

Workshop agenda

Translating radiotheranostic cancer research into clinical pratice in Europe JRC Ispra 27 April 2023

> Joint Research Centre

Location: Auditorium, Building 58C

08:30-09:30 Registration & coffee

09:30-10:05 Welcome and Introduction

EU Commissioner Mariya Gabriel JRC DDG Bernard Magenhann Representative of Swedish Presidency (t.b.c.) Group photo

- 10:05-12:35 Session 1 Radiotheranostics: radionuclide-based therapy and companion diagnostics (Chair: Uwe Holzwarth)
- 10:05-10:35 Principles of and clinical experiences with peptide receptor radiotherapy (PRRT) of neuroendocrine tumours and radioligand therapy (RLT) of advanced prostate cancer (Richard P. Baum; Curanosticum Wiesbaden-Frankfurt)
- 10:35-11:05 Results of <sup>177</sup>Lu-PSMA-617 phase II prospective trial IRST-185 and role of androgen receptor amplification in PSMA-RLT (Giovanni Paganelli; IRST-IRCCS, Istituto Romagnolo Studio Tumori "Dino Amadori" )
- 11:05-11:20 mCRPC patients receiving <sup>225</sup>Ac-PSMA-617 therapy in the post-androgen deprivation therapy setting (Alfred Morgenstern; JRC, Directorate Nuclear Safety and Security, Karlsruhe)
- 11:20-11:35 Coffee
- 11:35-12:05 The role of Centers of Excellence and multidisciplinary tumor boards for quality treatment of NET (Marianne Pavel; University Hospital Erlangen, Friedrich-Alexander University Erlangen-Nürnberg, Erlangen, Germany)
- 12:05-12:35 Radioligand therapy of metastatic prostate cancer– the oncologists view (Silke Gillessen; Oncology Institute of Southern Switzerland, Department of Medical Oncology, Bellinzona)
- 12:35-13:15 Session 2 The cancer patients' view (Chair: Alfred Morgenstern)

Erik Briers (Europa Uomo), Anna Nilsson (care giver), Luciano Licciardello and Barbara Picutti (Associazione Pazienti con Tumori Neuroendocrini)

13:15-14:30 Buffet Lunch and lunch discussions

14:30-15:30 Session 3 - Radiotheranostics: innovations and challenges (Chair: Alfred Morgenstern)

- 14:30-15:00 Exploiting radiobiological effects of targeted radionuclide therapy (Jean-Pierre Pouget; Institut de Recherche Cancerologie de Montpellier, Universite de Montpellier)
- 15:00-15:30 New developments and challenges facing clinical translation of radiotheranostics (Ken Herrmann; Department of Nuclear Medicine, University of Duisburg-Essen, Duisburg)
- 15:30 Coffee available

## 15:30-17:15 Session 4 – Translating radiotheranostics into clinical practice

Moderated by: Margarida Goulart (JRC) and Uwe Holzwarth (JRC)

Panelists: Odile Jaume (ICPO), Heinz-Peter Schlemmer (EACS), Stefano Fanti (University of Bologna), Konrade von Bremen (Nuclear Medicine Europe), Ulla Engelmann (JRC)

Topics for discussion:

- 15:30-16:15 Identification of critical factors, potential roadblocks and the relevant stakeholders
- 16:15-17:15 How to tackle roadblocks
- 17:15-17:25 Wrap-up & recommendations
- 17:25-17:30 Concluding remarks
- 17:45 Transport to the hotel or airport

### Background

This workshop is the first of a series of workshops with stakeholders from academia, industry, policy makers in research and health, to clinical end users, trying to understand and identify the challenges and roadblocks in the translation of nuclear medical research into clinical practice. In view of recent progress leading to the approval of new radiopharmaceuticals for cancer treatment which hold the promise of improved outcomes and better quality of life, this workshop starts with the cancer patient and his treatment as the final recipient of all these efforts. The access to such therapies by cancer patients will essentially define the demand for such therapies in future and, hence, the type and quantity of radionuclides, the required number of qualified personnel, as well as equipment and facilities, which must be provided in a sustainable manner. All this will require innovations, technical solutions, and specialised staff with various medical, nuclear, technical, and scientific profiles able to realise them.

EU Commissioner Mariya Gabriel has chaired a High-level European Nuclear Round Table on 13 February 2023, which focused on medical applications of nuclear technologies and access to nuclear research infrastructures. The round table aimed at launching concrete initiatives, in the remit of the research programmes, to explore the challenges that hinder the translation of technological advances into adequate and equal access to radionuclide procedures for European patients.

In this context, the JRC is organising this workshop looking into the current practice and research on precision oncology starting with the state of the art of radiopharmaceutical cancer therapy in clinical practice [3]. Radiopharmaceutical cancer therapy has made appreciable progress over the last years leading to the approval of <sup>177</sup>Lu-Lutathera<sup>TM</sup> (<sup>177</sup>Lu-DOTATATE) by EMA and FDA for the treatment of neuroendocrine tumours [1] and, more recently, of Pluvicto<sup>TM</sup> (<sup>177</sup>Lu-PSMA-617) for the treatment of metastatic castration resistant prostate cancer [2]. Many more compounds are in clinical trials and in process of approval [3]. In the approval process, these radiopharmaceuticals have shown the potential to improve progression-free and overall survival of patient groups with so far poor prognosis, and most importantly improve patients' quality of life as such therapies are usually well tolerated and serious adverse effects are rare [4].

