



Summary of Investigation Results

Radium (^{223}Ra) chloride

September 18, 2018

Non-proprietary name

Radium (^{223}Ra) 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.



Investigation results and background of the revision

A multi-regional phase III study (15369 Study) investigating administration of radium (^{223}Ra) 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 (^{223}Ra) 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 co-administration of radium (^{223}Ra) 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

N/A