Radiotheranostics Today

Oncidium foundation

Voicing the Challenges and Opportunities of Radiotheranostics for Cancer Care

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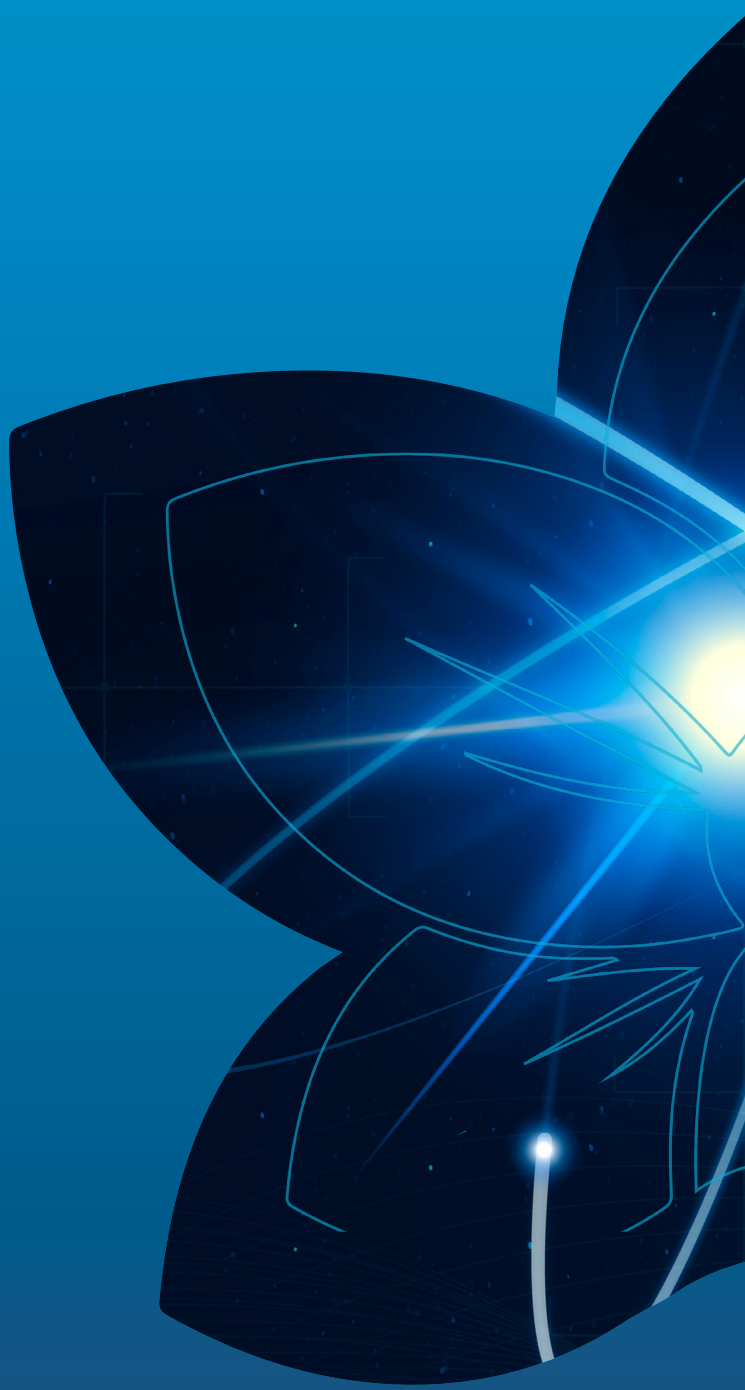
Index



CEO's Foreword

MIRE: The Real Barriers to RLT Access

Radioligand therapy represents an exciting advance in cancer care today. The science is moving fast, the clinical promise is clear, and new opportunities continue to emerge across multiple tumour types. And yet, for far too many people, access remains out of reach. The real challenge is no longer innovation. It is access.

That is why I have started using a simple framework to describe the barriers that continue to limit access to RLT across the world: **MIRE: Money. Infrastructure. Radiopharmaceuticals. Expertise.** These four barriers help explain why access remains so unequal. Treatments are costly and reimbursement is often limited, delayed, or absent. Many hospitals still lack the infrastructure required to safely deliver these highly specialised therapies. Radiopharmaceuticals remain complex to produce, regulate, transport, and administer. And too many health systems still face a shortage of trained professionals across the full care pathway.

Recent policy discussions have made one point very clear: the main barriers are not scientific. RLT is a **system-dependent therapy**, and approval alone is not enough. Access still depends too often on geography rather than clinical need. If we want people living with cancer to truly benefit from innovation, then funding must support delivery infrastructure, workforce development, referral pathways, and sustainable reimbursement, not only research and development.

At Oncidium foundation, this is exactly where we have chosen to act. Through our three pillars, **Access, Education and Hope**, we work to reduce these barriers in practical and meaningful ways. We raise awareness, support education, strengthen collaboration, and advocate for more equitable systems. Through **RLT Connect**, we have already enabled more than **4 million euros' worth of treatment** to reach underprivileged patients in countries where reimbursement is not available. But programs like this should not have to fill structural gaps forever. They are a bridge, not the destination.

If radiotheranostics is to fulfil its promise, we must be just as ambitious about access as we are about science. Because innovation only matters when it reaches the people who need it.

By **Rebecca Lo bue**

CEO of the Oncidium foundation

FAPI Theranostics:
A New Hope for End-Stage Cancer Patients

Dr. Swagat Dash
Oncidium Ambassador - India

Introduction

Cancer remains one of the leading causes of mortality worldwide, with late-stage disease accounting for the majority of deaths. Despite advances in surgery, chemotherapy, radiotherapy, and immunotherapy, patients with end-stage cancer often face limited therapeutic options, poor prognosis, and diminished quality of life. Conventional therapies frequently fail due to drug resistance, systemic toxicity, and the inability to target heterogeneous tumor biology.

Theranostics – the integration of therapy and diagnostics – has emerged as a revolutionary concept in nuclear medicine. By using molecular agents that can both visualize and treat disease, theranostics enables precision oncology. The success of prostate-specific membrane antigen (PSMA) theranostics in metastatic prostate cancer and peptide receptor radionuclide therapy (PRRT) in neuroendocrine tumors has paved the way for new targets.

Fibroblast Activation Protein (FAP), expressed on cancer-associated fibroblasts (CAFs), represents one such promising target. CAFs are abundant in the tumor microenvironment (TME) and play critical roles in tumor progression, angiogenesis, immune evasion, and therapy resistance. Unlike tumor cells, CAFs are genetically stable, making them less prone to mutation-driven resistance. FAP is minimally expressed in normal adult tissues but highly expressed in CAFs across a wide range of solid tumors, including pancreatic, gastric, cholangiocarcinoma, breast, sarcoma, and head-and-neck cancers.

