

# PRRT: From Europe to the US

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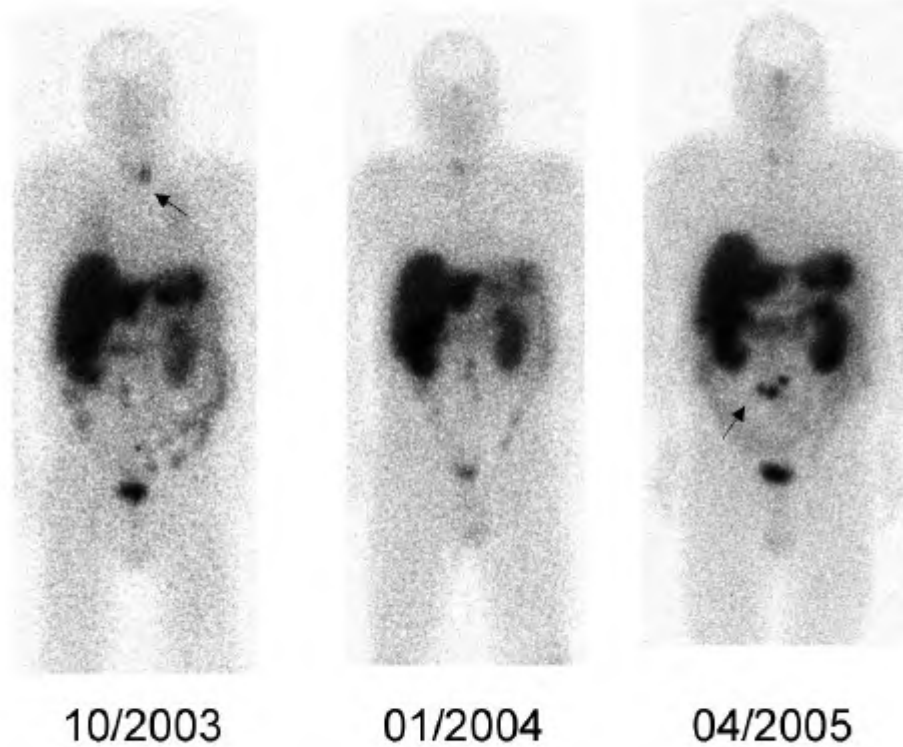


# Outline

1. What is Peptide Receptor Radionuclide Therapy (PRRT)?
2. History of PRRT
3. Current status and availability of PRRT in Europe and the US
4. Eligibility for NETTER-1 trial

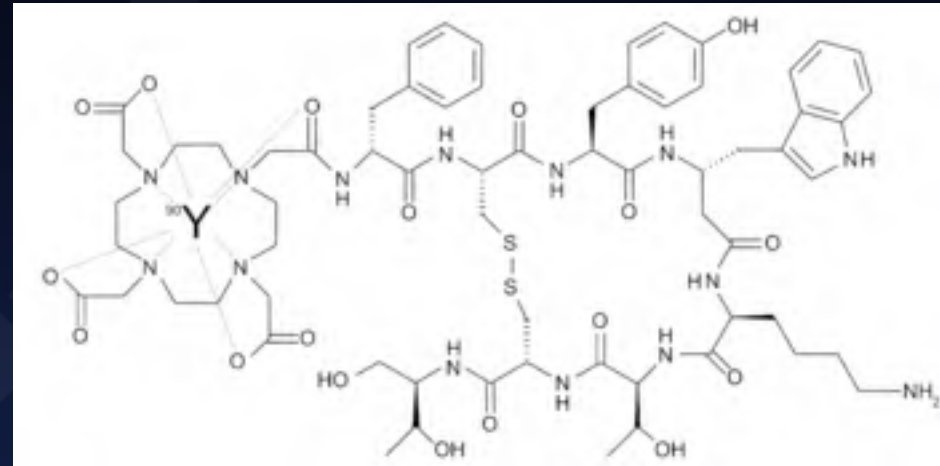
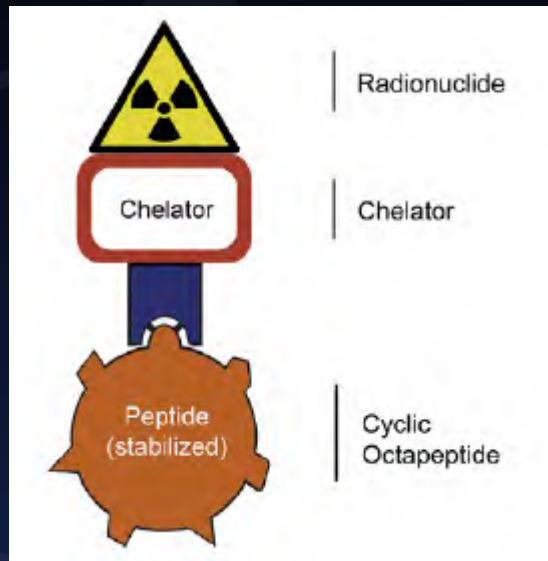


