August 25, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Apalutamide

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	Apalutamide	Erleada Tablets 60 mg (Janssen Pharmaceutical K.K.)
Japanese market launch	May 2019	
Indications	○ Non-metastatic castration-resistant prostate cancer ○ Metastatic prostate cancer	
Summary of revisions	1. A cautionary statement regarding agranulocytosis, neutropenia, and leukopenia should be added to the 8. IMPORTANT PRECAUTIONS section. 2. "Agranulocytosis, neutropenia, and leukopenia" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Cases involving agranulocytosis, neutropenia, and leukopenia were evaluated. Cases in which a causal relationship between apalutamide and agranulocytosis, neutropenia, and leukopenia was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	
Reference: Number of casesinvolving agranulocytosis, neutropenia, and leukopenia* reported in Japan	< Agranulocytosis > A total of 3 cases have been reported to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date. < Neutropenia > A total of 18 cases have been reported to date (including 7 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date. < Leukopenia > A total of 10 cases have been reported to date (including 5 cases in which a causal relationship between the drug and the event was reasonably possible). No deaths have been reported to date.	

*: Among cases collected in the PMDA's safety database for drugs and reported with PTs included in MedDRA ver. 28.1 SMQ "Haematopoietic leukopenia," cases assessed as Grade 3 or higher according to CTCAE ver. 6.0 were reviewed

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).