> **“This dual capability positions FAPI theranostics as a new hope for end-stage cancer patients, offering both diagnostic clarity and therapeutic potential.”**

Fibroblast Activation Protein Inhibitor (FAPI) ligands have been developed to selectively bind FAP. When labelled with positron-emitting isotopes (e.g., Ga-68, F-18), they enable high-contrast PET imaging. When labelled with therapeutic isotopes (e.g., Lu-177, Ac-225, Tb-161), they deliver targeted radiation to the tumor stroma. This dual capability positions FAPI theranostics as a new hope for end-stage cancer patients, offering both diagnostic clarity and therapeutic potential.

Tumor Microenvironment and FAP Biology

Cancer-Associated Fibroblasts (CAFs)

CAFs are activated fibroblasts within the tumor stroma. They secrete growth factors, cytokines, and extracellular matrix (ECM) proteins that support tumor growth and invasion. CAFs also remodel the ECM, creating a physical barrier that impedes drug delivery and immune cell infiltration.

Fibroblast Activation Protein (FAP)

FAP is a type II transmembrane serine protease with dipeptidyl peptidase and endopeptidase activity. It is expressed during embryogenesis, wound healing, and fibrosis, but is largely absent in normal adult tissues. In tumors, FAP is highly expressed on CAFs, particularly in desmoplastic cancers such as pancreatic adenocarcinoma.

Biological Rationale for Targeting FAP

- Universality: FAP is expressed across diverse tumor types, making it a pan-cancer target.
- Stability: CAFs are genetically stable, reducing risk of resistance.
- Microenvironment disruption: Targeting CAFs can dismantle the supportive niche that sustains tumor growth.
- Synergy: FAP inhibition may enhance efficacy of chemotherapy, radiotherapy, and immunotherapy by improving drug penetration and immune access.

Mechanism of FAPI Theranostics

FAPI Ligands

Quinoline-based FAPI ligands (FAPI-04, FAPI-46, FAPI-74) have been developed with high affinity for FAP. They demonstrate rapid tumor uptake and fast clearance from non-target tissues, yielding high tumor-to-background ratios.

Imaging

- 68Ga-FAPI PET/CT: Provides superior lesion detection compared to FDG-PET in many cancers.
- 18F-FAPI tracers: Offer longer half-life and wider distribution, enabling centralized production.

Therapy

- 177Lu-FAPI: Delivers β-radiation with moderate tissue penetration, suitable for bulky tumors.
- 225Ac-FAPI: Delivers α-particles with high linear energy transfer (LET), causing double-strand DNA breaks.
- 161Tb-FAPI: Combines β-emission with Auger electrons, enhancing DNA damage at short range.

Pharmacokinetics

FAPI ligands show rapid tumor uptake within minutes and fast clearance from blood and normal tissues. Current limitations include short tumor retention, necessitating ligand modifications for prolonged therapeutic effect.

Key Clinical Applications of FAPI Theranostics

Diagnostic Imaging (FAPI PET/CT)

- Pancreatic and gastric cancers: FAPI PET detects lesions missed by FDG due to low glycolytic activity.
- Cholangiocarcinoma: Provides superior delineation of primary and metastatic lesions.
- Sarcomas and breast cancer: High tumor to background contrast improves staging and restaging.
- Impact on management: In several studies, FAPI imaging altered therapeutic decisions compared to conventional imaging.

Radionuclide Therapy

- 177Lu FAPI: Beta emitter therapy used in pilot studies for pancreatic and gastric cancers, showing partial regression and pain relief.
- 225Ac FAPI: Alpha emitter therapy with high cytotoxicity, reported to reduce tumor burden in cholangiocarcinoma patients.
- 161Tb FAPI: Combines beta and Auger electron emissions, enhancing DNA damage at short range; under investigation for solid tumors.

Palliative Benefits

- Pain reduction in bone metastases.
- Improved appetite, energy, and overall quality of life compared to chemotherapy.
- Particularly valuable for **end-stage patients** who have exhausted conventional options.

Advantages for End-Stage Patients

- Broad applicability: Effective across CAF-rich tumors.
- Precision targeting: Minimal toxicity due to low normal tissue uptake.
- Rapid clearance: Favourable safety profile.
- Quality of life: Reduced pain, fatigue, and side effects.
- Survival extension: Potential to prolong life even in refractory disease.

Current Evidence and Case Studies

- Multicentric trials: Early studies in Germany, China, and India show high sensitivity of FAPI-PET.
- Therapy trials: Pilot studies with 177Lu-FAPI demonstrate safety and efficacy.
- Case narratives: Patients with pancreatic and gastric cancer showing regression and symptomatic improvement.
- Comparative outcomes: FAPI therapy vs palliative chemotherapy shows better tolerability and quality of life.

Challenges and Limitations

- Short tumor retention time.
- Need for ligand modifications.
- Regulatory hurdles for isotope production.
- Risks of hematological toxicity.
- Requirement for multidisciplinary expertise.

> **Continued innovation, clinical trials, and global collaboration will be essential to fully realize its transformative potential.**

Future Directions

- Next-generation ligands with improved pharmacokinetics.
- Combination with immunotherapy.
- AI-driven patient stratification.
- Expansion to non-oncological diseases (fibrosis, arthritis, cardiac remodelling).
- Global collaboration for isotope production.

9. Ethical and Social Considerations

- Equity in access.
- Cost-effectiveness.
- Balancing hope with realistic outcomes.
- Patient-centered communication.

10. Conclusion

FAPI theranostics represents a paradigm shift in oncology, offering hope for end-stage cancer patients. By targeting the tumor microenvironment, it transcends traditional approaches focused solely on tumor cells. Its dual diagnostic and therapeutic potential, broad applicability, and favourable safety profile make it a beacon of hope. Continued innovation, clinical trials, and global collaboration will be essential to fully realize its transformative potential.

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Radiopharmaceuticals: From Specialized Modality to Scalable Global Oncology Powerhouse

Taylor Prejna
Oncidium Ambassador - USA

Radioligand therapy, alongside their diagnostic counterparts, are entering a growth phase defined not only by scientific advancement but by commercial validation, capital deployment, infrastructure expansion, and accelerating clinical utilization. Once regarded as a specialized domain within oncology – technically sophisticated yet operationally constrained – the radiopharmaceutical field is now evolving into a globally scalable platform. The integration of high-performing diagnostic agents that enable precise visualization of disease and patient selection, paired with commercially validated therapeutic radiopharmaceuticals, has solidified the theranostic model as a functional component of contemporary patient care. Expanding pipelines, increasing multidisciplinary adoption, and sustained institutional investment are collectively transforming radiopharmaceuticals from a niche modality into a structurally supported, high-growth pillar of modern oncology and beyond.

