

Integrating Radioligand Therapies in European Policies: Launch of the Stakeholder Alliance for Radioligand Cancer Therapies

28 October 2020 – 14:00-15:30

Meeting report



About SPARC-Europe

SPARC-Europe (Stakeholder Political Alliance for Radioligand Cancer Therapies) is a European political initiative aiming to build a comprehensive policy framework for radioligand therapies. The mission of the group is to provide expert knowledge and the necessary guidance for policymakers to support them in the creation of clear pathway to institutionalise radioligand therapies and increase its accessibility for patients.

The overarching objective of the group is to work together with its Patron policymakers towards accommodating European innovation and changing the outcomes for cancer patients. By profiling the topic of radioligand therapies and providing expertise and patient voice, the Alliance has been engaging with relevant European policymakers to overcome existing barriers in access to radioligand therapies.

The Alliance is built under the patronage of two Members of the European Parliament Ms. Tanja Fajon (S&D, Slovenia) and Mr. Brando Benifei (S&D, Italy). Under the MEP patronage, SPARC-Europe will engage with the European Commission and other policymakers in discussions about the implementation of the Europe's Beating Cancer, the Pharmaceutical Strategy, as well as Horizon Europe. Similar activities will be undertaken as regards a dialogue with the Joint Research Centre on the Strategic agenda for medical, industrial and research applications of nuclear and radiation technology (SAMIRA).

SPARC-Europe is composed of experts in the field of nuclear medicine and oncology, as well as patient representatives. Its Steering Committee consists of seven members and is strongly supported by the MEP Patrons.

Steering Committee Members:

Catherine Bouvier (INCA), Martyn Caplin (Royal Free Hospital), André Deschamps (Europa Uomo), Nicola Fazio (European Institute of Oncology), Ken Herrmann (University Hospital Essen), Luka Ležaić (University of Ljubljana), Dermot O'Toole (Trinity College Dublin).

Observers to the Alliance: *Josep Maria Borrás (Catalonia Cancer Strategy)*

MEP Patrons: *Tanja Fajon (S&D, SL), Brando Benifei (S&D, IT)*

Secretariat to the Alliance: *RPP (Yordan Aleksandrov, Kinga Wójtowicz)*

Funding partners: *Advanced Accelerator Applications*



I. Launch event: Executive Summary

On 28 October the Stakeholder Political Alliance for Radioligand Cancer Therapies (SPARC-Europe) was officially launched. The launch of this Alliance, which aims to be instrumental in maximising the power of the EU in working towards achieving optimal cancer care, brought together policymakers, experts in the field of nuclear medicines and oncology and patient representatives. The discussions, which were moderated by Brian Maguire, elaborated on challenges that prevent radioligand therapies from being accessible to patients, and how to overcome these in the context of ongoing debates on EU policies, namely the Beating Cancer Plan, Pharmaceutical Strategy, SAMIRA Action Plan, Horizon Europe programme.

The obstacles facing radioligand therapies' accessibility and availability are many. From discrepancies and inequalities in terms of hospital infrastructure between regions and between European Union Member States, to the lack of education and training standards throughout Europe.

II. Welcoming Remarks



MEP Tanja Fajon

Member of the European Parliament **Tanja Fajon** (S&D, SL) opened the event by presenting how the Alliance was created. She thanked all experts and patient representatives for having responded positively to her call to establish a platform dedicated to radioligand therapies. A platform, which is needed to improve patient outcomes.

Ms Fajon elaborated on the importance of the European Commission's policy initiatives for the cancer community and for nuclear medicine, namely the [Beating Cancer Plan](#), the new [Pharmaceutical Strategy](#) as well as the Strategic agenda for medical, industrial and research applications of nuclear and radiation technology ([SAMIRA](#))¹. She highlighted that the expertise of the Alliance, composed of patients and experts in the field of nuclear medicines and oncology, would be crucial for policymakers to bridge the gaps between the delivery of radioligand therapies and patients.

Brando Benifei MEP (S&D, IT), who was unable to join the meeting live, delivered his address through a recorded video statement. Mr Benifei spoke about the challenges of radioligand therapies, on which SPARC-Europe is focusing on, ranging from infrastructure availability to hospital preparedness. He also expressed his belief that these can be tackled through multiple funding files of the Multiannual Financial Framework, including the [European Social Fund Plus](#), to which he is the rapporteur, as well as the EU4Health Programme.



