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Prostate cancer: Novel radiopharmaceuticals prolong survival of patients with bone metastases

(Vienna, January 20, 2015) At an advanced stage prostate cancer frequently leads to bone metastases which may result in pain, fractures, and disability and are associated with a poor prognosis. Recently a major breakthrough has been achieved which is about to improve the patients' situation, as Prof. Markus Luster, expert of the European Association of Nuclear Medicine (EANM), points out: "Radium-223-dichloride is the first bone-targeted drug that not only alleviates symptoms but also prolongs the life expectancy of these patients. Study results give us reason to believe that this is a promising path in the treatment of bone metastases linked to prostate cancer and potentially to other tumour types."

In severe cases of prostate cancer a hormone therapy is applied in order to reduce the level of testosterone upon which the carcinoma is dependent to a large extent. However, in a number of patients this therapeutic path is not efficient as they are resistant to hormone treatment. More than 90% of these patients develop bone metastases, often accompanied by considerable pain, disability and an overall decreased quality of life. Their prognosis is poor as for this type of cancer it is bone lesions and its complications that are a major cause of disability and may even be life-threatening.

A precisely aimed attack

"Until recently, existing bone-targeted therapies had not proven to be efficient beyond alleviation of pain. But now the situation has changed: The newly developed radiopharmaceutical radium-223-dichloride (Xofigo ©) has been shown to prolong survival as compared to placebo, in addition to pain reduction and delay of skeletal complications," says Prof. Luster (EANM). This is the main result of an international randomized control trial that included 921 patients from over one hundred treatment centers, located in 19 countries¹. The study was sponsored by pharmaceutical companies Algeta and Bayer HealthCare. The patients, selected for the study, had progressive prostate cancer with bone metastases but without visceral metastases (patients with metastatic lymph node involvement were included). Moreover, they were resistant to medical or surgical hormone therapy and not

suited for chemotherapy (with the frequently used drug docetaxel) because their health status precluded its use or because they refused this kind of treatment. As an estimated 20-40% of patients with this sort of prostate cancer never receive chemotherapy due to various reasons this condition of the study addressed an important but hitherto unmet need in a population that is not sufficiently served by current therapies. Two thirds of the study participants were injected with radium-223 every 4 weeks for a total of 6 injections. The amount of the radioactive medication to be used (i.e. administered activity) was calculated according to the patient's body weight (50 kilobecquerels per kilogram). The remaining third of the group was injected with placebo. In addition all patients received the best standard of care and were followed up for 3 years from the first injection.

Radium-223 is a radioactive substance that emits short-range radiation, so-called alpha particles. In the body, radium is handled like the calcium naturally found in the bones. Due to this, radium-223 accumulates particularly in those parts of the skeleton where new bone tissue formation is taking place as is the case with bone metastases. The high-energy alpha particles destroy the cancer cells and help to control the associated symptoms. A major advantage of radium-223 over other radiopharmaceuticals is the short path of its particles – about 0,1 millimetres – which leaves surrounding healthy tissue and particularly the bone marrow largely unaffected, thus reducing adverse side effects substantially.

Extended life expectancy

Prof. Luster sums up the results: “It turned out that the life expectancy of patients treated with radium-223 was superior to that of the placebo group by 3.6 months on average, the overall survival being 14.9 months compared to 11.3 months. In addition, the drug delayed the point of time at which patients started to suffer from bone fractures or pain.”

The convincing results of the study have led the European Medicines Agency (EMA) as well as the American Food and Drug Administration (FDA) to approve the radium-223 based drug Xofigo[®], which is now available for the treatment of prostate cancer patients who meet the required conditions. “New studies investigating the combination of radium-223 with other prostate cancer drugs such as abiraterone acetate are being currently performed in patients with bone predominant metastatic hormone-refractory prostate cancer. Apart from this, studies on the application of radium-223 on bone metastases in other tumours like breast cancer are under way,” says Prof. Luster.

¹Parker C. et al. Alpha emitter radium-223 and survival in metastatic prostate cancer. N Engl J Med. 2013 Jul 18;369(3):213-23. (Funded by Algeta and Bayer HealthCare Pharmaceuticals; ALSYMPCA ClinicalTrials.gov number, NCT00699751.).

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