In diagnostics, multiple high-performing assets have established radiopharmaceutical imaging as a durable and scalable commercial category. Piflufolastat F18 injection surpassed $1.05 billion in net sales in 2024, solidifying PSMA PET imaging as a standardized component of prostate cancer management rather than a niche tool.[1] Similarly, gallium 68 Ga gozetotide has driven substantial revenue growth for Telix Pharmaceuticals, contributing to FY2025 precision medicine segment revenue of $621.9 million.[4]

In therapeutics, radioligand therapies are demonstrating significant commercial strength and repeatability. ^{177}Lu -PSMA-617 has become a major growth driver within Novartis' oncology portfolio, reinforcing the scalability of the modality.[2] In parallel, ^{177}Lu DOTATATE reported net sales of $816 million in 2025, further underscoring the presence of multiple durable, revenue-generating therapeutic assets.[3]

The presence of multiple high-performing radiopharmaceutical products across the diagnostic and therapeutic segments has recalibrated the sector's risk profile. Radiopharmaceuticals are no longer perceived as technically complex outliers within oncology portfolios; they're increasingly recognized as commercially viable, scalable assets across clinical applications.

Commercial performance has been accompanied by measurable expansion in clinical utilization. A recent analysis of U.S. Medicare Part B professional claims demonstrated a more than 20-fold increase – exceeding 2,000% growth – in intravenous radiopharmaceutical therapy administrations between 2013 and 2023. Annual administrations rose from 529 to 12,395 over the decade, representing a 37% compound annual growth rate.5 While this data reflects a U.S. population and may undercount certain hospital outpatient services, it provides a clear illustration of accelerating adoption within a mature healthcare system. Importantly, the study also demonstrated broad multidisciplinary engagement: diagnostic and interventional radiology accounted for 45.2% of services, nuclear medicine at 36.6%, for radiation oncology 15.3%, and medical oncology and hematology at 2.5% in 2023.[5] This distribution underscores a defining feature of modern radiopharmaceutical therapy: the modality is increasingly integrated across specialties rather than siloed within a single domain.

The acceleration in utilization is occurring alongside sustained global market growth. Current estimates place the radiopharmaceutical market at approximately $6.7 billion in 2024, with projections reaching $14-15 billion by 2033-2034, effectively more than doubling over the next decade.[6,7] Compound annual growth rates are generally forecast in the 7-8% range for the overall market, with therapeutics often growing at higher rates due to label expansion and higher per-patient revenue estimates.[6] These projections are supported by earlier-line movement of approved therapies, continued expansion of PSMA-based imaging, and infrastructure build-out across North America, Europe, and Asia-Pacific markets.

Capital deployment has followed commercial validation. Over the past several years, major pharmaceutical companies have executed multi-billion-dollar acquisitions to secure radiopharmaceutical platforms, pipelines, and manufacturing capabilities. Strategic transactions involving RayzeBio, Fusion Pharmaceuticals, and POINT Biopharma reflect a broader industry consensus: targeted radiopharmaceuticals are evolving into a foundational oncology modality. The impact of this

investment is evident in the development pipeline. Industry analyses identify more than 100 active interventional radiopharmaceutical trials globally,[7] while broader assessments cite over 300 clinical trials involving radioligand therapies across development phases.[8] A substantial majority of these assets remain in early-stage development, signaling continued upstream innovation.[9] In practical terms, well over 120 therapeutic radiopharmaceutical assets are currently in early clinical development, targeting a widening range of tumor-associated antigens across both beta- and alpha-emitting isotopes.[9]

Historically, the expansion of next-generation targeted alpha therapies has been constrained by isotope supply limitations. Alpha-emitting isotopes such as actinium-225 have faced significant challenges, such as constrained raw material supply from a limited number of legacy sources, low-yield production capacity, and reliance on scarce high-energy accelerator infrastructure that introduces actinium-227 co-production and complex separations. Additional radiochemical, safety, and half-life logistical constraints further limit scalability, increase cost, and hinder reliable commercial supply. These supply chain constraints have periodically restricted clinical trial expansion and commercial scalability, prompting increased public–private investment in new production technologies and international supply partnerships.[9,10] While supply resilience is improving, isotope availability remains a critical strategic consideration as alpha programs advance.

This innovation is encouraging for patients and providers alike, but it carries operational implications. Early-stage development can be supported by relatively limited and localized infrastructure and phase-appropriate validation, while still requiring cGMP and Annex 1 compliance. Late-stage development and commercialization demand pharmaceutical-grade systems: robust cGMP- and Annex 1-compliant manufacturing, pressure-tested quality management systems, integrated regulatory oversight, isotope supply resilience, and tightly coordinated logistics models. Radiopharmaceuticals are uniquely constrained by radioactive decay kinetics, which compress manufacturing, quality release, and distribution timelines. Facilities require highly specialized equipment, strict radiation safety protocols, and compliance with both pharmaceutical and nuclear regulatory authorities.[9] Scaling these capabilities requires substantial investment and deliberate workforce development.

Regulatory complexity has also introduced periods of uncertainty. In the United States, radiopharmaceuticals sit at the intersection of pharmaceutical regulation and nuclear oversight, often requiring coordination between agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Nuclear Regulatory Commission (NRC)[11]. Historically, evolving expectations around chemistry, manufacturing and controls (CMC), dosimetry requirements, and facility credentialing

created variability in development timelines. In recent years, the FDA has issued additional guidance[12] specific to therapeutic radiopharmaceuticals; however, variability in interpretation among auditors and evolving regulatory perspectives within the agency continue to present challenges.

The Recent U.S. Medicare utilization data further reinforces the infrastructure imperative. As radiopharmaceutical therapy expands across specialties and institutions, coordinated planning becomes essential to address credentialing, workflow standardization, research alignment, and regulatory compliance.[5] The modality's multidisciplinary nature, once a distinguishing feature, now necessitates structured collaboration at scale.

Taken together, the evidence supports a clear conclusion: therapeutic radiopharmaceuticals have moved beyond proof of concept. Blockbuster diagnostics and therapeutics established commercial validation. Sustained revenue from multiple assets demonstrated durability. Utilization is increasing at an accelerated pace within established healthcare systems, and global market projections indicate the sector will more than double by 2034.[6,7] Meanwhile, a deep and expanding development pipeline suggests that current approvals represent only the initial phase of broader therapeutic expansion.

Radiopharmaceuticals are no longer defined by their novelty. They are increasingly defined by their integration – into standard-of-care treatment regimens, pharmaceutical portfolios, and global healthcare infrastructure. The defining challenge now is not whether the modality works, but whether the ecosystem can scale quickly enough to support their continued exponential growth. The transition from specialized modality to industrialized oncology platform is firmly underway.

