

Translating Novel Radiopharmaceutical Therapies to Transform the Medical Future

Establish Targeted Radiopharmaceuticals as the Next Pillar of Oncology **Drugs Through Innovating Novel Design Approaches, Showcasing Emerging Clinical Data, & Streamlining Isotope Supply & Distribution** 

45+ World-Class Speakers, Including:



**Mark Fielding** Director, CMC Regulatory Affairs, TRP **AstraZeneca** 



**Thomas Birger Eden-Jensen** Head, External Supply Management TRP **Bayer** 



Sandra Uhlenbroich Director, Discovery **Bicycle Therapeutics** 



Nicoletta Fabiano Head, RLT Analytical Development **Novartis** 



Thiis Spoor Chief Executive Officer **Perspective Therapeutics** 



**Josie Gayton** Chief Operating Officer **Precirix** 



Director, Regulatory CMC **Telix Pharmaceuticals** 

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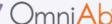




















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PRE-CONFERENCE WORKSHOP DAY

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## Welcome to the 7<sup>th</sup> Targeted Radiopharmaceuticals Europe **Summit**

Radioligand therapy is evolving rapidly - expanding into new targets, new tumour types, and new clinical strategies. As promising early data emerges beyond PSMA and SSTR2, and as interest continues to grow across industry and academia, the need for harmonised, cross-functional progress in Europe and beyond has never been greater.

The 7th Targeted Radiopharmaceuticals Europe Summit is the sector's leading platform dedicated to advancing the full development pipeline, from discovery and preclinical development through to clinical trial design, CMC. and commercialisation.

Designed in collaboration with key players including Bayer, Novartis, AstraZeneca, Perspective Therapeutics, and leading European academic centres, this meeting brings together experts across R&D, translational science, manufacturing, and regulatory affairs to address the unique challenges and opportunities facing the European radiopharmaceutical landscape.

#### Join your TRP colleagues to:

- Translate early clinical insights into robust preclinical and first-in-human (FIH) strategies to de-risk development and enhance likelihood of clinical success
- Optimise dosimetry, dosing, and trial design for novel targets including HER2 & FAP to improve therapeutic index and accelerate clinical translation
- Navigate isotope access, CMC compliance, and regional regulatory requirements to ensure timely development and global supply readiness
- Advance chelator and linker technologies to enhance stability, specificity, and safety
- Tackle cross-border supply chain and manufacturing constraints across Europe to streamline logistics

Whether you're progressing an early-stage pipeline or scaling for later-phase development, join this collaborative environment to gain practical insights, forge new partnerships, and accelerate your programmes' success.





Evaluate the radioligand therapy landscape with trailblazers in the space, including updates on the ProstACT GLOBAL from Telix Pharmaceuticals and first-hand insights into Novartis' next steps in the TRP space



Strategise and optimise molecular design through moiety selection and engineering for competitive differentiation and improved tumour selectivity, alongside C-suite executives from OncoOne and OranoMed



Delve into the latest advances in dosimetry, exploring the rationale behind personalised/non-personalised dosing through exciting novel data from Precirix and Star Pharma



Accelerate translation from bench to bedside by hearing from Affibody, Alpha-9 Oncology, and RayzeBio as they pioneer Phase Zero and first-in-human trial strategies, while harnessing real-world data to inform smarter, impact-driven late-phase studies



Shape the future of radiopharmaceuticals by exploring evolving supply chain dynamics and CMC strategies, examining isotope access, regulatory landscapes, and technological innovation across Europe and beyond, in collaboration with Novartis, **ARTBIO** and **AstraZeneca** 

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## What's New for 2025?

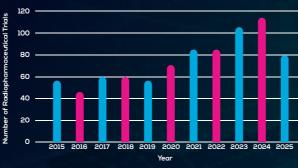
### **Brand New Content for 2025:**

**Newly Released Third Track of Content: Introducing** a brand-new stream of information, allowing you to attend any track from Preclinical & Discovery, Translational & Clinical, and CMC & Sourcing

6 Brand-New Workshops: Take a deep dive into topics ranging from targets beyond PSMA to Regulatory CMC, alongside academic KOLs and industry leaders from the likes of AstraZeneca, Telix Pharmaceuticals, Affibody and more

**Cutting-Edge Novel Talks:** Hear from **Novartis** and Telix Pharmaceuticals as they share updates on their developing pipeline and the progress of of ProstACT GLOBAL

Unprecedented Growth -**Radiopharmaceutical Trials by Start Date** 



The rising number of radiopharmaceutical trials highlights growing momentum and innovation in the field. This summit is the key forum to connect with leaders, explore new data, and stay ahead in this rapidly evolving space.

