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	PANAMA		PRIVACY		46 Years	Female	Unk		NOV	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
high cholesterol [Blood cholesterol increased]	OLAPARIB	No	No	Not Related	Not Related
tiredness [Fatigue]	OLAPARIB	No	Yes	Not Applicable	Related
Hair loss [Alopecia]	OLAPARIB	No	No	Not Applicable	Related
Weakness in the fingernails [Nail 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, q12h

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

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

18. THERAPY DATES(from/to)
#1) 20-OCT-2024 / 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	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 #: PA-ASTRAZENECA-202503CAM002736PA
Patient ID: Unknown
Study ID: PSP-23269
Case References: PA-AstraZeneca-CH-00821385A

24b. MFR CONTROL NO.
202503CAM002736PA

24c. DATE RECEIVED BY MANUFACTURER
19-MAY-2025

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

DATE OF THIS REPORT
22-MAY-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

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1979 (age 46 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Olaparib (olaparib) 300 milligram q12h, Oral use, on 20-OCT-2024 for breast cancer.

During 15-NOV-24, the patient experienced high cholesterol (preferred term: Blood cholesterol increased). On 29-JAN-25, the patient experienced tiredness (preferred term: Fatigue). On 01-MAR-25, the patient experienced hair loss (preferred term: Alopecia). On 01-APR-25, the patient experienced weakness in the fingernails (preferred term: Nail disorder).

The dose of Olaparib (olaparib) was not changed.

The patient recovered from the event(s) high cholesterol on an unspecified date. The patient recovered from the event(s) tiredness after 28 on 25-FEB-2025. At the time of reporting, the event hair loss and weakness in the fingernails was ongoing.

The events were considered non-serious.

The reporter did not assess causality for hair loss, tiredness and weakness in the fingernails.The reporter did not consider that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): high cholesterol.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): high cholesterol. The company physician considered that there was a reasonable possibility of a causal relationship between Olaparib and the following event(s): hair loss, tiredness and weakness in the fingernails.

Summary of follow-up information received by AstraZeneca AstraZeneca on19-MAY-2025 from Consumer via Patient Support Program: Study drug coded. Suspect product dosage regimen updated. New events added. Narrative updated.