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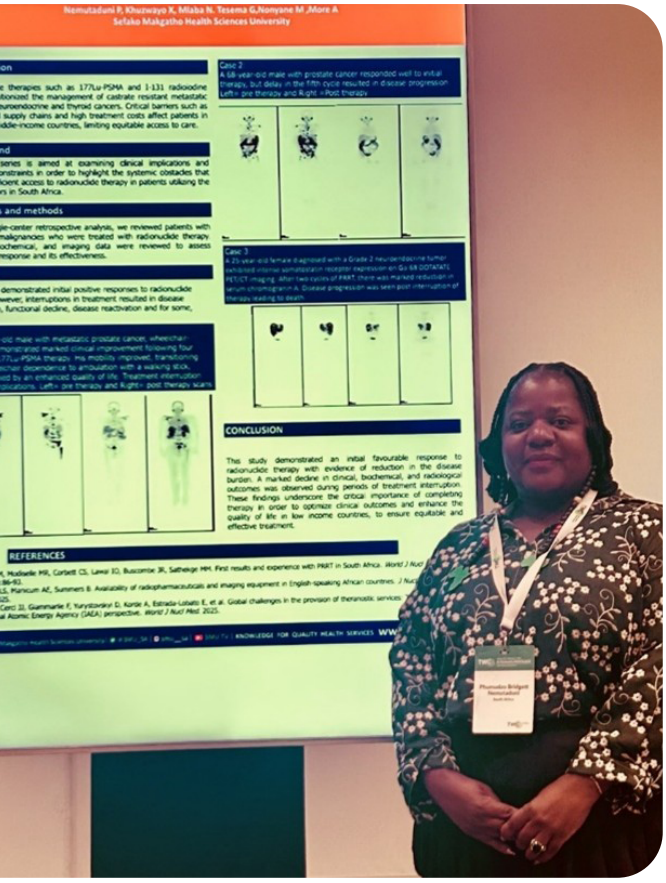
Beyond the cure:
Economic barriers limiting advanced radionuclide therapy

We are pleased to share this article by Dr. Phumudzo Nemutaduni, *which explores the real-world barriers patients in South Africa face when accessing radioligand therapy (RLT) and the systemic challenges surrounding its delivery.*

Dr. Nemutaduni's work was honoured with the Oncidium foundation Award at TWC 2026, a recognition well deserved.



Introduction

Advances in Nuclear Medicine have changed what is possible for people living with advanced cancer. Targeted radionuclide therapy, also known as theranostic, has emerged as a transformative modality in oncology by integrating precision molecular imaging with targeted radiopharmaceutical treatment. This dual strategy enhances diagnostic accuracy while simultaneously delivering therapeutic benefit, particularly in advanced prostate cancer, neuroendocrine tumours, and thyroid malignancies. It can deliver radiation directly to cancer cells. This helps with relieving pain, shrinking tumours, and restoring function when other treatments have failed.

In high-income countries, these therapies are now well established and already integrated into routine cancer care pathways[1].

Meanwhile in South Africa, access remains inequitable. Various factors such as persistent economic, infrastructural, and systemic barriers limit availability. This disproportionately affects patients in the public sector and lower-income communities[1,2] Early national experience with peptide receptor radionuclide therapy (PRRT) for neuroendocrine tumours demonstrated both clinical promise and implementation challenges. Vorster et al. reported favorable patient responses but also highlighted the scarcity of treatment centers and reliance on imported isotopes as major constraints[1]. More than five years later, these obstacles remain unresolved, continuing to restrict equitable access to theranostic care.

Our experience shows that access, continuity and systemic constraints can significantly influence outcome.

We reviewed four patients with advanced malignancies who were treated with radionuclide therapy. Clinical, biochemical, and imaging data were reviewed to assess treatment response and the consequences.

> **Results:** All patients demonstrated initial positive responses to radionuclide therapy. However, interruptions in treatment resulted in disease reactivation, functional decline, and for some, mortality.

Case 1: Early access, early recovery

Timely access can dramatically improve the outcome.

A 25 year old female from an underserved province located approximately 300 km from the treatment centre was diagnosed with a Grade 2 neuroendocrine tumour. ^{68}Ga-DOTATATE PET/CT demonstrated intense somatostatin receptor expression. Early access to peptide receptor radionuclide therapy (PRRT), resulted in rapid resolution of symptoms, marked reduction in serum chromogranin A and an improved quality of life after only two cycles.

Despite a favourable response, treatment was interrupted due to financial and logistical challenges associated with travel and therapy costs. During the interruption, disease progression was documented, and the patient subsequently succumbed to her illness.

Patients from outlying provinces often travel long distances, incurring additional costs for transport and accommodation, which further delays treatment initiation and completion[3,4]

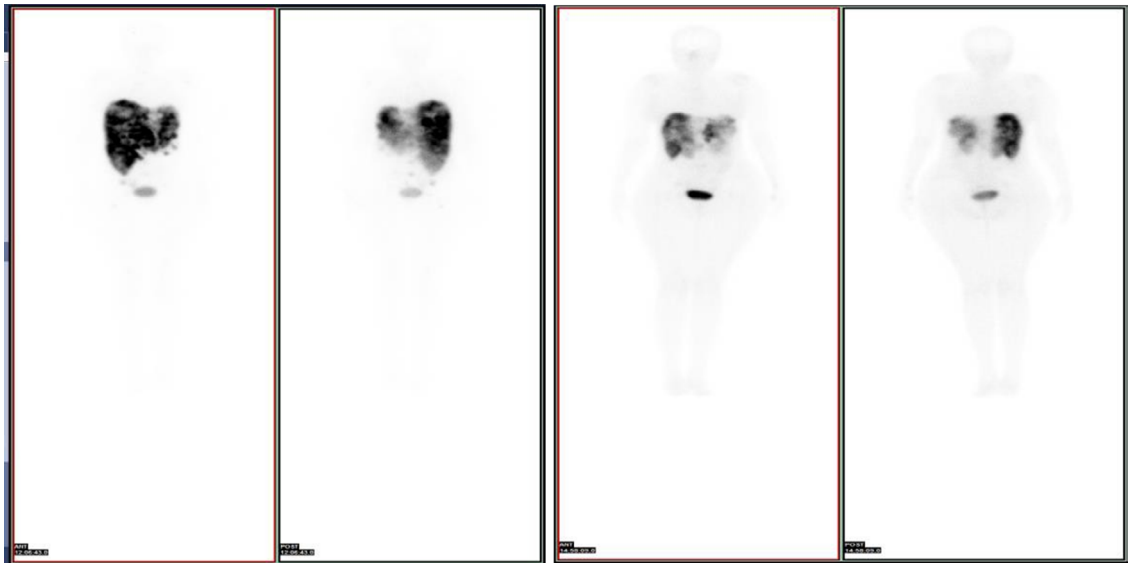


Fig 1. Images A Pre Lu -177 DOTATATE treatment scans and B Post Lu-177 DOTATATE

“Patients from outlying provinces often travel long distances, incurring additional costs for transport and accommodation, which further delays treatment initiation and completion.”