### **New C-Suite Speakers:**



Andreas Goutopoulos Chief Executive Officer **ActiThera** 



Chief Executive



Thijs Spoor Chief Executive Perspective **Therapeutics** 



Fredrik Freid Chief Scientific Officer **Affibody** 



Michael Thiele Chief Scientific Officer **OncoOne** 



Officer

Josie Gayton **Chief Operating** Officer **Precirix** 



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### New Speaking Companies for 2025:























### Your KOL Academics & **Clinicians:**



Harshad Kulkarni Chief Medical Advisor **Bamf Health** 



**Tim Witney** Chief Scientific Officer **Nuclide Therapeutics** 



Stephen Archibald Head. Research Department, Imaging Chemistry & Biology **Kings College London** 

NEW



**Arthur Braat** Associate Professor **UMC Utrecht** 



Stuart More Head of Department. Nuclear Medicine. **University of Cape** Town



10th -12th November 2025 | Amsterdam, Netherlands



Andreas Goutopoulos Chief Executive Officer Actithera



Fredrik Frejd
Chief Scientific Officer,
Vice President,
Research
Affibody



Maritina Rouchota
Partner, Chief Business
Officer
BIOEMTECH



Jarrod Longcor
Chief Operating Officer
Cellectar



Thom Tulip
Chief Business Officer
Cerveau Technologies



Setareh Shamisli
Chief Executive Officer,
Chief Medical Officer
Coretag



Jeffrey Cleland Co-Founder Iron Fist Therapeutics



Oystein Soug
Chief Executive Officer
Oncolnvent



Michael Thiele
Chief Scientific Officer
OncoOne



Volker Wagner
Chief Medical Officer
Oranomed



Julien Torgue
Chief Scientific Officer
Oranomed



Tim Witney
Founder, Chief Scientific
Officer
Nuclide Therapeutics



John Babich
President, Chief
Scientific Officer
Ratio Therapeutics



Thijs Spoor
Chief Executive Officer
Perspective
Therapeutics



Josie Gayton
Chief Operating Officer
Precirix



Abbas Sahili
Chief Executive Officer
Singzyme

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Jeremy Paull
Chief Scientific Officer
Star Pharma



Sigal Kalmanson
Chief Executive Officer
Starget Pharma

The speakers were very knowledgeable and shed new light on topics pertaining to the radiopharmaceutical field. I learned so much and left the daily panel discussions and presentations with more insight regarding the topics discussed.

Scientist, POINT Biopharma

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**Guido Wuerth** Head, Global Programs Affibody



Yusuke Kohno Head, Supply Chain **Alpha Fusion** 



Manuel Sturzbecher Head, CMC & Radioisotope Development **Ariceum Therapeutics** 



**Daniel Rossetto** Head, SVP, Supply Chain Management **ARTBIO** 



**Bala Atilli** Director, Oncology Safety Sciences **AstraZeneca** 



**Mark Fielding** Director, CMC Regulatory Affairs, TRP **AstraZeneca** 



Harshal Kulkarni Chief Medical Officer **BAMF Health** 



**Thomas Birger Eden-**Jensen Head, External Supply Management, TRP **Bayer** 



Sandra Uhlenbroich Director, Discovery **Bicycle Therapeutics** 



**Shaemus Gleason Executive Vice President** Clarity **Pharmaceuticals** 



**Angeliki Grammenos** Associate Lead, Global Regulatory Affairs **Debiopharm** 



Julia Jauch-Lembach **Executive Medical** Director **Debiopharm** 



Stephen Archibald Head. Research Department, Imaging Chemistry & Biology Kings College London



Nicoletta Fabiano **RLT Analytical Head Novartis** 



Isabel Jaco Senior Principal Scientist, Group Leader. RLT Drug Discovery **Novartis** 



Josefine Reber Lab Head, Molecular Imaging & RLT **Novartis** 



**Vimal Patel** Vice President, CMC **RadioPharm Theranostics** 



**Levente Meszaros** Head. Clinical Operations & Programs **RadioPharm Theranostics** 



Catello Somma Partner Seroba Life Sciences



**Anil Lalwani** Director, Regulatory CMC **Telix Pharmaceuticals** 



**Frederic Fantino** Global Medical Affairs **EMEA Telix Pharmaceuticals** 



**Arthur Braat** Associate Professor **UMC Utrcht** 



Luke Brzozwski Executive Director. **Theranostics University Health Network** 



**Stuart More** Head of Department. Nuclear Medicine **University of Cape Town** 

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# **Speaker Faculty**







**Labros Meimetis** Research Assistant Professor **University of Wisconsin Madison** 



Great sessions with speakers addressing relevant industry issues. Also, really good engagement with senior level biotech attendees.

