CIOMS FORM

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		62 Years	Female	Unk		SEP	2024

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Gripe [Influenza]	OLAPARIB	No	No	Related	Related
Nausea / Nauseous [Nausea]	OLAPARIB	No	Yes	Related	Related
It takes away your hunger [Appetite disorder]	OLAPARIB	No	No	Not Applicable	Related
Constipation [Constipation]	OLAPARIB	No	No	Related	Related
Vomiting [Vomiting]	OLAPARIB	No	Yes	Related	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

15. DAILY DOSE(S)
#1) 300 milligram, q12h

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

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

18. THERAPY DATES(from/to)
#1) Ongoing

19. THERAPY DURATION
#1) Unknown

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

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

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	Indication	Breast cancer (Breast cancer)

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-202502003960GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00802400A

24b. MFR CONTROL NO.
202502CAM003960GT

24c. DATE RECEIVED BY MANUFACTURER
10-JUL-2025

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

DATE OF THIS REPORT
15-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1962 (age 62 years).

The patient’s past and current medical history included recurrence of ca of the ovary (ongoing).

No concomitant products were reported.

The patient started treatment with Olaparib (olaparib) 300 milligram q12h, Oral use, on an unknown date for ovarian cancer.

During 15-SEP-24, the patient experienced constipation (preferred term: Constipation) and vomiting (preferred term: Vomiting). On 15-DEC-24, the patient experienced gripe (preferred term: Influenza). During 15-APR-25, the patient experienced nausea / nauseous (preferred term: Nausea). On an unknown date, the patient experienced it takes away your hunger (preferred term: Appetite disorder).

The dose of Olaparib (olaparib) was not changed.

At the time of reporting, the event nausea / nauseous was ongoing. The outcome of the event(s) of gripe was unknown. The outcome of the event(s) of constipation and vomiting was unknown. The outcome of the event(s) of it takes away your hunger was unknown.

The events were considered non-serious.

The reporter did not assess causality for it takes away your hunger.The reporter considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): constipation, gripe, nausea / nauseous and vomiting.
The company physician considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): constipation, gripe, it takes away your hunger, nausea / nauseous and vomiting.

Summary of follow up information received by AstraZeneca/MedImmune on 12-Mar-2025 from Other Health Professional via Solicited Source: Nausea, Hunger abnormal adverse event added, narrative updated.

Summary of follow-up information received by AstraZeneca on 07-May-2025 from the patient: indication of the suspect was updated, action taken updated to none. Start date of the event of nausea added, outcome updated to not recovered. Narrative was updated.

Summary of follow-up information received by AstraZeneca on 10-Jul-2025 from the patient: indication of the suspect was updated, New events constipation and vomiting added, Start date of suspect added, Current condition added, Narrative was updated.

23. OTHER RELEVANT HISTORY continued

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