Case 2: The Treatment Works. The Access Doesn't

Effective therapies require timely, uninterrupted delivery. Delays can negate even a dramatic initial response, and South Africa is uniquely positioned to address some of these gaps. The country has established expertise in nuclear medicine and a history of isotope production capacity, which, if strengthened, could reduce dependence on imports[4].

A 73-year-old male with castrate-resistant metastatic prostate cancer presented with severe pain and loss of mobility. Following ^{177}Lu-PSMA therapy, he experienced marked biochemical and clinical improvement, progressing from wheelchair bound to walking with a stick, accompanied by a notable enhancement in the quality of life. Unfortunately, delay in local production interrupted his treatment schedule, preventing timely administration of the third dose. Although compassionate dose access approval was granted promptly from the Oncidium foundation, the interruption and postponement

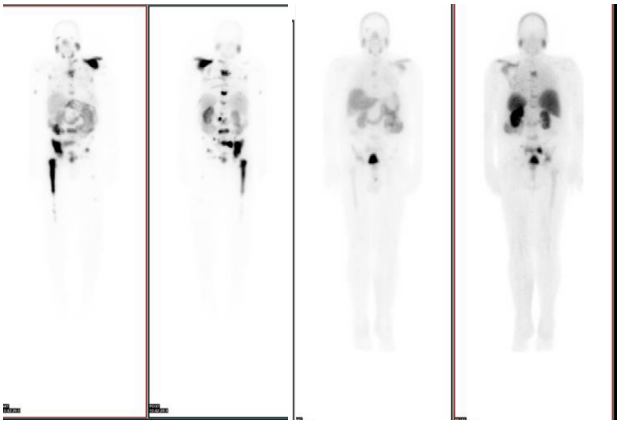


Fig 2. Images A Pre ^{177}Lu-PSMA therapy scans and B Post ^{177}Lu-PSMA

of therapy contributed to subsequent complications. The delays resulted in rapid disease progression and death before therapy could resume.

Case 3: Disease reactivation after treatment hiatus

Treatment interruptions can close the therapeutic window, especially in patients who develop side effects.

A 68-year-old male with prostate cancer responded well to initial ^{177}Lu-PSMA therapy, with pain relief and biochemical improvement. A prolonged delay before the fifth cycle due to radioligand unavailability led to disease progression. Subsequent renal deterioration, a side effect of ^{177}Lu-PSMA, halted further treatment, despite receiving compassionate doses from the Oncidium foundation via NTP.

^{177}Lu-PSMA therapy in advanced prostate cancer is generally well tolerated, but side effects such as fatigue, nausea, dry mouth (xerostomia), and hematologic toxicities (anemia, thrombocytopenia, leukopenia) can impact treatment continuation.

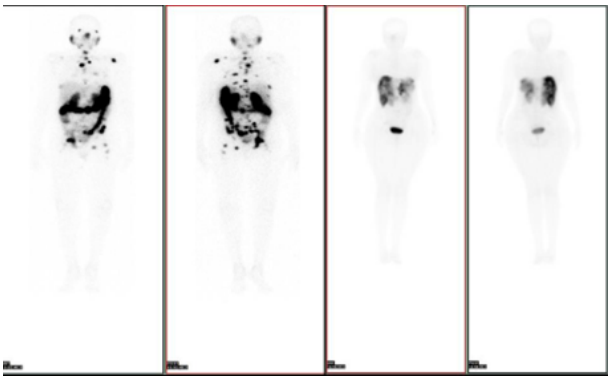


Fig 3. Images A Pre ^{177}Lu-PSMA treatment scans and B Post ^{177}Lu-PSMA

Most discontinuations occur due to disease progression rather than toxicity, though grade 3-4 hematologic events and severe renal failure occasionally necessitate stopping therapy[(6,7,8)].

Case 4: The added advantage of combination therapy

Cancer biology evolves, and access to multiple advanced radionuclide options is essential.

A 65-year-old female with aggressive, radioiodine-refractory dedifferentiated thyroid cancer demonstrated disease progression despite standard therapy. Advanced imaging allowed treatment with peptide receptor radionuclide therapy (PRRT), yielding partial benefits after two cycles. Subsequently, complementary alpha therapy led to notable improvements in pain control and mobility.

Combined alpha and beta therapy for thyroid cancer is an emerging approach that leverages the complementary strengths of both beta emitters such as radioactive iodine-131 for broader tissue penetration and alpha emitters such as astatine-211 or actinium-225 for highly localized, potent DNA damage[9].

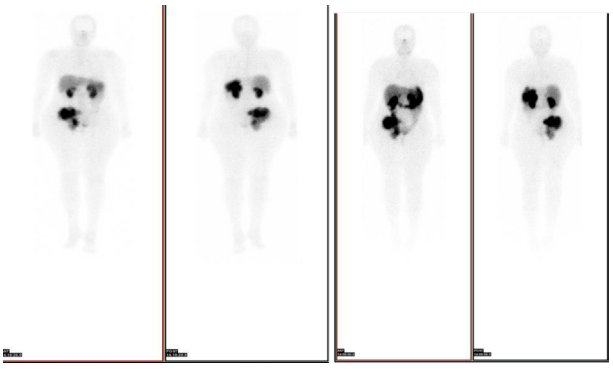


Fig 4. Images A Pre Combination (Alpha and Beta) therapy scans and B Post therapy

Conclusion

Radionuclide therapy represents a powerful frontier in cancer care. These patients' journeys highlight that medical innovation alone is insufficient. To fully realize its benefits, health systems must ensure reliable access, protected funding, infrastructure expansion, collaborative efforts and patient-centered access strategies.

> **"To fully realize its benefits, health systems must ensure reliable access, protected funding, infrastructure expansion, collaborative efforts and patient-centered access strategies."**

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Radioligand Therapy Snapshot:
Situation in Iraq

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Medical Physicist University of Thi Qar
Oncidium Ambassador - Iraq

In Iraq, the application of Lutetium-177 (Lu-177) radiopharmaceuticals for targeted radionuclide therapy remains in its early and limited stage, in particular for neuroendocrine tumors (NETs) and metastatic castration-resistant prostate cancer (mCRPC). As of now, only two hospitals in the country provide this therapy, and services are delivered intermittently. This is primarily due to logistical challenges in the continuous importation of radiopharmaceuticals, as well as a shortage of experienced nuclear medicine personnel.