Ionetix

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Targeted Radiopharmaceuticals

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## Pre-Conference Workshop Day | Monday, 10<sup>th</sup> November



10th -12th November 2025 | Amsterdam, Netherlands

8.00 Check In & Coffee

**Discovery & Preclinical Track** 

OR

**Translational & Clinical Track** 

OR

**CMC & Sourcing Track** 

Workshop A

**Workshop B** 

Workshop C

#### 9.00 Evolving Tumours & Smarter Targets: Advancing **Novel TRPs with HER2 & FAP**

As tumours evolve, their surface and stromal protein expressions shift, demanding precision strategies in targeted radiopharmaceutical development. To ensure sustained therapeutic efficacy, it's essential to choose radiopharmaceutical targets that reflect these dynamic changes, especially as we move beyond traditional oncogenic markers.

- Adapt TRP Targeting to Tumour Evolution: Track changes in tumour biology and adapt radiopharmaceutical targeting strategies accordingly
- Redefining What Makes a Good TRP Target: Focus on targets with strong tumour specificity, high expression density, and internalisation potential, as these are key attributes for radioligand efficacy
- Why HER2 and FAP are Leading Candidates: HER2 enables tumour-cell directed TRP approaches, while FAP provides access to the tumour stroma, broadening reach across solid tumours

Guido Wurth, Head, Global Programs, Affibody

Rebecca Ferissi, Postdoctoral Researcher, University of Milan

#### 9.00 Bridging the Gap - Translating Dosimetry from **Animal Models to Human Applications in TRPs**

Accurate dosimetry translation from animal models to humans is crucial for the safe and effective clinical application of targeted radiopharmaceuticals. This workshop delves into the methodologies, challenges, and best practices in extrapolating dosimetric data, ensuring that preclinical findings reliably inform human therapeutic strategies.

- Comparing various extrapolation techniques and assessing their accuracy and applicability
- Review real-world examples where dosimetric translation informed clinical dosing, highlighting both successes and areas for improvement
- Optimising a novel nanomedicine to maximise tumour uptake
- Evaluating the impact of specific activity and isotope selection
- Leveraging in vivo (PET) and ex vivo biodistribution
- Dosimetry and scaling to human doses

Jeff Cleland, Co-Founder, Iron Fist Therapeutics

#### 9.00 Evaluating Regulatory Perspectives for CMC in **Europe to Navigate Requirements & Ensure Product** Quality

TRPs represent a rapidly advancing therapeutic modality, offering precision treatment for various cancers and other diseases. However, the development and approval of TRPs in Europe require stringent adherence to regulatory standards for CMC. This workshop will provide an in-depth analysis of the EU regulatory framework governing CMC for TRPs, covering the critical requirements for ensuring product quality, manufacturing consistency, and regulatory compliance throughout the product lifecycle.

- CMC Regulatory Framework: Understand the key EU regulations for CMC in TRPs, focusing on product quality and manufacturing standards
- Submission & Approval Process: Navigate the requirements for submitting CMC data to regulatory authorities, including EMA guidelines
- Ensuring Compliance: Address challenges in demonstrating consistency and control over TRP manufacturing processes to meet regulatory expectations

Mark Fielding, Director, CMC Regulatory Affairs TRP, **AstraZeneca** 

Anil Lalwani, Director, Regulatory CMC, Telix **Pharmaceuticals** 

12.00 Lunch Break & Networking

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TRP Event Series

## Pre-Conference Workshop Day | Monday, 10<sup>th</sup> November



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**Discovery & Preclinical Track** 

OR

**Translational & Clinical Track** 

OR

**CMC & Sourcing Track** 

Workshop D

#### Workshop E

**Workshop F** 

### 13.00 Designing Safer Radiopharmaceuticals -**Balancing Innovation with Toxicity Management**

As radiopharmaceutical therapies advance, ensuring patient safety remains paramount. This workshop offers a comprehensive overview of designing novel radiopharmaceuticals with an emphasis on minimising toxicity. We'll explore the intricacies of molecular designrom targeting moieties to payloads and discuss strategies to mitigate associated toxicities.

- Designing safer tumour-targeted in situ RadioIMmunoStimulants (RIMS) for metastaticcastration resistant prostate cancer
- Disease Biology Insights: Understanding diseasespecific biology to inform safer drug design
- Optimising pharmacokinetics and safety to improve radiation exposure
- Toxicity Exploration: Identifying common toxicities in radiopharmaceuticals and strategies to avoid them across different modalities

Labros Meimetis, Research Assistant Professor. **University of Wisconsin Madison** 

Stephen Archibald, Head, Research Department of Imaging Chemistry & Biology, Kings College London

Bala Attili, Director, Oncology Safety Sciences, **AstraZeneca** 

#### 13.00 Engaging Healthcare Providers Before & During Radiopharmaceutical Rollout: Models for Successful **Implementation**

As radiopharmaceuticals advance toward regulatory approval and standard-of-care (SOC) designation, the demand for theranostic services is rapidly increasing. In response, the University Health Network (UHN), a major multi-site Canadian hospital system, has launched a strategic, interdisciplinary initiative to transition theranostics from clinical research to routine care. Guided by a multi-year implementation roadmap, UHN addresses critical elements such as infrastructure, reimbursement, capacity planning, fundraising, and governance. This approach draws on clinical trial expertise and industry partnerships to enable scalable, sustainable integration of theranostics into mainstream healthcare.

