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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Radium ( $^{223}\text{Ra}$ ) chloride

September 18, 2018

### Non-proprietary name

Radium ( $^{223}\text{Ra}$ ) chloride

### Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Important Precautions section (revised language is underlined):

A clinical study investigating administration of this drug 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 this drug compared to the patients who were given a placebo. Based on these findings, co-administration of this drug with abiraterone acetate and prednisolone is not recommended in chemotherapy-naïve patients with asymptomatic or mildly symptomatic castration-resistant prostate cancer accompanied by bone metastases.