

## Radioligand Therapy's Rise: Precision Targeted Isotopes Transforming Oncology with Novel Pipeline & Infrastructure Surge

Radioligand therapy is emerging as a precision oncology pillar-fast-growing market, robust pipeline across cancer types, challenges, expansion via AI & M&A

AUSTIN, TX, UNITED STATES, June 24, 2025 /EINPresswire.com/ -- 1. Scientific Principles & Therapeutic Mechanism RLT employs radioisotopes affixed to tumor-targeting ligands, enabling the delivery of lethal radiation (alpha or beta particles) directly to cancer cells while sparing healthy tissue. Common



isotopes include lutetium-177, actinium-225, gallium-68 (diagnostic), fluorine-18, and radium-223. The therapy combines isotopic radiance with molecular targeting-e.g., PSMA in prostate cancer or somatostatin receptors in neuroendocrine tumors. Labeled ligands bind to specific antigens, internalize into malignant cells, and deliver DNA-damaging radiation. Alpha particles

## "

RLT is poised to shift cancer care-but success hinges on navigating isotope supply chains, infrastructure build Dout & regulatory complexity. Al-enhanced dosimetry and strategic partnerships."

DataM Intelligence

offer high linear energy transfer (LET) with minimal tissue penetration, enhancing precision.

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2. Market Evolution & Forecast The RLT market was estimated at USD 7–80billion in 2024 and is projected to grow to USD 13–140billion by 2030–2031, reflecting a 5–9% CAGR. Growth is driven by:

- Rising incidence of prostate cancer and neuroendocrine tumors

- Maturing pipeline with approvals in multiple oncology indications

- Expansion of both therapeutic isotopes and diagnostic companion agents

North America leads adoption, supported by regulatory and healthcare investment. Asia–Pacific is the fastest-growing region due to expanding nuclear medicine infrastructure and cancer burden. Europe shows solid gains as government programs endorse nuclear oncology.

3. Technological & Clinical Advancements

- Alpha therapies (225Ac, 212Pb): Deliver high-energy, short-range radiation with reduced offtarget damage. Supply bottlenecks for actinium-225 remain a key challenge.

- Beta therapies (177Lu): Widely adopted; lutetium-177 labeled agents like PSMA-617 (Pluvicto) and dotatate (Lutathera) have demonstrated strong clinical outcomes and blockbuster potential.

- Dosimetry and AI-enabled theranostics: Advanced imaging, quantitative dose modelling, and personalized treatment planning are emerging as standard-of-care technologies.

- Innovative delivery platforms: Automated manufacturing systems, relocatable clinics, and isotope-supply integration are lowering logistical complexity and enhancing patient access.

4. Leading Pipeline & Approvals

- PSMA-617 (Pluvicto): Approved for metastatic castration-resistant prostate cancer (mCRPC); expanded label in early 2025.

- Lutetium dotatate (Lutathera): Approved for neuroendocrine tumors; generated ~USD 450 million through early 2023, aiming for ~\$1 billion in peak sales.

- 225Ac-PSMA-617: Alpha-emitter candidate showing high PSA response rates; early toxicities (e.g., salivary gland and hematologic adverse effects) are driving refined dosing strategies.

- 225Ac-PSMA-R2: In Phase I/II development, targeting both hormone-sensitive and castration-resistant prostate cancer.

- 177Lu-NeoB: Beta-labeled GRPR-targeted agent in trials for breast, prostate, GIST, and glioblastoma.

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5. Expansion of Industry Activity

Acquisitions & Alliances

- Novartis acquired Mariana Oncology to deepen its RLT pipeline beyond Pluvicto and Lutathera.

- Eli Lilly purchased POINT Biopharma (PNT2002, PSMA-targeted) and invested in actinium-225 producers to secure upstream supply.

- AstraZeneca acquired Fusion Pharmaceuticals to enhance access to alpha-based therapeutics and isotope manufacturing.

Integrated Supply Model

- Acquiring control of isotope production-through ties with suppliers like OranoMed, Ionetix, and

on-site cyclotron facilities-reduces supply disruptions.

- Centralized manufacturing and mobile radiopharmacies are being implemented to service larger geographic regions.

6. Strategic Obstacles & Operational Constraints

- Isotope scarcity: Actinium-225 production remains limited, prompting interest in alternative isotopes like lead-212 and focusing on supply chain vertical integration.

- High cost structure: Radiopharmaceutical production and cold-chain logistics result in steep treatment costs and reimbursement complexities.

- Regulatory complexity: Treatments require coordination across pharmaceutical and nuclear regulatory bodies, complicating global approvals.

- Workforce readiness: RLT administration needs trained nuclear medicine clinicians and infrastructure, which remain a bottleneck in many regions.

7. Competitive Landscape: Key Players and Strategic Roles

- Novartis: Market leader with Pluvicto, Lutathera, ongoing expansion in isotope production, and diverse pipeline.

- Eli Lilly / POINT Biopharma: Strengthened by PNT2002 and upstream actinium-225 investmentbuilding an end-to-end radioligand strategy.

- AstraZeneca / Fusion: Entered RLT with alpha-emitter capabilities and manufacturing assets.
- Sanofi / OranoMed: Partnering to develop lead-212-based therapies for neuroendocrine oncology, with in-house isotope production.

- Curium, Bayer, Telix, Lantheus, OranoMed: Offer SPECT/PET diagnostics and therapeutic isotopes-positioned for both organic and inorganic growth.

- Emerging biotech: Focused on novel ligands, Al-driven dosimetry, and conjugates targeting alternate receptors (e.g., GRPR, EGFR).

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8. Strategic Imperatives for Pharma Executives

- Secure isotope supply: Acquire or partner upstream with isotope producers to buffer against shortages and support alpha therapy scale-up.

- Enhance therapeutic diversity: Expand indications beyond prostate and neuroendocrine cancers, including breast, lymphoma, and cardiology.

- Invest in theranostic infrastructure: Deploy AI-enabled dosimetry systems, mobile treatment units, and decentralized manufacturing for regional market access.

- Engage regulators early: Align with dual pharma/nuclear frameworks for RLT approval and define long-term safety and dosimetry standards.

- Design payer-aligned evidence packages: Demonstrate improved survival, precision dosing, and lower ancillary care costs to justify reimbursement.

- Workforce development: Support training for nuclear medicine teams and equip oncology networks for RLT protocols.

- Logistics proficiency: Build cold-chain distribution and mobile pharmacy models to service remote oncology centers.

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