



ICNAS/University of Coimbra granted with first EU marketing authorization for the distribution of cyclotron produced Gallium-68

The Institute of Nuclear Sciences Applied to Health (ICNAS) from the University of Coimbra (UC) and IBA announce the granting of the first EU marketing authorization for the distribution of cyclotron-produced Gallium-68 using a liquid target for human use

Coimbra, Portugal, 28 September 2021 – ICNAS/UC, leading institution in molecular probe development and molecular imaging and IBA (Ion Beam Applications S.A., EURONEXT), the world's leading provider of solutions for the diagnosis and treatment of cancer, today announce that the Portuguese regulatory agency (INFARMED), has granted the first EU marketing authorization to distribute [⁶⁸Ga]GaCl₃ with a new process for producing gallium-68 with an IBA cyclotron using a liquid target.

⁶⁸Ga has played an outstanding role in clinical research worldwide, particularly in routine clinical studies for oncological applications with Positron Emission Tomography (PET), during the last 10 years. In particular, ⁶⁸Ga is very well suited as a diagnostic isotope for pairing with therapeutic radiometal isotopes (ex: ¹⁷⁷Lu and ²²⁵Ac). The growth of ⁶⁸Ga in routine clinical applications is mainly due to the [⁶⁸Ga]Ga-PSMA-11 for PET imaging of the prostate specific membrane antigen (PSMA). The imaging of PSMA expression with [⁶⁸Ga]Ga-PSMA-11 and PET/CT has proven to be a highly specific and sensitive tool for patient management.

“This optimized new production process is the result of the strong collaboration between IBA and ICNAS” said **Bruno Scutnaire, Vice-President of IBA's RadioPharma Solutions Division**.

This FGD-like production process is easy to implement and allows cyclotron production centers to maximize the use of their equipment. The process consists of the irradiation of an enriched ⁶⁸Zn solution in a ⁶⁸Ga liquid target installed on a Cyclone® KIUBE. The target solution is then transferred to a Synthera® extension module which purifies the irradiated solution to obtain [⁶⁸Ga]GaCl₃, which is equivalent to [⁶⁸Ga]GaCl₃ from the commercial ⁶⁸Ge/⁶⁸Ga generators.

“Currently, the availability and efficiency of ⁶⁸Ge/⁶⁸Ga generators is not enough to meet global demand and they have limited elution capacity per day and decay over time, while the ⁶⁸Ga-cyclotron process allows stable, on-demand production throughout the whole year” commented **Antero Abrunhosa, Director at ICNAS**. *“We can see a clear benefit to producing ⁶⁸Ga with a cyclotron using a liquid target; the production is consistent and allows a higher production volume. This new patented process provides a viable alternative for facilities with cyclotrons securing ⁶⁸Ga access locally and for distribution.”*

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About ICNAS/University of Coimbra

ICNAS is a leading institution in molecular probe development and molecular imaging (given strong cyclotron and radiopharmacy related facilities). These pillars unite within the leading medical imaging center in Portugal (with PET and MR facilities) and have technical and scientific relevance at a European scale. ICNAS has unique expertise and equipment for development of imaging markers and studies in multi-modal and multi-organ imaging (eye, brain, heart, liver, prostate).

ICNAS can run preclinical trials and Phase 0 microdosing studies, and imaging clinical trials in Humans. It also develops new imaging techniques in partnership with the industry and labels candidate drugs for scientific and industry studies.

About IBA

IBA (Ion Beam Applications S.A.) is the world leader in particle accelerator technology. The company is the leading supplier of equipment and services in the field of proton therapy, considered to be the most advanced form of radiation therapy available today. IBA is also a leading player in the fields of industrial sterilization, radiopharmaceuticals and dosimetry. The company, based in Louvain-la-Neuve, Belgium, employs approximately 1,500 people worldwide. IBA is a certified B Corporation (B Corp) meeting the highest standards of verified social and environmental performance.

IBA is listed on the pan-European stock exchange EURONEXT (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB).

More information can be found at: www.iba-worldwide.com

About IBA RadioPharma Solutions

Based on longstanding expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotopes production by providing them with global solutions, from project design to the operation of their facility. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up GMP radiopharmaceuticals production centers. More information can be found at: www.iba-radiopharmaSolutions.com

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2



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