- Key components of UHN's multi-year roadmap for implementing theranostics as a standard of care
- Operational and systemic challenges in transitioning theranostics from research to routine clinical use
- The role of hospital-industry collaboration in scaling and sustaining a theranostics program

Luke Brzozwski, Executive Director, Theranostics, **University Health Network** 

#### 13.00 Managing Logistics & Distribution Networks to **Streamline TRP Supply Chains**

The development and administration of TRPs require a robust and efficient logistics and distribution framework. Due to the short half-lives of many medical isotopes. including Lu-177, Ac-225, I-131 & Pb-212, precise timing and temperature control are critical to ensure the efficacy and safety of these therapies. Delve into the complexities of isotope logistics, emphasising strategies to mitigate supply chain disruptions and enhance delivery reliability.

- · Optimising Isotope Supply Chains: Implement multisupplier strategies and advanced tracking systems to ensure consistent isotope availability and timely delivery
- Navigating Regulatory and Safety Protocols: Adhere to stringent regulatory requirements and safety standards to maintain compliance and ensure patient safety during transportation
- Enhancing Distribution Efficiency: Utilise proximitybased distribution networks and real-time monitoring technologies to reduce transit times and maintain the integrity of radiopharmaceuticals

Vimal Patel, Vice President, CMC, RadioPharm **Theranostics** 

Daniel Rossetto, Head, SVP, Supply Chain Management, **ARTBIO** 

**16.00 End of Pre-Conference Workshop Day** 

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Check-In & Coffee 7.30

**Chair's Opening Remarks** 8.20

#### A Booming Radiopharmaceutical Landscape: Evaluating the Progress of TRPs in Europe & Beyond

Radiopharmaceuticals are on the rise worldwide. Join key players to explore how Europe is driving progress in this exciting field - and what it means for the future of cancer care around the world.



**Isabel Jaco** Senior Principal Scientist, Group Leader, RLT Drug Discovery **Novartis** 

#### Examining the Success Story of Pluvicto: Strategies, Approaches & Next Steps

- Demonstrating significant progression-free survival benefits for mCRPC patients treated with Pluvicto
- Enhancing treatment outcomes when combining Pluvicto with enzalutamide in mCRPC therapy
- · Increasing real-world use of Pluvicto in both academic and community settings to improve patient accessibility



#### 9.00 An Update on ProstACT Global: Comparing Standard of Care With or Without 177Lu-DOTA-Rosopatamab

- Evaluating the impact of adding 177Lu-DOTA-Rosopatamab to standard care in PSMA-positive mCRPC
- Assessing the safety and effectiveness of 177Lu-DOTA-Rosopatamab with androgen inhibitors or taxanes
- Exploring new therapeutic strategies for advanced prostate cancer using 177Lu-DOTA-Rosopatamab



#### Delivering on the Promise of Targeted Radiopharmaceuticals: Emerging Therapy & Innovation Platforms 9.30

- Developing first-in-class versus best-in-class radiopharmaceuticals
- Emerging clinical data from best-in-class approaches
- Validation of preclinical platforms to deliver blockbuster after blockbuster



Morning Break & Speed Networking

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#### **Discovery & Preclinical Track**

Chair: Josefine Reber, Lab Head, Molecular Imaging & RLT **Novartis** 

#### **Translational & Clinical Development Track**

Chair: Julia Jauch-Lembach. Executive Medical Director. Debiopharm

#### **CMC & Sourcing Track**

Chair: Thom Tulip, Chief Business Officer, Cerveau Technologies

Radioisotope Selection: Exploring Alpha VS Beta **Emitters** 

**Translating Dosimetry to Humans to Understand** the Impact of Biodistribution on Drug Efficacy

**Optimising Isotope Supply Chain Resilience to Enable Scalable & Stable Radiopharmaceutical** 

#### 11.00 Elucidating Radiobiological Mechanisms of Cytotoxicity & Immune Modulation to Inform Selection of **Optimal Radiopharmaceutical Targets**

- · Investigating the cellular and molecular mechanisms underlying radiopharmaceutical-induced cell death to optimise therapeutic outcomes
- · Exploring how radiopharmaceuticals interact with the immune system to enhance anti-tumour immunity and reduce
- Leveraging insights from radiobiology and immune modulation to identify and select optimal radiopharmaceutical targets for improved tumour control and reduced toxicity

