

## PP23

### USE OF GALLIUM-68 TRACERS AND THERANOSTIC POINT OF VIEW (LU-177 COMPOUNDS) IN CLINICAL SETTINGS IN THE UNITED STATES (U.S.) AND THE EUROPE UNION (EU) FOR FUTURE PERSONALIZED MEDICINE: AN OVERVIEW, REGULATIONS, IMAGING FEATURES AND FUTURE PROSPECTIVE

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**Introduction:** Ga-68 labeled peptides have been identified as potential class of radiopharmaceuticals displaying fast target localization and blood clearance. However, there is not an authorized commercial kit yet.

**Methods:** This poster will: (a) examine the use of Ga-68 in clinical settings in the U. S. and EU, (b) compare the U. S. and EU regulations for Ga-68 radiopharmaceuticals, and (c) focus on Theranostic applications.

**Results:** We have reviewed multiple factors, including:

#### 1. **Infrastructure in clinical practices using Ge-68/Ga-68 generators**

Several generators are available from Obninsk, Cyclotron Co, Eckert & Ziegler, IGG100, and ITG Isotope Technologies. The generators are eluted with acid offering Ga-68 in cationic form. The techniques for purification and concentration could follow the Good Manufacturing Practices guidelines.

#### 2. **Clinical applications of Ga-68 radiopharmaceuticals**

Since 2000, there has been increasing applications of Ga-68-radiopharmaceutical for imaging. The success of utilizing Ga-68-DOTA-octreotides facilitated the entrance for the imaging of gastro-entero-pancreatic neuroendocrine tumours (GEP-NETs).

#### 3. **Regulations from U. S. Food and Drug Administration (FDA) and European Medicine Agency (EMA)**

The Ge-68/Ga-68 generator cannot be submitted as New Drug Application in FDA. A Drug Master File (DMF) is pathway and should contain: Source of the Ge-68, composition, production method, and quality control methodology.

Eckert & Ziegler Radio pharma received approval from the Federal Institute for Drugs and Medical Devices for Ge-68/Ga-68 generator for the German market on 2014. In addition, EMA has approved in 2015, and orphan designation (EU/3/15/1450) for Gallium-68-edotreotide for GEP-NETs.

With respect of Lu-177, EMA has authorized the use of Lumark (Lutetium Lu-177 chloride) for either kill cancer cells or to obtain images on 2015.

#### 4. **Future perspectives of new radiopharmaceuticals such as Ga-68 PSMA and Lu-177-PSMA**

Prostate specific membrane antigen (PSMA) is strongly expressed on prostate cancer cells. Consequently, PSMA is a promising target for the prostate cancer imaging and therapy. There has been some studies reporting <sup>68</sup>Ga-PSMA and <sup>177</sup>Lu-PSMA-617 is used as prostate cancer diagnosis and therapy, respectively, with good results.

**Conclusions:** This poster will highlight the importance of Ga-68 and Lu-177 radiopharmaceuticals. Our group is focusing on a theranostic approach which could provide an efficacious targeted radionuclide therapy.

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