Lu-177 radiopharmaceuticals are not manufactured locally and are typically imported on a case-by-case basis, requiring coordination with international suppliers. In public hospitals under the Ministry of Health, some costs may be covered, while in private and semi-private centers, patients are often responsible for the full expense. Consequently, the reimbursement system is partial and inconsistent.

As a result, access to Lu-177 therapy in Iraq is limited, both geographically and financially. For many patients, the only viable option is referral abroad. The primary destinations for such treatments are in India, Turkey, and Iran, where this therapy is more established, and logistics, availability, and expertise are more developed. In Iraq specifically, The Ministry of Health operates several medical travel programs to facilitate such referrals.

To bridge this gap, efforts are underway to build national capacity through training programs for nuclear medicine physicians and medical physicists. Alongside this are plans to establish local production facilities for radiopharmaceuticals, including cyclotron infrastructure.

Regionally, Iran has achieved notable progress, offering Lu-177 therapy in several centers and developing local production capability. India is widely regarded as a global leader in Lu-177-based therapies (for NET and prostate cancer), providing broad access in both public and private sectors, while also attracting patients from across the region.

In summary, while Iraq is making initial advances toward integrating Lu-177 therapy into its cancer treatment framework, substantial investment and strategic partnerships are still needed to ensure equitable, sustainable, and nationwide access to this advanced therapeutic option.

Radioligand Therapy Snapshot:
Situation in Canada

Dr. Patrick Veit-Haibach
Oncidium Ambassador - Canada

Dr. Nicolas Rondeau Lapierre
Oncidium Ambassador - Canada

Radioligand therapy (RLT), particularly with lutetium-177–based radiopharmaceuticals, is increasingly available in Canada and is becoming an important part of precision oncology. Treatments such as ^{177}Lu-DOTATATE for neuroendocrine tumors and ^{177}Lu-PSMA for prostate cancer are now available in several centres, mostly in larger hospitals with established nuclear medicine programs.

Canada is generally well positioned for delivery and expansion of RLT. Ontario has a well-developed theranostic landscape, Québec has one of the highest PET/CT densities per capita, and provinces like British Columbia and Alberta are also investing significantly, particularly on the research side (e.g., BC Cancer).

That said, access remains relatively concentrated, as RLT is primarily delivered in large academic centres and requires dedicated infrastructure, trained multidisciplinary teams, and complex logistics – especially given the relatively short half-life of the isotopes. Canada's geography adds another layer of complexity, and patients in smaller provinces or more remote regions often need to travel significant distances for treatment.

On the reimbursement side, there has been meaningful progress. Lu-177–based therapies are now publicly reimbursed in several major provinces, including Ontario, Québec, British Columbia, and Alberta. However, the pathway to reimbursement – particularly through the federal negotiation committees – can introduce delays. Even once funding decisions are made, implementation at the provincial level is not always immediate and needs the physician group, local healthcare authorities and hospital to work together for the implementation and establishment of funding mechanisms.

It is also important to note that reimbursement does not automatically translate into access. Capacity remains a key issue. Workforce challenges, particularly among technologists and specialized nuclear medicine teams, are foreseeable and could limit the ability to scale RLT programs. Private insurance plays only a limited role, as most of these oncology therapies in Canada are funded through provincial public healthcare systems.

Overall, while access to RLT in Canada is still concentrated in above mentioned jurisdictions rather than universal, there is work currently being undertaken to establish more centres for delivery of RLT. However, the provincially organized implementation and approval pathways can lead to variability in timelines, infrastructure, and capacity across the country. In practice, access can still depend significantly on where a patient lives.

Canada is in a strong position scientifically and clinically, with growing reimbursement, institutional engagement and – last but not least – a highly engaged nuclear industry which is one of the (if not the) world leader in medical isotope production. The next phase will need to focus on scaling capacity, addressing workforce challenges, and improving alignment across provinces to ensure more consistent and equitable access nationwide.

From Life-Changing Donations to Catalyst of Systemic Change

Dr. Alice Viana
Scientific Director

Elisa Cannarozzo
Patient Access Coordinator

Watch the story of Fernando

The journey of RLT-Connect began with a single patient's resolve to navigate a complex healthcare landscape. In 2018, Fernando Acosta was diagnosed with an inoperable prostatic adenocarcinoma. After undergoing 25 radiotherapy sessions and 42 chemotherapy sessions over four years, the metastases remained.

While his oncologist identified ^{177}Lu-PSMA therapy as the last resort, coverage in Argentina is typically denied by the insurances and it frequently requires judicial appeal to be granted, making it financially inaccessible even for a medical professional like Fernando. In response, he organized an online petition to request that social insurance cover the therapy. This effort successfully connected him with Dr. Guillermo Casale, Dr. Maria Bastianello, and the Oncidium foundation, who collaborated to facilitate the donation of his treatment

This first success inspired us to create the RLT-Connect donation program, a visionary project connecting healthcare professionals and radiopharmaceuticals suppliers and directly impacting the lives of people living with cancer across the world, mainly in low- and medium-income countries.

RLT-Connect does more than connect patients with life-changing therapies, it also exposes the deeper, systemic barriers that stand in the way of equitable access. The challenges encountered in implementing the program at the local level serve as critical signals, informing Oncidium's and fuelling efforts to integrate radioligand therapy (RLT) into national healthcare systems.

The Argentinian case provides a clear illustration of how this is unfolding as a natural extension of our work, in line with Oncidium's mission. Despite the formal availability of RLT products in the country, market constraints and the high cost of these therapies continue to limit the healthcare system's ability to deliver optimal cancer care. Furthermore, fragmented reimbursement structures have yet to include radioligand therapy in their formularies for automatic reimbursement, failing to acknowledge the Argentinian regulation on the Mandatory Medical Scheme[1] and the endorsement on radioligand therapy from the World Health Organization resolution 78/13 on Strengthening Medical Imaging Capacity[2,3].

Consequently, physicians often face a difficult choice of whether or not to recommend RLT to patients with metastatic neuroendocrine tumors or metastatic castration-resistant prostate cancer (mCRPC), as doing so may expose them to legal challenges or significant financial toxicity.

After listening to these needs, we started collaborating

with a local patient organization Fundación **ACIAPO** to reach a common objective: **make private reimbursement to RLT automatic, without the need for judicialization to get treatment access.**

Thanks to the support of our local Ambassadors, Dr. Fernando Acosta and Dr. Maria Bastianello, and a representative of ACIAPO, Ignacio Zervino, we have achieved a few important milestones in the path to advocacy focusing our work on:

- **General public awareness and Media Outreach.**

  Information on RLT was shared across 20 Argentinian oncology patient groups, supported by four filmed patient testimonials highlighting barriers to access. Interviews across TV, radio, YouTube, and online podcasts, reached an estimated 3.5 million people.