Bala Attili, Director, Oncology Safety Sciences, AstraZeneca

#### 11.00 Engineering Targeted Radiopharmaceuticals: DEP **Dendrimer Nanoparticles for Optimised Biodistribution and Efficacy**

- DEP dendrimers can be precisely engineered to achieve targeted pharmacokinetic and biodistribution objectives, illustrated by contrasting dendrimer profiles.
- Methods for predicting human radiation doses from preclinical data to validate dendrimer design criteria are being combined with the strategic use of predicted human dosimetry estimates to guide the selection of lead dendrimer candidates.
- DEP dendrimers represent a versatile solution to overcome biodistribution challenges, and enhance therapeutic efficacy.

Jeremy Paull, Chief Scientific & Regulatory Officer, Star **Pharma** 

#### 11.00 Strategies to Mitigate Isotope Supply Challenges for **Actinium to Ensure Consistent Supply**

- Navigating reliance on decommissioned nuclear materials and government-controlled isotope stock
- Exploring scalable actinium and terbium generation methods
- How companies are hedging risk by contracting with multiple suppliers and monitoring delivery readiness

Shaemus Gleason, Executive Vice President, Clarity **Pharmaceuticals** 

#### 11.30 Session Reserved for BIOEMTECH



#### 11.30 Roundtable Discussion: Rethinking Dose Strategy: **Balancing Dosimetry with Practicality in Human Trials**

- Contrasting fixed-dose, weight-based, and dosimetry-guided approaches in radiopharma
- Regulatory and operational hurdles to implementing personalised dosing strategies
- Potential of AI and automation to streamline dosimetry without increasing burden

#### 11.30 Roundtable Discussion: Addressing the Global Supply **Chain Constraints for Terbium: Emerging Solutions for Scalable Isotope Production**

- Exploring how global partnerships are mitigating supply shortages and ensuring access to critical isotopes
- Innovations in small-scale, flexible production technologies to meet increasing demand
- Examining the economics of commercialising terbium isotopes while maintaining cost-effective, high-yield production

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#### 12.00 Strategies for Targeted Isotope Delivery to Tumours

- · Exploring how different targeting strategies enhance selective isotope delivery to tumour sites
- Identifying key factors (e.g., half-life, energy emission, tissue penetration) for choosing the most effective isotopes for tumour treatment
- Assessing how optimal isotope selection improves tumour targeting, minimises off-target effects, and enhances therapeutic efficacy

Brian Santich, Vice President, Research, Y-mAbs

#### 12.00 Toward Personalised Radiopharmaceutical Therapy: **Optimising Protein & Drug Dose Through Imaging**

- Examining the role of imaging probes in assessing receptor occupancy and tumour-targeting dynamics
- Highlighting the importance of protein dose optimisation for maximising tumour uptake and minimising off-target effects
- Using early human imaging and dosimetry to guide dose selection and escalation in clinical trials

Josie Gayton, Chief Operating Officer, Precirix

#### 12.00 Innovations in Generator Technologies to Enhance Reliability & Sustainability of Radiopharmaceutical Supply Chains

- Advances in generator systems to decouple production from centralised isotope sources
- Engineering improvements for more efficient isotope extraction and longer operational windows
- · Leveraging generator portability to support regional radiopharmacies and minimise transportation risks

Daniel Rossetto, Head, SVP, Supply Chain Management, ARTBio



#### **Exploring Targets Beyond PSMA: Ongoing Discovery to Find Real Hits on Novel Targets**

#### 1.30 Characterising Key Attributes of an Ideal **Radiopharmaceutical Target for Alignment with Radiotherapeutic Properties**

- Evaluating receptor expression profiles and proximity to radiosensitive tissues
- Defining target selection criteria based on emission characteristics of alpha versus. beta emitters
- Exploring strategies for stromal and internalising target engagement, including FAP-directed approaches

Setareh Shamisli, Chief Executive Officer, Coretag

#### Designing a First in Human Study: Phase Zero, **Safety Parameters & Study Design**

#### 1.30 HER2 Targeted Affibody Radioligand Therapy: Rationale & First in Human Design

- Translating mouse data to clinical doses
- Considering novel imaging diagnostic versus histochemistry gold standard
- Developing riskadjusted stepwise clinical development path

Fredrik Freid, Chief Scientific Officer, Affibody

#### **Test & Release & Formulation Development for** Improved Delivery Strategy: Stabilisation of **Oxidation & Radiolysis**

