

A new way to detect prostate cancer: ABX receives marketing authorisation for radiotracer Radelumin® in Germany

- **Novel radiotracer for the detection of prostate cancer gets green light in Germany**
- **Marketing authorisation now obtained in eight European countries**
- **Radelumin® already in application in France since December 2022**
- **Production and marketing in the additional seven countries to start by beginning of next year**

Radeberg, 8 November 2023. German radiopharmaceutical company ABX has received marketing authorisation for its diagnostic Radelumin® ($[^{18}\text{F}]\text{PSMA-1007}$) in Germany. Radelumin® is a novel radiotracer for PET imaging, targeting the prostate-specific membrane antigen, or short PSMA-targeted PET imaging. It is used for primary staging of patients with high-risk prostate cancer as well as for patients with suspected prostate cancer recurrence due to increasing levels of serum PSA. Prostate cancer is the most common cancer among men. More than 65,000 new cases are diagnosed in Germany each year.

Radelumin® successfully passed a clinical phase III study (ABX-CT-301). It was subsequently approved in France at the end of 2021. ABX then started a Mutual Recognition Procedure (MRP), in order to obtain the marketing authorisation in further European countries. The MRP process was decided positively in March 2023 and since then, seven European countries – Austria, Belgium, Italy, Luxembourg, Spain, The Netherlands and now Germany – approved Radelumin®.

Radelumin® ($[^{18}\text{F}]\text{PSMA-1007}$) was a follow-up to the success of ^{177}Lu -PSMA-617 in 2018 by the Deutsche Krebsforschungszentrum (DKFZ). It was developed with the support of Prof. Dr. Frederik L. Giesel, director of the Clinic for Nuclear Medicine at the University Hospital Düsseldorf, as well as Prof. Dr. Klaus Kopka, director of the Institute of Radiopharmaceutical Cancer Research at the Helmholtz Center Dresden-Rossendorf and formerly head of Radiopharmaceutical Chemistry at the DKFZ.

The compound is injected into the patient and binds to the prostate-specific membrane antigen (PSMA) – a cell surface protein which is highly overexpressed in prostate cancer cells. The radioactive fluorine-18 subsequently makes the cancer visible for positron emission tomography (PET) and at the same time decays quickly in the body.

Due to its radioactive short-lived nature, the production and application of Radelumin® needs extensive preparation of supply chains. Production sites, hospitals and partners from all over the European continent are in the process of being onboarded; marketing and application of Radelumin® on a grand scale is expected to launch beginning of 2024.

“The approval in Germany, our home market and the most populous European country, is another important step in the success story of 18-Fluoride-based PSMA diagnostics”, says Dr. Peter Moll, CEO of ABX. “It will facilitate diagnostics, bring a whole new level of accuracy to the detection and treatment of prostate cancer and will help saving hundreds of thousands of lives.”

About ABX

ABX advanced biochemical compounds is a global frontrunner in radiopharmaceuticals, with a focus on positron emission tomography (PET) tracers. We develop and produce compounds and components for any kind of radiotracer – from PET and SPECT precursors, PET reagent kits and cassettes, to complete radiopharmaceutical drug production in GMP environment.

Based in Radeberg, Germany, our team of more than 350 employees is specialised in custom synthesis and manufacturing of precursors and peptides according to GMP for active pharmaceutical ingredients. Thanks to our expertise combined with bleeding edge equipment, we reach highest research, production, and quality standards. For example, we operate a hot lab for R&D of new radiopharmaceutical kits and cassettes for our own product portfolio and in cooperation with pharmaceutical companies. Our extensive laboratory space enables us to perform stability studies of our products and in-house sterility testing of radioactive pharmaceuticals. We are also authorized producer of radiopharmaceutical drugs. Furthermore, we are experts in ASMFs, US-DMFs and technical documents for reagent kits, cassettes, PET and SPECT precursors.

ABX is a global success story: As market leader for radiopharmaceutical consumables we developed over the last years the ^{177}Lu -PSMA-617 – until phase II (then sublicensed to Endocyte, now Novartis) as well as ^{18}F PSMA-1007 – now approved in selected countries in Europe.

To learn more, please visit www.abx.de