- **Regulatory & Policy-informed engagement.**

  Specific cases were presented to the national regulatory agency (ANMAT). At the same time, with a view to long-term impact, we initiated discussions with key stakeholders: a preliminary meeting was held with the Ministry of Health (Chair of the Oncology Unit), alongside engagement with the technology assessment body (CONETEC) and the Institute for Clinical and Health Effectiveness (IECS) to support updates on health economics evidence.

Looking ahead, Oncidium will remain actively engaged in the conversation by providing documented evidence to all key stakeholders. This supports the ultimate ambition of RLT-Connect: to make itself obsolete by successfully building sustainable bridges between healthcare professionals, nuclear medicine physicians, and radioisotope suppliers.

If you are a healthcare professional working with RLT and are willing to collaborate, please get in contact at rlt-connect@oncidium-live.org!

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The ACIAPO Foundation is an Argentine nonprofit organization that addresses cancer issues from a biopsychosocial perspective. Its work includes support programs, family counseling, access to treatment, research, and prevention.

Learn more

A Life in Radiotheranostics:

A conversation between the Oncidium Foundation and Professor Kalevi Kairemo

Professor Kalevi Kairemo *is a leading nuclear medicine expert and a pioneer in radioligand therapy. He has actively worked in advanced treatments such as* ^{177}*Lu-PSMA and* ^{225}*Ac-PSMA and supported the establishment of therapy programs across Europe, North America, and Africa.*

In this interview, we explore the evolution of nuclear medicine, the clinical impact and challenges of radioligand therapy, and his vision for the future of the field.

From Early Nuclear Medicine to Theranostics

How has nuclear medicine evolved over your 40-year career?

My book, "*Prostate Cancer from a Nuclear Oncology Perspective – A Personal Journey*", reflects both the scientific evolution of radiotheranostics and my own journey in the field.

I began in the mid-1980s, and my enthusiasm continued to increase in the early 1990s at MSKCC in New York, when I learned that different radioiodine isotopes (I-123, I-124, I-125, I-131) could be used not only for imaging, such as SPECT and PET, but also for therapy through beta and auger emissions.

What fascinated me was the versatility: we could study radiopharmacokinetics through blood and urine samples, analyze tissue distribution with autoradiography or radio immunohistochemistry, and, when needed, validate findings through nonclinical experimental studies using the same compounds. This naturally led to the concept of **theranostics**, using the same compound for both diagnosis and treatment.

> **"In summary, the basic knowledge was there, but the environment was not yet ready for radionuclide therapies."**

In the 1990s, I introduced radioimmunotherapy in Finland, followed by work in peptide receptor radionuclide therapy (PRRT) in Helsinki and Uppsala. Later, I contributed to early clinical development of lutetium-177 therapies in France at AAA.

At Docrates Cancer Center in Helsinki, I led a department dedicated to molecular radiotherapy, introducing advanced PET tracers, Lu-177 therapies, and voxel-based dosimetry for personalized treatment.

Clinical Innovation and Global Expansion

What drove your early adoption of radioligand therapies and how did this evolve into global implementation?

My motivation has always been a strong belief in targeted radionuclide therapy, reinforced by early exposure to alpha therapies in the 1990s.

In Helsinki, we began ^{177}Lu-octreotate treatments in 2010 and quickly attracted international patients, supported by voxel-based dosimetry. As prostate cancer became a major focus, we expanded our diagnostic capabilities by introducing Na^{18}F, ^{18}FCH, ^{18}FACBC and soon ^{68}Ga-PSMA-11 and ^{18}F-PSMA-compounds diagnostics

This led to early adoption of ^{177}Lu-PSMA and later ^{225}Ac-PSMA therapies.

From the mid-2010s onward, our work expanded internationally. I supported the implementation of treatment protocols across Northern Europe, while also contributing to global training and dissemination.

As Emeritus President of the World Association of Radiopharmaceutical and Molecular Therapy (WARMTH), I have focused on hands-on capacity building—training physicians, supporting new centers, and promoting international collaboration.

A defining moment was attending the IAEA congress in Beijing in 2002, where the global momentum of the field became clear.

In Africa, this work has been particularly meaningful. Milestones such as the first ^{177}Lu-PSMA therapy administered in Accra in 2023 highlight the real-world impact of these efforts. I continue to support programs across the continent, including in more remote regions.

> **The discipline speaks for itself, but awareness must grow.**

What are the main challenges in expanding radioligand therapy worldwide?

Radioligand therapies such as ^{177}Lu-PSMA and ^{225}Ac-PSMA are complex therapies in the clinical practice that require a multidisciplinary team with specialized expertise.

Key success factors include:

- strong infrastructure
- dedicated training
- international collaboration

At the same time, disparities in access remain significant, driven by regulatory, logistical, and educational differences.

Another critical challenge is workforce shortage. Nuclear medicine must become more visible and attractive to the next generation.

The Future of Radiotheranostics

Where do you see the field heading in the next decade?

Radionuclide therapies are uniquely powerful due to their unique combination of sensitivity, specificity, and ability to capture biological processes over time and at depth.

In addition, therapeutic radiopharmaceuticals can be precisely designed for optimal targeting and pharmacokinetics. I have believed in this field for over 30 years, and we are now seeing its impact with treatments like ^{177}Lu-PSMA, which are transforming clinical practice. Theranostics is clearly here to stay. While precision oncology faces regulatory challenges, I remain confident in its future, both in Scandinavia and globally.

How will nuclear medicine shape the future of oncology?

The most striking progress has been in neuroendocrine tumors and prostate cancer, but expansion across oncology is accelerating.

Prostate cancer illustrates this evolution clearly from no tracers two decades ago to more than ten today.

Advances in molecular imaging will ive drug development and enable increasingly precise, targeted therapies.

Mutation-driven cancers can sometimes be treated with specific ”blockers”; theranostics may offer an ideal diagnosis/therapy treatment combination possibility. Very often, these treatments are based on the use of radiopharmaceuticals.

> **When used correctly, these therapies are not only safe, they can be remarkably powerful, even in resistant disease.**

Closing Reflections

What advice would you give to young physicians?

Nuclear medicine is such a fascinating field: a person has to understand cell and atomic nuclear behavior and make a clear difference between nuclear physics and cell biology. This has to be understood and one can follow these events.

If you had to describe nuclear medicine in one sentence to a patient or a non-specialist, what would you say?

The radioactive atoms decay in a way which is known very precisely, but how they behave in organisms is not that easy to understand, but they can be tracked in a quantitative and dynamic manner. With nuclear medicine methods we can follow online physiology.