# OctreoScan Imaging of NETs



Klinik für Nuklearmedizin, Universität Leipzig

# Peptide Receptor Radionuclide Therapy (PRRT)



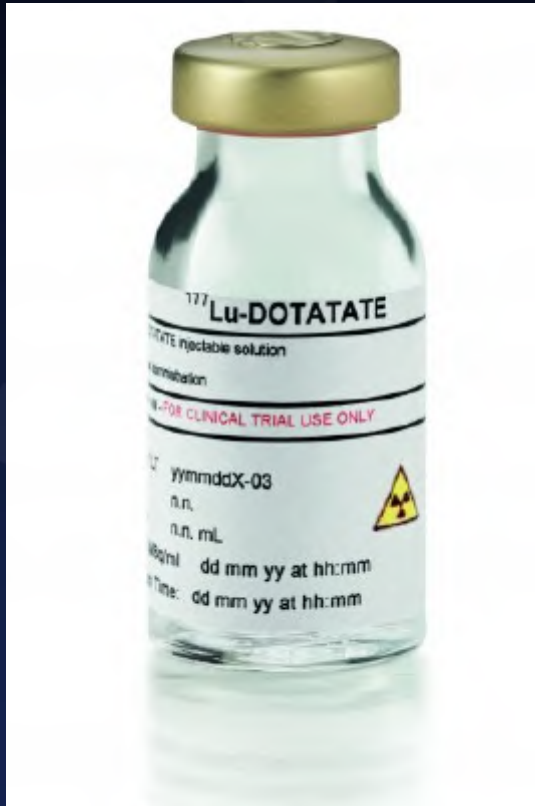
- PRRT started with [ $^{111}\text{In}$ ]-DTPA<sup>0</sup>-octreotide (1990s)
- Next: [ $^{90}\text{Y}$ ]-DOTA<sup>0</sup>-Tyr<sup>3</sup>-octreotide (mid 2000s)
- Most recent: [ $^{177}\text{Lutetium}$ ]-DOTA<sup>0</sup>-Tyr<sup>3</sup>-octreotate (Lutathera<sup>®</sup>) (late 2000s)

Treatment With the Radiolabeled Somatostatin Analog  
[<sup>177</sup>Lu-DOTA<sup>0</sup>,Tyr<sup>3</sup>]Octreotate: Toxicity, Efficacy, and Survival

*Dik J. Kwekkeboom, Wouter W. de Herder, Boen L. Kam, Casper H. van Eijck, Martijn van Essen,  
Peter P. Kooij, Richard A. Feelders, Maarten O. van Aken, and Eric P. Krenning*

- Phase II results in progressive midgut carcinoid showed Progression-Free Survival of more than 44 months compared to the reported 14.6 months of Novartis' Sandostatin<sup>®</sup> LAR
- Lutathera<sup>®</sup> was shown to increase overall survival by between 3.5 and 6 years in comparison to current treatments, including chemotherapy.
- Quality of life may also be improved.

# Lutathera



- Lutathera<sup>®</sup> ( $[^{177}\text{Lu}]\text{-DOTA}^0\text{-Tyr}^3\text{-Octreotate}$ ), is a radiolabeled somatostatin analog that can be used to treat metastatic gastro-entero-pancreatic neuroendocrine tumors (GEP-NETs).
- Lutathera<sup>®</sup> kills these tumors by selectively targeting somatostatin receptors that are over-expressed on tumor cells.