MEP Brando Benifei

As cancer is the leading cause of mortality in the EU, Mr. Benifei informed the audience about the recent efforts of the European Parliament to enhance European cancer care. He spoke about the creation of the Special Committee on Beating Cancer and called for SPARC-Europe to collaborate closely with its Members.

III. Radioligand therapies barriers and how to address them

The first panel saw a discussion amongst the SPARC-Europe Steering Committee Members, who explained to attendees what radioligand therapies are, elaborated on the hope they offer to cancer patients as well as on what needs to be done to increase the accessibility of this new cancer paradigm to patients.



Prof. Martyn Caplin, Royal Free Hospital

Prof. Martyn Caplin presented how radioligand therapy (RLT) works. He highlighted the importance of the meeting by explaining that RLTs, established currently for neuroendocrine tumours (NETs) and prostate cancer, have the potential to be applied to other cancers. As ongoing research studies explore how this treatment may apply to advanced stages of breast, kidney, colon and pancreatic cancer, prof. Caplin stressed the need for European healthcare systems to be ready to accommodate these treatments.

Prof. Caplin also spoke about the role of the EU in improving patient outcomes, in particular through the European Reference Networks (ERNs). Thanks to the platforms of the multidisciplinary tumor board (MTDs) within ERNs, patients across Europe can benefit from the latest available knowledge and treatments.

¹ SAMIRA initiative seeks to identify cross-cutting actions that the European Commission can take in collaboration with stakeholders to maximise the societal benefits of nuclear and radiation technologies, whilst maintaining the highest achievable level of quality and safety.

Prof. Caplin presented the SPARC-Europe's composition and informed about the Alliance's commitment to providing a clear understanding about RTLs benefits for patients, namely the improved duration of response compared to other forms of therapies and the quality of life (QoL) improvement.

As it is crucial to create political awareness, the audience was informed that SPARC-Europe is working on a high-level position on radioligand therapies, to highlight the barriers and provide specific recommendations on how to overcome them in the context of the European policies. The position, politically supported by MEP Patrons, will be further discussed with the European Commission. The end goal would be for policymakers to become aware of the challenges and to support them in the development of cancer care pathways.

Dr. Nicola Fazio, Director of the Division of Gastrointestinal Medical Oncology and NETs and Director of Program in Digestive and NETs at the European Institute of Oncology, discussed the role of MTDs in optimising radioligand therapies for NET patients. He outlined their crucial importance in providing the right treatment to the right patient, at the right time. Yet, to improve the outcomes of NET patients it is crucial for the multidisciplinary teams to be NET dedicated and receive continuous training on the most recent developments available. Further to that, more centers of excellence certified by the European Neuroendocrine Tumor Society (ENETS) should exist across the EU.



Dr. Nicola Fazio, European Institute of Oncology

Dr. Fazio emphasised the importance of education as well as of interaction between various specialists to improve patient outcomes. This interaction should be encouraged not only within MTD setting, but also between various referral centers. From the European perspective, the EU can contribute to strengthening the collaboration thanks to an excellent structure for cross-border knowledge sharing, while European medical societies can collaborate to build homogeneous guidance and guidelines. Dr. Fazio finally called for all interested stakeholders that are willing to join the Alliance to contact SPARC-Europe Secretariat.

To address these issues, SPARC-Europe will focus on the implementation of European policies, on addressing barriers to radioligand therapies and on interactions with medical societies. The activities of the groups will be aligned with European developments in the field of ERNs (their evaluation) as well as with the European Commission's 2021 programme.



Catherine Bouvier, President, INCA

Ms. Catherine Bouvier, President of International Neuroendocrine Cancer Alliance (INCA), explained the complexity of NETs. By bringing patient perspective into the discussion, Ms Bouvier spoke about the [INCA survey](#) on challenges in access to diagnostics and treatment for NET patients. The assessment identified unmet needs across education, access to the latest diagnostic, essential services, and access to proper multidisciplinary care. It showcased the need to focus on improving knowledge and expertise amongst all healthcare professionals and patients as well as to create at least one NET center of excellence per

country. She further noted that the Commission's Beating Cancer Plan has the potential to support at least one center of the 27 Members of the EU and to require primary healthcare professionals to possess clinical knowledge to strengthen the primary diagnosis.

