SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		93 Years	Male	Unk		Unk	

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
PATIENT PRESENTED COVID-19 DURING TREATMENT [COVID-19]	LYNPARZA	No	No	Not Applicable	Not Related
PATIENT BEGAN TO DECLINE A LOT [Asthenia]	LYNPARZA	No	Yes	Not Applicable	Not Related
DOCTOR FELT THE MEDICATION WAS NOT WORKING FOR THE PATIENT [Drug ineffective]	LYNPARZA	No	No	Related	Not Applicable
PATIENT WAS LIKE GONE [Distractibility]	LYNPARZA	No	No	Related	Related
PATIENT DIDN'T ALWAYS REACT [Hypokinesia]	LYNPARZA	No	No	Not Applicable	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) LYNPARZA (OLAPARIB) Capsule

15. DAILY DOSE(S)
#1) UNK

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

17. INDICATION(S) FOR USE
#1) (Not Coded)

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

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-202506CAM016183GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00894638A

24b. MFR CONTROL NO.
202506CAM016183GT

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

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

DATE OF THIS REPORT
24-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

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
PATIENT WAS ALWAYS SLEEPY [Somnolence]	LYNPARZA	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 male elderly patient (age 93 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Lynparza (olaparib) UNK, Oral use, on an unknown date.

On an unknown date, the patient experienced patient presented covid-19 during treatment (preferred term: COVID-19), patient was always sleepy (preferred term: Somnolence), patient didn't always react (preferred term: Hypokinesia), patient was like gone (preferred term: Distractibility), doctor felt the medication was not working for the patient (preferred term: Drug ineffective) and patient began to decline a lot (preferred term: Asthenia).

The report described lack of effect for Lynparza. The reported term was "doctor felt the medication was not working for the patient" (preferred term: Drug ineffective).

The outcome of the event(s) of patient didn't always react, patient presented covid-19 during treatment, patient was always sleepy and patient was like gone was unknown. At the time of reporting, the event doctor felt the medication was not working for the patient and patient began to decline a lot was ongoing.

The events were considered non-serious.

The reporter did not assess causality for patient began to decline a lot, patient didn't always react, patient presented covid-19 during treatment and patient was always sleepy.The reporter considered that there was a reasonable possibility of a causal relationship between Lynparza and the following event(s): doctor felt the medication was not working for the patient and patient was like gone. The company physician did not consider that there was a reasonable possibility of a causal relationship between Lynparza and the following event(s): patient began to decline a lot, patient didn't always react, patient presented covid-19 during treatment and patient was always sleepy. The company physician considered that there was a reasonable possibility of a causal relationship between Lynparza and the following event(s): patient was like gone.