# Current Clinical Trial: NETTER-1



- International, multi-center trial comparing Lutathera<sup>®</sup> to Sandostatin<sup>®</sup> LAR in patients with midgut carcinoid tumors.
- **Sponsor:** Advanced Accelerator Applications
- **Eligibility:** Patients with inoperable, progressive, OctreoScan positive, well-differentiated neuroendocrine tumors of the small bowel (midgut carcinoid tumors), who are treated with 20-30 mg Octreotide LAR every 3-4 weeks for at least 12 weeks prior to enrollment
- **Primary objective:** To compare Progression Free Survival (PFS) of Lutathera to high dose (60 mg) Octreotide LAR



# NETTER-1 US Sites



# Lutathera vs High Dose LAR Arm

## Treatments and Assessments (18 months)

### Arm 1: <sup>177</sup>Lu Octreotate + Octreotide LAR

dose 1 | dose 2 | dose 3 | dose 4

4 administrations of 7.4 GBq  
<sup>177</sup>Lu Octreotate + 30mg  
Octreotide LAR every 8 weeks

30 mg Octreotide LAR treatment every 4 weeks

### Arm 2: High Dose Octreotide LAR

60 mg Octreotide LAR treatment every 4 weeks

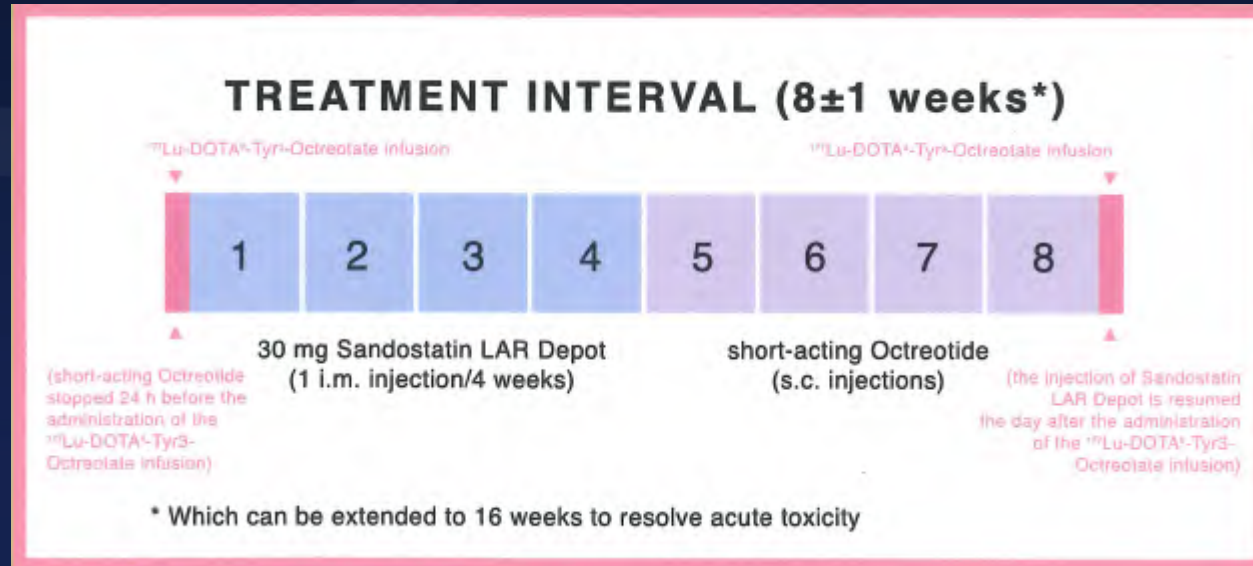
Disease Assessment by RECIST (CT Scan or MRI) Every 12 Weeks

Follow up (6 months to 3 years)

Baseline and Randomization

# Lutathera Arm: Details

- 4 injections of Lutathera given every 8 +/- 1 weeks for a cumulative dose of 800 mCi.
- Remain at clinical site for 4-5 hrs after administration, and then must follow precautions to reduce radiation exposure to others.



-- Thank you --

<http://nuclearmedicine.stanford.edu>