The lack of awareness, specialties and inequality of expertise, as well as the lack of importance attached to the NET community are the main barriers presented to RLT access. An additional barrier outlined was that due to access inequalities, balance in informing about new treatments must be ensured.

Speaking about SPARC-Europe 2021 workplan, Ms. Bouvier outlined that the Steering Committee will ensure that activities will be structured in a way to ensure that access barriers are addressed without duplicating the efforts of other organisations. The Alliance will be working with the policymakers to continue profiling the RLT topic, supporting policymakers and ensuring unified guidance on RLTs.

Mr André Deschamps, Chairman, Europa Uomo, provided information about metastatic-castration resistant prostate cancer (mCRPC), which is a form of advanced prostate cancer. He pointed out that in the field of prostate cancer, 50% of diagnosed cases are already in the metastatic case and explained that limited options are available once cancer becomes castration-resistant. A [study of prostate cancer treatment on quality of life](#) by Europa Uomo showed that other treatments have a negative effect on all areas of health-related QoL, including increased fatigue, pain and insomnia.

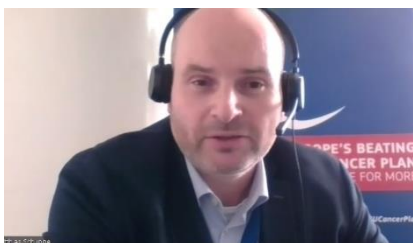


André Deschamps, Chairman, Europa Uomo

Speaking about hospital readiness and radioligand therapies, Mr Deschamps outlined significant inequalities across Europe and called on the European Commission to ensure that these inequalities, in particular hospital readiness and MTD from the radioligand therapy point of view, will be investigated. As RLTs represent potential not only to other forms of prostate cancer, but also to different states of the disease, research and innovation in this area should be enhanced to improve the QoL of cancer patients.

IV. Political panel discussion: Synergies between EU policies

The political panel discussion featured the representative of the European Commission, Mr Matthias Schuppe (Team Cancer Leader, DG SANTE), Dr. Said Abousahl from the Joint Research Center (JRC), as well as MEP Tanja Fajon (S&D, SL).



Matthias Schuppe, DG SANTE

Mr Matthias Schuppe ensured the participants that despite the ongoing pandemic, cancer remains the priority of the Commission, with no delays foreseen as to the adoption and implementation of the Beating Cancer Plan. He also underlined that the Commission considers a holistic approach in its development. The Plan, which is to be adopted on 9 December, will cover the entire disease pathway. Speaking about its implementation, the Commission representative underlined the relevance of stakeholder consultation. The consultation mechanisms will run alongside the implementation of the plan and will focus on different actions

that will be consulted with a variety of stakeholders.

Mr Schuppe further addressed how European hospital infrastructure is planned to be strengthened by listing a variety of funding mechanisms of the EU. These include the EU4Health programme, the European Regional Development Fund (ERDF) and Cohesion Fund, and Structural Reform Support Programme (SRSP). New programmes foreseen as part of the Recovery Plan will also provide the possibility for Member States to invest in hospital infrastructure.

Dr. Said Abousahl informed the audience about the Strategic Agenda for Medical Ionising Radiation Applications of Nuclear and Radiation Technology (SAMIRA initiative), which will cover a variety of elements of RLT relevance. The initiative, planned to be adopted by the end of 2020, will feed into the Commission's Beating Cancer Plan.



Dr. Said Abousahl

Dr. Abousahl elaborated on synergies between the two files. He expressed his content about the fact that great progress has been made in recent years as to the collaboration between the Commission services DG SANTE, DG RTD, DG ENER and the JRC as for the first time the Euratom Research and Training and the Commission's Horizon Europe programmes include references to each other. These synergies bring together the Commission's programmes in the field of research, health and radioisotopes. However, **Dr. Abousahl pointed out that similar collaboration is also crucial at the policy level, in particular in the field of clinical trials and radiation protection and safety policies.**

The SAMIRA Action Plan will be based on three pillars: supply chain of radioisotopes, quality and safety of medical application and innovation in the medical application of radioisotopes and radiopharmaceuticals. **Specific synergies as to the last pillar were outlined, in particular with the Beating Cancer Plan and the Health Cluster of Horizon Europe.**

Dr. Abousahl also informed about the role of JRC in the implementation of the Cancer Plan. He outlined that the JRC has dedicated nuclear European infrastructure, open for all European scientists. When speaking about the infrastructure needed to carry out R&I activities in the field of nuclear medicine, he pointed out that it involves infrastructure adapted to the safety and security guidelines, as well as waste management policies. As regards challenged related to nuclear waste management, the JRC will also investigate the matter.

