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	15	DEC	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 [Nausea]	OLAPARIB	No	Yes	Not Applicable	Related
It takes away your hunger [Appetite disorder]	OLAPARIB	No	No	Not Applicable	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, bid

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

17. INDICATION(S) FOR USE
#1) Breast Cancer (Breast cancer)

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

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	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

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

24c. DATE RECEIVED BY MANUFACTURER
12-MAR-2025

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

DATE OF THIS REPORT
17-MAR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

No medical history was reported.

No concomitant products were reported.

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

On 15-DEC-24, the patient experienced gripe (preferred term: Influenza). On an unknown date, the patient experienced nausea (preferred term: Nausea) and it takes away your hunger (preferred term: Appetite disorder).

It is unknown if any action was taken with Olaparib (olaparib).

The outcome of the event(s) of gripe was unknown. The outcome of the event(s) of it takes away your hunger and nausea was unknown.

The events were considered non-serious.

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