Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/fda-approval-targeted-radioligand-therapy-treatment-metastatic-prostate-cancer

FDA approval for targeted radioligand therapy for treatment of metastatic prostate cancer

On March 23, 2022, the U.S. Food and Drug Administration (FDA) granted approval to the first targeted radioligand therapy against metastatic prostate cancer based on a joint patent of the German Cancer Research Center (DKFZ) and the University of Heidelberg. The agent significantly improves the chances of survival for those affected. The invention is an outstanding example of the transfer of excellent research results into clinical application, said Michael Baumann, Chairman and Scientific Director of the DKFZ.

The compound Lutetium-177 PSMA-617 was approved in the U.S. for the treatment of metastatic prostate cancer carrying the surface molecule PSMA (prostate specific membrane antigen). Approval of the drug, marketed by Novartis, is limited to patients who have received prior chemotherapy and who do not respond to hormone deprivation.

The compound had been developed in years of interdisciplinary translational research by scientists at DKFZ, Heidelberg University and Heidelberg University Hospital.

In the pivotal study (VISION III), which was conducted at several U.S. hospitals, lutetium-177 PSMA-617 in combination with standard therapy reduced all-cause mortality by 38 percent and disease progression by 60 percent of subjects during the study observation period.

"The FDA approval is a great opportunity for the affected men and a great success for the DKFZ: Our mission is to provide knowledge and solutions for clinical practice through excellent basic research. With the invention of Lutetium-177 PSMA-617, our scientists have achieved an outstanding example of this transfer," said Michael Baumann, Chairman and Scientific Director of the DKFZ. "Patients with advanced prostate cancer who otherwise have few promising treatment options can now benefit from this new drug worldwide."

"This joint success of DKFZ, Heidelberg University and Heidelberg University Hospital once again demonstrates the outstanding achievements of our researchers, in this case in the development of modern pharmaceutical agents. At the same time, this is also a result of the excellent cooperation between our institutions in research and transfer," emphasizes Matthias Weidemüller, Prorector for Innovation and Transfer at Heidelberg University.

Additional clinical trials are already underway to determine whether lutetium-177 PSMA-617 also provides a survival benefit to patients with metastatic prostate cancer who have not previously received chemotherapy. The drug, marketed by Novartis, is expected to be approved in Europe soon.

Prostate cancer is the most common cancer, with 70,000 new cases/year, and the second leading cause of cancer death in men in Germany. If the tumor is still confined to the prostate gland at diagnosis, the probability of surviving the first five years after diagnosis is almost 100 percent, whereas for metastatic tumors it is only 30 percent.

Lutetium-177 PSMA-617 is a ligand coupled with radioactive lutetium-177 that can dock precisely to the prostate-specific membrane antigen, or PSMA. The majority of all prostate cancer cells carry the glycoprotein PSMA on their cell membrane, but it is rarely found in the rest of the body. The cancer cells take up the agent into the cell interior so that it accumulates in the tumors and delivers its lethal dose of radiation from within, making the effect of the therapy particularly precise and targeted.

Under the leadership of DKFZ, Lutetium-177 PSMA-617, was initially licensed out exclusively to ABX GmbH in Radeberg in 2014 for further development and commercialization. In 2017, US-based Endocyte Inc. acquired the licensing rights from ABX. In 2018, Endocyte was acquired by Novartis.

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Source: German Cancer Research Center

Further information

- German Cancer Research Center (DKFZ), Heidelberg