#### 1.30 Improving the Shelf Life of Alpha Emitters Through **Antioxidant Formulation**

- Leveraging excipients, buffers, and antioxidants to protect radiolabelled molecules from alpha and beta-induced degradation
- Impleneting strategies for reconstitution stability and maintaining radiochemical purity at point the of care
- Developing formulation innovations that enable regulatorycompliant shelf life without compromising clinical efficacy

Elaheh Khozemi, Principal Scientist, POINT Biopharma

#### 2.00 Session Reserved for Navigo Proteins



#### 2.00 Mastermind Session: Integrating Imaging-Derived **Dosimetry & Target Confirmation to Optimise Therapeutic** First-in-Human Study Design

- Translating diagnostic imaging biodistribution into therapeutic dose estimates and dosimetry thresholds for cycle scheduling
- Defining target expression and on-target binding criteria through pre-treatment scans to guide patient selection and reduce off-target-risk
- Planning treatment cycles and follow-up intervals based on calculated organ dose limits, expected adverse-event-kinetics, and recovery profiles

#### 2.00 Session Reserved for ITM Radiopharma



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## 2.10 Towards Optimising Tumour Retention of FAP-Targeting Theranostics

- Discussing the promise of FAP as a target for the imaging and therapy of various solid tumours
- Summarising approaches used in the FAP field to optimise tumour AUC
- Exploring insights into Actithera's approaches and molecules

4.00

Andreas Goutopoulos, Chief Executive Officer, ActiThera

## 2.10 Roundtable Discussion: Strategic Dose Escalation Models to Accelerate Proof-of-Concept & Ensure Safety in First-in-Human Radioconjugate Studies

- Designing hybrid escalation schemes that balance rapid concept validation with cohort size requirements
- Incorporating interim analyses and adaptive dose-finding to minimise patient numbers and time to biologically active exposure
- Aligning starting mass and radioactivity doses with preclinical dosimetry to optimise safety margins

## 2.10 Optimising Control Strategies & Release Testing to Maximise Radiopharmaceutical Shelf Life & Clinical Readiness

- Tailoring analytical and release strategies from early clinical to commercial stages to ensure product integrity
- Innovations in rapid-release methods and predictive analytics to reduce time-to-patient
- Ensuring timely patient delivery through scalable, flexible production strategies

Vimal Patel, Vice President, CMC, RadioPharm Theranostics



2.40 Afternoon Break & Networking

### Investigating a Well-Rounded Approach to Isotope Selection from Discovery to Manufacturing



Sigal Kalmanson Chief Executive Officer Starget Pharma

#### 3.30 Lutetium 177 VS Terbium 161 - What are the Potentials for Next-Gen Radioisotopes?

- Evaluating the differences in emission profiles, half-lives, and tissue penetration between <sup>177</sup>Lu and <sup>161</sup>Tb
- Assessing the potential of <sup>161</sup>Tb to enhance tumour cell kill through higher linear energy transfer and Auger electron emission
- Discussing production, labelling, and regulatory considerations for integrating <sup>161</sup>Tb into next-generation radiopharmaceuticals



Manuel Sturzbecher-Hohne
Head, CMC &
Radiopharmaceutical
Development
Ariceum Therapeutics

#### Optimising Isotope Selection for Scalable Radiopharmaceutical Commercialisation

- Evaluating isotope availability, production capacity, and logistics for reliable clinical and commercial use
- · Aligning isotope half-life, emission type, and energy with therapeutic goals and pharmacokinetics
- Addressing regulatory, technical, and cost considerations for efficient scale-up and market readiness



Thomas Birger Eden-Jensen Head, External Supply Management, TRP Bayer

#### 4.30 Exploring Strategies for Improved Global Radio-Isotope & Therapy Supply Chain Management

- Investigating current challenges and solutions in global actinium-225 production and distribution
- Emerging technologies and infrastructure for scalable, high-purity isotope generation
- Addressing regulatory, logistical, and economic barriers to support widespread adoption of actinium-based therapies

#### 5.00 Chairs Closing Remarks

5.10 End of Scientific Programme Day One

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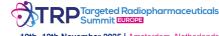
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Check-In & Coffee 7.50



8.50 **Chair's Opening Remarks** 

Commercial Readiness & Global Harmonisation: Demystifying the Strategies for Widespread Clinical Success & Regulatory Approval

Getting radiopharmaceuticals to patients is about more than just approvals. This session evaluates the strategies needed to launch successfully and navigate global regulations with confidence



#### Understanding Global Differences in TRP Procedure & Regulation to Gain Harmonisation for Worldwide Administration 9.00

- · Comparing procedural and regulatory differences in TRP use across major global markets
- · Highlighting key challenges in harmonising clinical standards, manufacturing, and approval pathways
- Discussing strategies to align stakeholders and streamline international TRP administration

