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Pharmaceuticals and Medical Devices Agency

Summary of Investigation Results Radium (²²³Ra) chloride

September 18, 2018

Non-proprietary name

Radium (223Ra) chloride

Branded name (Marketing authorization holder)

Xofigo Injection (Bayer Yakuhin, Ltd.)

Indications

Castration-resistant prostate cancer accompanied by bone metastases

Summary of revisions

A cautionary statement concerning co-administration of this drug with abiraterone acetate and prednisolone in chemotherapy-naïve patients with asymptomatic or mildly symptomatic castration-resistant prostate cancer accompanied by bone metastases should be added to the Important Precautions section.

> Pharmaceuticals and Medical Devices Agency Office of Safety I 3·3·2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u>



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Investigation results and background of the revision

A multi-regional phase III study (15369 Study) investigating administration of radium (223Ra) chloride or a placebo in combination with abiraterone acetate plus prednisone (currently unapproved in Japan) or prednisolone to chemotherapy-naïve patients with asymptomatic or mildly symptomatic castration-resistant prostate cancer accompanied by bone metastases showed a tendency for a higher mortality rate and incidence of bone fracture after receiving radium (²²³Ra) chloride compared to the patients who were given a placebo. MHLW/PMDA considered the necessity of regulatory actions based on these findings and the results of their investigation of the currently available evidence in consultation with expert advisors to reach a conclusion that a precaution was necessary that coadministration of radium (²²³Ra) with abiraterone acetate and prednisolone is not recommended to chemotherapy-naïve patients with asymptomatic or mildly symptomatic castration-resistant prostate cancer accompanied by bone metastases taking into account the possibility for a higher mortality rate and incidence of bone fracture indicated by the study and the ongoing practice to use this drug in combination with abiraterone acetate plus prednisolone and/or in chemotherapy-naïve patients as identified in post-marketing surveillance in Japan.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

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