



# IBA and ABX Announce the Successful Implementation of <sup>18</sup>F-FDOPA Nucleophilic Pathway on Synthera<sup>®</sup> Platform

<sup>18</sup>F-FDOPA is a diagnostic positron emission tomography agent used to detect, stage and restage neuroendocrine tumors

**ABX** (Advanced Biochemical Compounds GmbH), the world's leading provider of radiochemistry solutions and **IBA** (Ion Beam Applications S.A.), the world's leading provider of proton therapy and radiopharmacy solutions, announce today the establishment of a reliable synthetic route for <sup>18</sup>F-FDOPA via a nucleophilic pathway on the **Synthera**® platform. This milestone is the result of a collaboration between IBA and ABX and capitalizes on ABX's strong investments in an own PET research facility which further enhances its expertise in new radiopharmaceutical technologies.

<sup>18</sup>F-FDOPA is a well-known radiopharmaceutical used in neurology and oncology. <sup>18</sup>F-FDOPA can be synthesized either via electrophilic or nucleophilic substitution reaction methods. Some of the advantages of the nucleophilic approach include an easier production of F-18, improved specific activity and yield. This simplifies the manufacturing process of the tracer and, consequently, allows more PET centers to be involved in its production and distribution.

Bruno Scutnaire, Vice President of IBA RadioPharma Solutions commented: "The <sup>18</sup>FDOPA achievement is the culmination of several years of successful collaboration between both companies. The addition of <sup>18</sup>F-FDOPA (nucleophilic pathway) to our product portfolio (<sup>18</sup>FDG, Na<sup>18</sup>F, <sup>18</sup>F-Choline, <sup>18</sup>FLT, <sup>18</sup>FMISO and other compounds developed by the Synthera® users), strengthens Synthera's leadership when it comes to the development of new molecules. Synthera's robustness and versatility continue to support the advancement of Nuclear Medicine through new radiopharmaceutical development."

**Marco Mueller, Head of Radiochemistry and R&D at ABX commented:** "The patented precursor for the nucleophilic production of <sup>18</sup>F-FDOPA is the latest achievement of ABX's interdisciplinary research centre. The flexibility and user-friendly interface of the Synthera<sup>®</sup> synthesizer enabled us, with the support of IBA, to implement the synthesis of <sup>18</sup>F-FDOPA with high radiochemical yield and purity in a reliable way.

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<sup>\*18</sup>F-FDOPA is Investigational Diagnostic PET Radiopharmaceutical in the US and already approved for clinical use in some European countries.

# Press release



#### **Notes to Editors**

## **About IBA RadioPharma Solutions**

Based on longstanding expertise, IBA RadioPharma Solutions supports the in-house radioisotope and radiopharmaceutical development and production in PET centers around the world by providing global solutions, ranging from project design to facility operation. In addition to high-quality technology production equipment, IBA has developed in-depth experience in setting up GMP radiopharmaceutical production centers.

# **About Synthera**

Synthera<sup>®</sup> is a multi-purpose automated synthesizer for the production of various <sup>18</sup>F radiopharmaceuticals, such as <sup>18</sup>F-FDG, <sup>18</sup>F-Choline, <sup>18</sup>FLT, Na<sup>18</sup>F, <sup>18</sup>FMISO, etc. Synthera<sup>®</sup> is designed to accommodate a wide range of radiochemistry pathways, which provides invaluable versatility for any current and future development work. With more than 350 Synthera<sup>®</sup> installed worldwide, it has become the reference for radiopharmaceutical production due to its unique features, such as its smallest footprint, and multi-tracer and multi-run capabilities. http://www.iba-radiopharmasolutions.com/products/chemistry#synthera

## **About IBA**

IBA (Ion Beam Applications S.A.) is a cancer diagnostics and treatment equipment company, and the worldwide technology leader in the field of proton therapy, the most advanced form of radiotherapy available today.

The Company's primary expertise lies in the development of next generation proton therapy technologies that provide oncology care providers with premium quality services and equipment. IBA's proton therapy solutions are scalable and adaptable, offering universal full scale proton therapy centers as well as next generation compact, single room solutions. IBA also focuses on the development and supply of dosimetry solutions for Quality Assurance of medical equipment and increased patient safety as well as particle accelerators for medical and industrial applications.

IBA employs more than 1,000 people worldwide and is listed on Euronext Brussels, (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB), more information can be found at: www.iba-worldwide.com

#### **About ABX**

ABX is the world leading supplier of PET precursors and consumables. State-of-the-art GMP assembly and filling areas with clean room conditions A-D and in-house hot labs for research and development of new kits for production of radiopharmaceuticals strenghtens the position of ABX on the PET market. In addition, ABX has strong expertise in establishing Drug Master Files and performing stability studies in compliance with ICH Q7. ABX also offers the custom synthesis and GMP-compliant manufacturing of PET precursors, reference standards and peptides. ABX is audited and accepted as GMP API manufacturer by German pharmaceutical authorities and the US Food and Drug Administration (FDA). Recently, ABX has been successfully certified with ISO 9001 and ISO 13485.

ABX currently employs 200 people at the company's headquarter in Radeberg, Germany.

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