Salvagene GROUP

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Salvagene SARS CoV-2 Task Force: 177Lu-PSMA-617: The new hope in prostate cancer therapy

KEYNOTE

The radioactive drug 177Lu-PSMA-617 was developed for the treatment of metastatic castration-resistant prostate cancer (CRPC) and is intended to safely treat cancer through targeted radioligand therapy. The drug utilizes the concept of endoradiotherapy, effectively irradiating the diseased cancer cells from the inside. Approval for use on prostate cancer patients is believed to be imminent.

Endoradiotherapy (targeted radionuclide therapy) is currently advancing to become a major new method of cancer medicine, capable of halting and even reversing cancer in susceptible patients.

The radioactive medication that is administered intravenously during the treatment is called 177Lu-PSMA-617. It was first formulated by Klaus Kopka, Director at the Institute for Radiopharmaceutical Cancer Research in Dresden, working in

collaboration with researchers in Heidelberg. The Swiss pharmaceutical giant Novartis acquired manufacturing rights in 2017.

In mid-June of this year, Novartis announced that the FDA had granted 177Lu-PSMA-617 “Breakthrough Therapy Designation” (BTD) status, a category covering drugs which early clinical evidence indicates may have the potential for a significant improvement in the treatment of serious diseases as compared with therapies already in use. At the beginning of October, the FDA accepted the licensing application for 177Lu-PSMA-617 and agreed to fast-track the review process. The Prescription Drug User Fee Act (PDUFA) date is now expected to come sometime in the first half of 2022. Priority review from the FDA is granted to therapies that have the potential to significantly improve the treatment, diagnosis or prevention of serious diseases.

The BTD status was granted on the basis of the positive data coming out of the pivotal Phase III VISION trial, which evaluated 177Lu-PSMA-617 in combination with standard of care (SOC) versus SOC alone in patients with progressive PSMA-positive metastatic castration-resistant prostate cancer.

The Phase III study showed that 177Lu-PSMA-617 significantly improved overall survival rates as well as radiographic progression-free survival (rPFS) in men with progressive prostate cancer, and that it was safe and well tolerated. The subjects lived an average of four months longer, and their quality of life did not decline as quickly as that of the control group. In half of the cases, tumor sites actually shrank.

These benefits suggest that the therapy may become the new standard of care for advanced prostate cancer with metastases. Two other ongoing trials are now investigating 177Lu-PSMA-617 in earlier lines of treatment for patients with metastatic prostate cancer.

How exactly does 177Lu-PSMA-617 work?
The drug is administered intravenously. In the body, it then docks onto the cancer cells in a targeted manner. To do this, it binds to a protein on the envelope of the tumor cells, namely the PSMA (prostate-specific membrane antigen). The drug then radiates in situ. The “Lu” element in the name stands for lutetium, which projects electrons up to 1.2 millimeters into the tissue. In an ideal scenario, this electron bombardment destroys the cancer cells completely.

For decades, doctors only sent cancer patients to nuclear medicine departments when the tumor needed to be mapped – in other words, for diagnostic purposes – but therapy and diagnostics in nuclear medicine are now being merged into the new combined discipline of theranostics. Radioactive substances not only render the tumors visible but also fight them at source. Current developments are very promising and, in our opinion, could also have relevance in other areas of cancer medicine. Initial studies are already underway in this regard. What is particularly remarkable is the ability of endotherapy – here specifically 177Lu-PSMA-617 – to successfully fight cancer, even when it has reached an advanced stage. Of particular interest to us are the findings of studies that investigate the effectiveness of endotherapy in earlier lines of treatment.

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