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

Summary of Investigation Results

Apalutamide

May 19, 2020

Non-proprietary name

Apalutamide

Branded name (Marketing authorization holder)

Erleada Tablets 60 mg (Janssen Pharmaceutical K.K.)

Indications

Castration-resistant prostate cancer without remote metastasis

Summary of revisions

1. A cautionary statement for toxic epidermal necrolysis (TEN) should be added to the Important Precautions section
2. “Toxic epidermal necrolysis (TEN)” should be added to the description of “Severe skin disorder” in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of toxic epidermal necrolysis have been reported in patients treated with apalutamide in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 2 cases involving toxic epidermal necrolysis have been reported to date (A causal relationship between the drug and event was reasonably possible for these cases.)

1 instance of patient mortality has been reported to date (A causal relationship between the

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drug and the death subsequent to event was reasonably possible for this case.)

(Japanese market launch: May 2019)

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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