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SMC approves Bayer's Xofigo for treatment of castration-resistant prostate cancer in NHS Scotland

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The Scottish Medicines Consortium (SMC) has today announced that Xofigo® (radium-223 dichloride) has been accepted for use within NHS Scotland for the treatment of adult patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastases.

While the National Institute for Health and Care Excellence (NICE) has published draft guidance recommending radium-223 dichloride in advanced prostate cancer, this does not cover all patients and may not be confirmed for a number of months and could change. In Scotland, under SMC guidance clinicians will have the choice to use Xofigo prior to chemotherapy or after. So while patient access has improved in Scotland, it is worsening in the rest of the UK.

"This is a positive step for advanced prostate cancer patients in Scotland. However, the picture in England, Wales and Northern Ireland is very different. Historically radium-223 dichloride has been available only in England, funded through the Cancer Drugs Fund (CDF). This CDF funding is due to cease later this year following the recent CDF delisting round," said Mr Hugh Gunn, Tackle Prostate Cancer. "If NICE pass radium-223 dichloride for use, this will be for post chemotherapy patients only. This will prevent the use of radium-223 dichloride in men who, for one reason or another do not progress to chemotherapy."

Prostate cancer is the most common cancer affecting men in the UK. In 2011 there were approximately 41,700 men diagnosed with prostate cancer, which is more than 110 every day.

In Scotland prostate cancer accounted for over one in five new cases of cancer in men in 20133 and between 2008 and 2012, there were 14,935 new cases in Scotland alone and the number of cases is projected to increase by 35% within the next 10 years.

In some cases prostate cancer may spread to other parts of the body, particularly the bones, in certain cases leading to debilitating pain, and/or bone fractures.

"We are pleased that NHS Scotland leads the way in providing radium-223 dichloride to all patients who could receive benefit from this innovative therapy. The next step for Bayer is to ensure patients in England, Wales and Northern Ireland have the same level of access to radium-223. By working closely with both NICE and All Wales Medicines Strategy Group (AWMSG) we hope, in the near future, that no suitable patient is denied access to this life-changing treatment. At Bayer, we remain committed to developing treatments to reduce significant unmet needs in hard to treat cancers," said Dr Alexander Moscho, CEO Bayer UK & Ireland.

In the phase III ALSYMPCA study, radium-223 dichloride was shown to significantly extend median overall survival (OS), the primary endpoint of the study. Median OS was 14.9 months for radium 223 dichloride compared to 11.3 months for placebo (HR=0.70 [95% CI, 0.58-0.83]; p<0.001). In addition, there was a delay in the time to first symptomatic skeletal event for patients treated with radium-223 dichloride compared to placebo (HR=0.66 [95% CI, 0.52-0.83] p<0.001).

The most frequently observed adverse reactions (≥10%) in patients receiving radium-223 dichloride were diarrhoea, nausea, vomiting and thrombocytopenia.

Radium-223 dichloride was approved for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases, in November 2013 in the European Union.

Source:
http://www.bayer.com/

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