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	COSTA RICA		PRIVACY		Unk	Female	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
HOSPITALIZATION (UNKNOWN CAUSE) [Hospitalisation]	ACALABRUTINIB	Yes	No	Related	Not Applicable
My gallbladder burst and contaminated it. [Gallbladder rupture]	ACALABRUTINIB	Yes	No	Not Applicable	Not Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: MAY-2025
- ☒ 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) ACALABRUTINIB (ACALABRUTINIB) Capsule

15. DAILY DOSE(S)
#1) 100 milligram, q12h

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

17. INDICATION(S) FOR USE
#1) MANTLE CELL LYMPHOMA (Mantle cell lymphoma)

18. THERAPY DATES(from/to)
#1) 08-DEC-2023 / 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	Mantle cell lymphoma (Mantle cell lymphoma)

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 #: CR-AstraZeneca-2024A053519
Study ID: PSP-23269
Case References: CR-AstraZeneca-2024A053519

24b. MFR CONTROL NO.
2024A053519

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

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
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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 concerning a female patient born in 1948.

No medical history was reported. No concomitant products were reported.

On 08-DEC-2023, the patient started treatment with Acalabrutinib (acalabrutinib) 100 milligram q12h, Oral use, for mantle cell lymphoma.

On an unknown date, the patient experienced hospitalization (unknown cause) (preferred term: Hospitalisation) and my gallbladder burst and contaminated it (preferred term: Gallbladder rupture).

The patient died from the event my gallbladder burst and contaminated it. on an unspecified date. At the time of reporting, the event hospitalization (unknown cause) was ongoing.

The patient died during MAY-2025. It is not known whether an autopsy was performed. The cause of death was my gallbladder burst and contaminated it.

The reporter assessed event of hospitalization (unknown cause) as serious due to Hospitalized criterion.

The reporter assessed the event of my gallbladder burst and contaminated it as serious due to Death criterion.

The reporter did not assess causality for my gallbladder burst and contaminated if. The reporter considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): hospitalization (unknown cause).

The company physician did not consider that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): my gallbladder burst and contaminated it.

Summary of follow up information received by AstraZeneca/MedImmune on 27-May-2025 from consumer via solicited source: Report type was updated. New event my gallbladder burst and contaminated it was added. Narrative amended.