#### Panel Discussion - Challenges & Opportunities for Securing Ongoing Funding for Radiopharmaceuticals 9.30

- Assessing differences in US and European markets
- · Understanding the nuances in European market to appreciate what investors are looking for
- Hearing directly from investors about their priorities to secure new funding

#### **Moderated By:**



John Babich Chief Scientific Officer **Ratio Therapeutics** 







**Jarrod Longcor** Chief Operating Officer **Cellectar Biosciences** 



10.30 Morning Break & Poster Session

Take this opportunity to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships whilst exploring the latest radioligand therapy



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**Discovery & Preclinical Track** 

Chair: John Babich, Chief Scientific Officer, Ratio Therapeutics OR

Translational & Clinical Development Track
Chair: Shaemus Gleason, Executive Vice President, Clarity
Pharmaceuticals

CMC & Sourcing Track

Peptides, Antibodies, Microspheres & More: Targeting Molecule Selection Strategies

Establishing Relationships to Optimise Industry Collaborations & Work Alongside Clinicians for Clinical Trials & Widespread Administration of TRPs

Understanding Quality Control Differences for TRPs: Regulatory Expectations & CMC Method Requirements

# 11.30 Introducing a Tumour Agnostic Pre-Targeted Radiotherapeutic Platform to Target Tumour Associated Macrophages

- Pretargeting to increase therapeutic windows in RLTs
- OncoOne's Pretarg-it® platform
- Data from preclinical tumor models and outlook

Michael Thiele, Chief Scientific Officer, OncoOne

### 11.30 Bridging Clinical & Industry Priorities for TRP Trial Success

- Identifying the right clinical partners: who to approach
- Navigating variability across institutions in TRP trial experience and infrastructure
- Aligning timelines, expectations, and communication between sponsors and sites

Arthur Braat, Associate Professor, UMC Utrecht

# 11.30 Strategic Insight into Regional Regulatory Variability Impacting Biopharmaceutical Manufacturing & Supply Chain Operations in Europe & the US

- Differentiating kit for radiopharmaceutical preparation from ready to use solutions for injection/infusion
- Overview of guidelines to be followed for dossier preparation
- Control strategy, where to start? Control of chemical and radioactive precursors
- Building up the information/data for submission from clinical to commercial stages

**Nicoletta Fabiano**, RLT Analytical Development Team Head, **Novartis** 

## 12.00 Targeting ALDH1A1 for the Identification & Treatment of Therapy Resistant Cancers

- Targeting the cancer stem cell marker AzLDH1A1
- Identifying refractory disease with our first-in-class theranostic, [18F]NTx-10
- Treating therapy-resistant non-small cell lung cancer with [131I] NTx-11

Tim Witney, Chief Scientific Officer, Nuclide Therapeutics

## 12.00 Roundtable Discussion: Creating an Ecosystem for Widespread TRP Adoption Across Regions

- Showcasing successful national TRP rollouts (e.g., Belgium) to guide broader uptake
- Understanding the role of government buy-in, reimbursement pathways, and commissioning
- Scaling physical infrastructure and staffing to meet growing therapeutic demand

Shaemus Gleason, Executive Vice President, Clarity Pharmaceuticals

# 12.00 Mastermind Session: Advancing Release Testing & CMC Methodologies for Radioconjugates Integrating HPLC, Gamma Spectrometry, & Isotope Supply Constraints

- Developing rapid radioHPLC and gamma-spectrometry protocols to monitor- radiochemical purity and metal impurities
- Adapting release workflows to address hot verus cold material differences and short isotope h-alf-lives
- Defining critical quality attributes and phase III CMC expectations based on binder and isotope-specific characteristics

12.30 Lunch

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Targeting Moiety Engineering: Gaining
Competitive Differentiation Through Optimised
Molecular Design

## 1.30 Internalisation of Targeted Radiopharmaceuticals: Strategic Imperative or Situational Choice?

- DARPin optimizations to achieve an RLT suitable profile via iterative design - test cycles
- Integrating of these insights for optimized lead selection of the next programs
- How this differs from standard RLT vector development and allows to optimize timelines, costs, resources

Julien Torque, Chief Scientific Officer, OranoMed

## 2.00 Exploring Peptide Engineering for Improved Activity & Survival Alongside Radioisotopes

- Engineering peptides to improve tissue penetration and receptor binding, thereby increasing tumour uptake and retention of radioisotopes
- Modifying peptide stability and clearance rates to extend half-life and reduce systemic toxicity, enhancing therapeutic efficacy.
- Designing peptides to deliver radioisotopes directly to tumour sites, maximising localised radiation delivery and minimising damage to healthy tissues

Abbas Sahili, Chief Executive Officer, Singzyme

## 2.30 Targeted Delivery of Radioisotopes to Solid Tumours Using Bicyclic Radionuclide Conjugates Directed at Novel Tumor-Associated Antigens

