独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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

Olaparib

March 17, 2026

Non-proprietary name

Olaparib

Brand name (marketing authorization holder)

Lynparza Tablets 100 mg, 150 mg (AstraZeneca K.K.)

Japanese market launch

April 2018

Indications

○ Maintenance treatment of recurrent ovarian cancer responding to platinum-based chemotherapy

○ Maintenance treatment of *BRCA* mutation-positive ovarian cancer after first-line chemotherapy

○ Maintenance treatment of homologous recombination deficiency-positive ovarian cancer after first-line chemotherapy including bevacizumab (genetical recombination)

○ Treatment of inoperable or recurrent *BRCA* mutation-positive HER2-negative breast cancer previously treated with chemotherapy

○ Adjuvant pharmacotherapy for *BRCA* mutation-positive HER2-negative breast cancer with a high risk of recurrence

○ Treatment of *BRCA* mutation-positive metastatic castration-resistant prostate cancer

○ Maintenance treatment of incurable, unresectable *BRCA* mutation-positive pancreatic cancer after chemotherapy including platinum-based antineoplastic drugs

○ Maintenance treatment of advanced or recurrent endometrial cancer with proficient mismatch repair (pMMR) in patients who have received chemotherapy including treatment with durvalumab (genetical recombination)

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Summary of revisions

1. Precautions for hepatic impairment should be added to the 8. IMPORTANT PRECAUTIONS section.
2. “Hepatic impairment” 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 hepatic impairment were evaluated. Cases in which a causal relationship between olaparib and hepatic impairment 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 cases* and patient mortalities involving hepatic impairment reported in Japan and overseas

A total of 10 cases have been reported in Japan to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 11 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for 3 cases, including 1 case in which the drug was administered outside the approved dosage and administration.)
No patient mortalities have been reported overseas to date.

*: Cases meeting both of the following conditions were retrieved from those collected in the PMDA’s database for adverse drug reactions, etc. reports:

• Cases that fell under MedDRA ver. 27.0 SMQ (narrow) “Hepatitis, non-infectious,” “Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions,” or “Liver-related investigations, signs and symptoms”

• Cases in which the hepatic function test values (either of ALT, AST, ALP, γ-GTP, or T-Bil) at the time of onset of the event and after discontinuation of olaparib were available

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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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