Further to that, Dr. Abousahl is positive that the Euratom research and training programme will support research activities related to cancer and radioligand therapies in particular. The newly created Cancer Knowledge Centre will support the implementation of the Beating Cancer Plan as well as European guidelines on cancer.



MEP Tanja Fajon

Ms Fajon stated that in recent years she has been actively involved in discussions on cancer, as an MEP and as a cancer patient herself. As she belongs to the group of rare cancer patients, for years she has been engaging in many platforms and advocating for novel treatments to be available to European patients across Europe. For this reason, she made a call to the experts and patients from the field of radioligand therapies, as she believes this treatment offers a new window of opportunities for cancer patients.

MEP Fajon voiced the readiness of the European Parliament in fighting cancer through the establishment of the Special Committee on Cancer, Challenge Cancer Intergroup as well as through the MEP Against Cancer Group (MAC Group), of which she is a member. With this, she emphasised that cancer remains their top priority despite the ongoing pandemic and called for more investment to be done in education and hospital infrastructure to ensure patients have access to radioligand therapies.

When speaking about the achievements and next steps for SPARC-Europe, the participants were informed about the engagement with the European Commission through public consultations. MEP Fajon highlighted the need for policymakers to be provided with specific recommendations to be brought forward by the parliamentarians and stressed her content that the Steering Committee will present them by the end of the year in a form of a position paper on radioligand therapies. To agree on the 2021 workplan, SPARC-Europe will hold another teleconference to be ready to start its implementation alongside the Beating Cancer Plan and the Pharmaceutical Strategy.

V. Q&A Session

Christian Davis, from Telix Pharmaceuticals, asked whether funding can also be considered a barrier to RLTs acceptance. Prof. Caplin replied that education represents a stronger barrier than funding and it remains for the Steering Committee to make a business case to say that although it seems expensive, its benefits are significant in terms of tumour reduction and QoL.

Ms. Bouvier stated that more data is needed to understand the patient perspective and their experience in order to enhance the evidence about the improvement of QoL when treated with radioligand therapies. Mr. Deschamps pointed out the economic value of QoL stressing that in most cases evidence measures are considered as a secondary end mode, not the primary mode. The question how to measure and value QoL should be addressed.

Dr. Fazio added that to overcome heterogeneity in the educational context, networks among different scientific societies as well as training and education activities should be set up in different geographical contexts.

To the questions of Ms. Annette Stolz, AAA, on how to ensure that European authorities for radioprotection and healthcare are collaborating on this topic, prof. Caplin responded by pointing out the need for a clear understanding of the specificities of radioligand therapies first. He stated that there has always been a distance between doctors and politicians, scientists and hospital managers as well as authorities working in different fields. He pointed out that SPARC-Europe was created to bridge these gaps and, thanks to patient advocates within, it will aim to improve the chain of information on radioligand therapies amongst policymakers as well.

Answering a question of Vivienne Becket on challenges in informing patients about radioligand therapies, Ms. Bouvier stated that the barrier is not just as to communicating about radioligand therapies per se, but about the need for patients to receive best care possible. When it comes to patients, a holistic approach should be considered which includes psychological care. Mr Deschamps added that to communicate about radioligand therapies, they need to be available to all.

Prof. Caplin pointed out that the pharmaceutical industry should not be left out of the conversation, as they have a significant role to play in improving the education process. This can be done by providing education and training grants or earmarking specific budgets to improve education across Europe.

In final remarks, panellist provided key takeaways: Prof. Caplin appreciated seeing cancer on the political agenda and stressed the need to improve patients' QoL. Taking radioligand therapy as an example, he underlined the importance of the treatment being provided equally to all and in a timely manner. While Mr. Deschamps one more time highlighted QoL and equal access to MTDs and cancer centres, Dr. Fazio voiced the need to improve the link between financial and education policies.

VI. Closing remarks

MEP Tanja Fajon thanked the speakers and the audience for their engagement and invited all interested stakeholder to contact SPARC-Europe Secretariat should they be interested in joining the Alliance.

If you are interested in learning more about SPARC-Europe or you would like to join the Alliance, please contact the Secretariat

secretariat@sparc-europe.com