For these approved radiotherapeutics, <sup>68</sup>Gallium-labelled diagnostics compounds are available using exactly the same tumour targeting molecule. These allow visualising and even quantifying the density of receptors and binding sites by positron emission tomography (PET/CT) [5]. Thus, diagnostics, patient selection and therapy can directly be linked, which makes this *radiotheranostic* approach a truly personalized method of precision oncology as the patients are treated based on the molecular profile of their cancer. Despite this progress, it is still a challenge to ensure equal access to such new therapies to all European cancer patients, which would be medically eligible [6-8].

Several EU initiatives including Europe's Beating Cancer Plan, the Cancer Mission and related nuclear research under the Euratom programme reflect a political commitment to mobilise the collective power of the EU to enable research and innovation in health, patients' access to cancer knowledge, and the latest state of the art technologies for diagnosis and cancer treatment to improve the quality of life of cancer patients and survivors.

#### References

[1] Strosberg J, El-Haddad G, Wolin E, Hendifar A, Yao J, Chasen B, Mittra E, Kunz PL, Kulke MH, Jacene H, Bushnell D, O'Dorisio TM, Baum RP, Kulkarni HR, Caplin M, Lebtahi R, Hobday T, Delpassand E, Van Cutsem E, Benson A, Srirajaskanthan R, Pavel M, Mora J, Berlin J, Grande E, Reed N, Seregni E, Öberg K, Lopera Sierra M, Santoro P, Thevenet T, Erion JL, Ruszniewski P, Kwekkeboom D, Krenning E. **NETTER-1 Trial Investigators. Phase 3 Trial of <sup>177</sup>Lu-Dotatate for Midgut Neuroendocrine Tumors**. *N Engl J Med.* **376** (2017) 125-135.

- Sartor O, de Bono J, Chi KN, Fizazi K, Herrmann K, Rahbar K, Tagawa ST, Nordquist LT, Vaishampayan N, El-Haddad G, Park CH, Beer TM, Armour A, Pérez-Contreras WJ, DeSilvio M, Kpamegan E, Gericke G, Messmann RA, Morris MJ, Krause BJ; VISION Investigators. Lutetium-177-PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 385 (2021)1091-1103.
- [3] Herrmann K, Schwaiger M, Lewis JS, Solomon SB, McNeil BJ, Baumann M, Gambhir SS, Hricak H, Weissleder R. Radiotheranostics: a roadmap for future development. Lancet Oncol 21 (2020) e146e156
- [4] Chantadisai M, Kulkarni HR, Baum RP. Therapy-related myeloid neoplasm after peptide receptor radionuclide therapy (PRRT) in 1631 patients from our 20 years of experiences: prognostic parameters and overall survival. Eur J Nucl Med Mol Imaging 48 (2021)1390-1398
- Baum RP (Handbook Editor). Therapeutic Nuclear Medicine. Springer-Verlag Berlin Heidelberg 2014.
  eBook ISBN: 978-3-540-36719-2; Hardcover ISBN: 978-3-540-36718-5
- [6] Ambrosini V, Kunikowska J, Baudin E, Bodei L, Bouvier C, Capdevila J, Cremonesi M, de Herder WW, Dromain C, Falconi M, Fani M, Fanti S, Hicks RJ, Kabasakal L, Kaltsas G, Lewington V, Minozzi S, Cinquini M, Öberg K, Oyen WJG, O'Toole D, Pavel M, Ruszniewski P, Scarpa A, Strosberg J, Sundin A, Taïeb D, Virgolini I, Wild D, Herrmann K, Yao J. Consensus on molecular imaging and theranostics in neuroendocrine neoplasms. European Journal of Cancer 146 (2021) 56-73
- [7] Kratochwil C, Fendler WP, Eiber M, Baum RP, Bozkurt MF, Czernin J, Delgado Bolton RC, Ezziddin S, Forrer F, Hicks RJ, Hope TA, Kabasakal L, Konijnenberg M, Kopka K, Lassmann M, Mottaghy FM, Oyen W, Rahbar K, Schöder H, Virgolini I, Wester HJ, Bodei L, Fanti S, Haberkorn U, Herrmann K. EANM procedure guidelines for radionuclide therapy with <sup>177</sup>Lu-labelled PSMA-ligands (<sup>177</sup>Lu-PSMA-RLT). Eur J Nucl Med Mol Imaging 46 (2019) 2536-2544.
- [8] Herrmann K, Giovanella L, Santos A, Gear J, Kiratli PO, Kurth J, Denis-Bacelar AM, Hustinx R, Patt M, Wahl RL, Paez D, Giammarile F, Jadvar H, Pandit-Taskar N, Ghesani M, Kunikowska J. Joint EANM, SNMMI and IAEA enabling guide: how to set up a theranostics centre. Eur J Nucl Med Mol Imaging 49 (2022) 2300–2309

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