- Explaining how screening platforms can identify novel peptide binders to challenging targets and optimise them into highaffinity, selective molecules
- Highlighting the creation of targeted radionuclide conjugates aimed at MT1-MMP and EphA2 for precision therapy
- Presenting preclinical findings on proteins widely expressed across cancers with significant unmet clinical needs

Sandra Uhlenbroich, Director, Discovery Bicycle Therapeutics

## 1.30 Building a Skilled Workforce: Training & Education for TRP Therapy Delivery

- Addressing the diagnostic-heavy focus of nuclear medicine training programs
- Advocating for post-residency fellowships in therapeutic radiopharmaceuticals
- Supporting initiatives like INSPIRE and EARL to elevate competence and consistency across Europe

Stuart More, Head of Department, Nuclear Medicine, University of Cape Town

Determining Dose Scheduling & Dose Selection: Cost Effective Research to Maximise Treatment Efficacy

### 2.00 Monoclonal Antibodies: New Opportunities & Translational Dilemmas

- Optimising biodistribution by target selection and engineering
- Reducing off-target toxicity to improve tolerability
- Selecting the right non-clinical models to demonstrate efficacy and estimate dosimetry

Levente Meszaros, Head, Clinical Operations & Programs, RadioPharm Theranostics

# Logistical Expectations for Isotope Transport: Approaches to Ensure More Manageable & Scalable Manufacturing

## 1.30 Enabling Clinical Translation of Astatine-211 Therapies: Overcoming CMC & Supply Chain Hurdles

- Overview of Astatine-211's therapeutic potential in targeted alpha therapy
- Key CMC and supply chain hurdles in clinical-stage development
- Practical strategies to enable scalable, compliant manufacturing

Yusuke Kohno, Head, Supply Chain Development, Alpha Fusion

# 2.00 Roundtable Discussion: Decentralised VS Centralised Manufacturing: Isotope Dependent Decisions to Ensure Appropriate Manufacturing Strategy

- Weighing the trade-offs between centralised production hubs for quality control and the logistical challenge of rapid, decentralised distribution to a wider patient base
- Considering how short half-life isotopes like lead-212 drive the need for localised production and affect the balance between decentralisation and centralised control
- Reducing shipping costs, minimising decay-related losses, and enhancing product stability by limiting exposure to radiolysis in decentralised manufacturing models

Oystein Soug, Chief Executive Officer, OncoOne

## **2.30** Comparing Dose Escalation Versus Dose Accumulation Strategies in Radiopharmaceutical Therapy

- Exploring the benefits and trade-offs of escalating dose levels versus repeated fixed dosing cycles
- Assessing cumulative toxicity risks and therapeutic thresholds in long-half-life isotopes
- Integrating dosimetry data to guide selection of the most effective and tolerable approach

Harshad Kulkarni, Chief Medical Advisor, BAMF Health

## **2.30** From Reactor to Patient: Building Agile Supply Chains for Radiotherapeutics

- Dynamic routing strategies optimized for half-life variability
- Hub and spoke manufacturing network to ensure scale and zero missed patient doses
- Regulatory Industry potential collaborations to harmonize transport protocols and potentially accelerate access to treatments

Jarrod Longcor, Chief Operating Officer, Cellectar Biosciences

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3.00 Afternoon Break

### **Driving TRP Innovation: Broadening Target Landscapes & Advancing Clinical Applications**

Oystein Soug
Chief Executive Officer
Oncolnvent

3.30 Assessing Future Directions for Addressing Unmet Medical Need by Expanding Indications & Selecting Novel Targets

- Identifying existing targets to be adapted to radiopharmaceuticals
- Exploring areas of unmet need and market potential
- Uncovering market predictions for novel tumour applications and expansion



4.00 Expanding TRP Therapy into Neuroendocrine Tumours: Targeting SSTR2 with 212Pb

- Discussing Orano Med's unique approach to TAT with <sup>212</sup>Pb
- Presenting the latest updates on <sup>212</sup>Pb-DOTAMTATE
- Exploring Orano Med's portfolio of <sup>212</sup>Pb-based TATs



4.30 Chairs Closing Remarks

4.40 End of Scientific Programme Day Two

I enjoyed the content and mixture of talks / attendees from different fields of radiopharmaceuticals. The panel discussions were very valuable and interesting

**Bicycle Therapeutics** 

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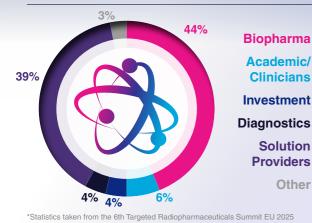
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**Mehmet Gul** Senior Partnership Director -TRP Tel: +1 617 455 4188 Email: sponsor@hansonwade.

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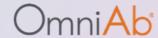


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