SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		71 Years	Female	Unk		JAN	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Patient sometimes ate and sometimes did not [Eating disorder]	OLAPARIB	Yes	No	Not Related	Not Related
Patient was not walking [Gait disturbance]	OLAPARIB	Yes	No	Not Related	Not Related
Notifier indicates that patient throws a tantrum [Aggression]	OLAPARIB	No	No	Not Related	Not Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☒ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) OLAPARIB (OLAPARIB) Tablet

(Continued on Additional Information Page)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)
#1) 150 milligram, bid

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Ovarian cancer (Ovarian cancer)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1) 08-OCT-2024 / Ongoing

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Ovarian cancer (Ovarian cancer)
Unknown to Ongoing	Current Condition	Blood pressure abnormal (Blood pressure abnormal)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: GT-ASTRAZENECA-202503CAM014874GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00830584A

24b. MFR CONTROL NO.
202503CAM014874GT

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
06-JUN-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
12-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202503CAM014874GT

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
the patient sometimes does not take their drug of their own accord/patient consumes medication intermittently [Intentional dose omission]	OLAPARIB	No	No	Not Related	Not Applicable
Patient presents severe nausea [Nausea]	OLAPARIB	Yes	Yes	Related	Related
Neuropathy [Neuropathy peripheral]	OLAPARIB	Yes	No	Not Applicable	Related
Patient was dehydrated [Dehydration]	OLAPARIB	No	No	Not Applicable	Not Related
patient was malnourished [Malnutrition]	OLAPARIB	No	No	Not Applicable	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female elderly patient born in 1953 (age 71 years).

The patient's past and current medical history included blood pressure problems (ongoing) and spinal problems (ongoing).

No concomitant products were reported.

The patient started treatment with Olaparib (olaparib) 150 milligram bid, Oral use, on 08-OCT-2024 for ovarian cancer.

During 15-JAN-25, the patient experienced patient was not walking (preferred term: Gait disturbance). On an unknown date, the patient experienced severe patient was malnourished (preferred term: Malnutrition), notifier indicates that patient throws a tantrum (preferred term: Aggression), the patient sometimes does not take their drug of their own accord/patient consumes medication intermittently (preferred term: Intentional dose omission), patient sometimes ate and sometimes did not (preferred term: Eating disorder), severe patient was dehydrated (preferred term: Dehydration), neuropathy (preferred term: Neuropathy peripheral) and severe patient presents severe nausea (preferred term: Nausea).

The dose of Olaparib (olaparib) was not changed.

The outcome of the event(s) of neuropathy, notifier indicates that patient throws a tantrum, patient sometimes ate and sometimes did not, patient was not walking, and the patient sometimes does not take their drug of their own accord/patient consumes medication intermittently was unknown. At the time of reporting, the event patient presents severe nausea, patient was dehydrated, and patient was malnourished was ongoing.

The following event(s) were considered serious due to medically significant: neuropathy. The following event(s) were considered serious due to hospitalized: patient presents severe nausea, patient was not walking, and patient sometimes ate and sometimes did not.

The following events were considered non-serious: notifier indicates that patient throws a tantrum, patient was dehydrated, patient was malnourished, and the patient sometimes does not take their drug of their own accord/patient consumes medication intermittently.

The reporter did not assess causality for neuropathy, patient was dehydrated, and patient was malnourished. The reporter considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): patient presents severe nausea. The reporter did not consider that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): notifier indicates that patient throws a tantrum, patient sometimes ate and sometimes did not, patient was not walking, and the patient sometimes does not take their drug of their own accord/patient consumes medication intermittently.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): notifier indicates that patient throws a tantrum, patient sometimes ate and sometimes did not, patient was dehydrated, patient was malnourished, and patient was not walking. The company physician considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): neuropathy and patient present severe nausea.

Corrected Report 04-Apr-2025: Study drug added, narrative amended.

Summary of follow up information received by AstraZeneca/MedImmune on 06-Jun-2025 from consumer via solicited source: New serios events of Severe nausea, dehydration & Neuropathy were added as new events. New non-serious event Intentional dose omission was added as new event. Narrative amended.

Company Clinical Comment: Neuropathy peripheral is not listed in the company core data sheet of Olaparib. Advanced age and underlying malignancy could be possible risk factors. Due to limited information on circumstances leading to event, event onset date and outcome, clinical course, treatment provided, predisposing risk factors, relevant medical history, concurrent conditions, concomitant medications, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to exclude a causal relationship between the event and suspect drug

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION

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ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) OLAPARIB (OLAPARIB) Tablet; Regimen #2	600 milligram, qd; Oral use	Ovarian cancer (Ovarian cancer)	08-OCT-2024 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Spinal disorder (Spinal disorder);
Unknown	Procedure	Chemotherapy (Chemotherapy);
Unknown	Procedure	Ovarian surgery (Ovarian operation);