, lymphoma, peripheral primitive neuroectodermal tumors (Ewing family sarcomas), gastrointestinal sarcoma, or rhabdomyosarcoma.

### METHODS

KinLET is a phase I, multicenter, open-label, interventional trial that aims to determine the appropriate pediatric dosage based on the safety profile and evaluate pharmacokinetics of [$^{177}$Lu]Lu-edotreotide in pediatric participants with recurrent, progressive, or refractory SSTR-positive solid tumors and lymphoma. Furthermore, the anti-tumor activity by tumor type will be preliminarily assessed using the parameters objective response rate, overall survival, progression-free survival, and duration of response. The correlation between immunohistochemical SSTR expression and functional imaging will be determined. In addition, the safety of [$^{177}$Lu]Lu-edotreotide RPT as monotherapy or following sequential standard of care will be evaluated and a quality-of-life evaluation will take place. At least 20 pediatric participants (≥2 to <18 years old) will be included in three sequential age cohorts.

**Sequential Age Cohorts and Dose of [$^{177}$Lu]Lu-edotreotide**

| | Cohort 1 | Cohort 2 | Cohort 3 |
|---|---|---|---|
| Age | ≥12 - <18 years | ≥6 - <12 years | ≥2 - <6 years |
| Number of participants* | ≥6 | ≥6 | ≥6 |
| Starting dose** | 100 MBq/kg, at maximum 7.5 GBq | Based on at least cycle 1 data from 4 participants of Cohort 1*** | Based on at least cycle 1 data from 4 participants of Cohort 2*** |

*Total ≥20 eligible participants; ≥6 of them with gastroenteropancreatic neuroendocrine tumors
**Dosing within each cohort based on at least cycle-1 data from 2 participants
***Decision by Data Monitoring Committee

Treatment will consist of two to six cycles of intravenous infusion of [$^{177}$Lu]Lu-edotreotide at eight-week (± 2 w) intervals. For kidney protection, an arginine-lysine solution will be co-infused. Dosimetry assessments, based on SPECT/CT, whole-body planar imaging and blood radioactivity PK measurements will be assessed at several time points post [$^{177}$Lu]Lu-edotreotide infusion.

For all cycles, the median kidney absorbed dose may not exceed 23 Gy and the median bone marrow dose should remain below 2 Gy. Cycles can be delayed for recovery from dose-modifying toxicity. Follow-up will consist of two years of monitoring for progression-free survival and an additional simplified follow-up for three years.

## RESULTS

NA

## CONCLUSIONS

Trial in progress, Clinical Trial Information: NCT06441331

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