Some of my health issues have been diagnosed with nuclear medicine techniques and I have received radionuclide treatments. From my own experience, I know that there is no need for an irrational fear of nuclear medicine imaging or therapy studies, because of radiation.

Radiation is a natural part of our environment (e.g. soil, cosmic), and the body has mechanisms to manage it. In medicine, its use is highly controlled, precisely targeted, and carefully planned.

European Prostate Cancer Coalition (Europa Uomo)

Founded in 2004 and based in Antwerp, Belgium, Europa Uomo (Italian for "Europe Man") is a European advocacy movement representing 31 national prostate patient groups across Europe.

> **From the patient perspective, what men want above all is a cure; and if cure is not possible, then control of their disease with good quality of life and dignity at the end of life.**
>
> *- Dr. Erik Briers, Chair of Europa Uomo*

Prostate cancer is the most commonly diagnosed cancer among men in Europe and worldwide. Its incidence and mortality increase with age, with most cases diagnosed in men around 70 years of age.

Across Europe, approaches to diagnosis and treatment vary considerably, and public awareness, as well as access to clear information on early detection, remains limited.

In response to these challenges, patients, families, and healthcare professionals came together to establish Europa Uomo, an independent international non-profit coalition of patient-led prostate cancer support groups across Europe.

This coalition brings forward priorities and concerns identified by its members at the local level, contributing to action and policy at the European level.

The organization's priorities are to:

- Improve support and quality of life for people affected by prostate cancer
- Promote effective and equitable screening programmes across Europe
- Enhance treatment options and raise awareness
- Advance research and contribute to policy development
- Work with health professionals to help them understand patient perspectives
- Support national member organisations in strengthening services and advocacy

For more information and patient resources, visit Europa Uomo's website:
https://www.europa-uomo.org
or follow them on Facebook:
https://www.facebook.com/EuropaUomo.

Patient Sessions Take the Stage to Share Their View

Patient perspectives were part of the discussions at two major meetings in nuclear medicine this year: the **Theranostics World Congress (TWC)** in Cape Town, South Africa, and the **World Federation of Nuclear Medicine and Biology (WFNMB)** congress in Cartagena, Colombia.

> **When patients lead the conversation, care becomes more precise, more equitable, and more human.**

Across both meetings, the conversations emphasized a common message: behind every treatment pathway is a patient experience that can guide research, clinical practice, and healthcare policies. Listening to these perspectives helps ensure that developments in radiotheranostics remain closely connected to the needs and realities of those receiving care.

WFNMB - World Federation of Nuclear Medicine and Biology 2026 in Cartagena, Colombia

TWC – Theranostics World Congress 2026 in Cape Town, South Africa

Launch of the Oncidium Foundation LATAM

The new regional entity, launched in February, aims to support efforts to expand access to radioligand therapy across Latin America by addressing regional barriers to implementation and strengthening collaboration with local stakeholders. The founding board includes Denio Mustrangi (President), Rebecca Lo Bue (Vice-President), Dr. Maria Bastianello (Chief Medical Officer), and Efrain Perini (Director).

The initiative will also contribute to expanding the reach of **RLT-Connect**, the foundation's treatment donation program, which has already supported patient access to radioligand therapy in several Latin American countries. To date, partnerships in Brazil, Argentina, Uruguay, and Mexico have enabled the donation of 122 treatment doses to 40 patients.

Latin America faces unique challenges, but also tremendous opportunities. Through Oncidium foundation LATAM, we can not only raise awareness of radiotheranostics but also bring concrete solutions that give patients hope and a chance at better outcomes. This is about building a future where cutting-edge cancer care is no longer a privilege, but a right.

- Denio Mustrangi,
Head of Oncidium foundation LATAM

Read the full press release

Check out our factsheet on RLT for NETs

RLT Channel
Episode 2: Shedding Light on NET Patients and PRRT

Following the successful launch of the RLT Channel's first episode focusing on prostate cancer, this second episode focuses on people living with neuroendocrine tumors (NETs) and the peptide receptor radionuclide therapy (PRRT) or radioligand therapy (RLT) option.

Designed for patients, caregivers, and anyone seeking to better understand NETs, the episode brings together expert insights to explain how PRRT works, when it becomes a treatment option, and how it fits into the overall care pathway. It also explores real-world challenges such as access to treatment and the patient experience throughout the journey.

If you would like to bring a similar broadcast to your region, contact us.

World Radiotheranostics Day:
Raising Awareness to Improve Access

On March 31st, 2026, on the occasion of World Radiotheranostics Day the Oncidium foundation launched an international awareness campaign aimed at improving global access to radiotheranostics.

Radiotheranostics has been transforming cancer care for decades, yet it remains insufficiently known beyond specialized fields. Through this initiative, the foundation emphasized that innovation only fulfills its promise when patients who need it can actually access it.

Partners worldwide came together to support this important cause. The campaign demonstrated strong global engagement, with:

24
partners involved

300,000+
views on social media

1,500+
website visits

These results highlight growing interest, but also the ongoing need for greater awareness. Healthcare systems must continue to engage, invest, and educate around this rapidly evolving pillar of cancer care to ensure equitable access worldwide.

Because greater awareness means more people living with cancer can access it.

Discover more

The Oncidium foundation at the European Parliament

Oncidium foundation's CEO, Rebecca Lo bue, represented the foundation at the European Parliament on April 9th during the panel discussion “European and National RLT Policy & Reality”, co-hosted by MEPs Tomislav Sokol and Nicholas Papandreou.

Rebecca highlighted the critical need to overcome real-world barriers to access in Radioligand Therapy (RLT), including reimbursement, awareness, infrastructure, and patient-centric support. She shared examples of disparities across Europe and called for harmonized referral pathways, cross-border collaboration, and targeted investment in nuclear medicine to ensure every patient benefits from these innovative therapies.

We sincerely thank SPARC Europe for inviting us to join this important discussion on patient access to Radioligand Therapy.

See you soon at:

- **ANZSNM - 56th Annual Scientific Meeting of the Australian and New Zealand Society of Nuclear Medicine** in Canberra, Australia on May 15th - 17th
- **ASCO - American Society of Clinical Oncology** in Chicago, USA on May 29th - June 2nd
- **SNMMI** in Los Angeles, USA, on May 29th - June 2nd
- **Best of ASCO** in Abuja, Nigeria on July 10th - 11th
- **ICRT 2026** in Cairo, Egypt, on September 23rd - 26th
- **Nuclear Medicine Day** in Brussels, Belgium, on October 8th
- **EANM - European Association for Nuclear Medicin**e in Vienna, Austria, on October 17th - 21st
- **ESMO - European Society for Medical Oncology** in Madrid, Spain, on October 23rd - 27th

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