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	COSTA RICA		PRIVACY		Unk	Female	Unk		MAY	2025

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

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
DIZZINESS [Dizziness]	ACALABRUTINIB	No	Yes	Related	Related
STOMACH PAIN [Abdominal pain upper]	ACALABRUTINIB	No	Yes	Related	Related
GENERAL MALAISE [Malaise]	ACALABRUTINIB	No	No	Related	Related
HEADACHE [Headache]	ACALABRUTINIB	No	Yes	Related	Related
pneumonia [Pneumonia]	ACALABRUTINIB	Yes	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) ACALABRUTINIB (ACALABRUTINIB) Capsule

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

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

17. INDICATION(S) FOR USE
#1) CLL (Chronic lymphocytic leukaemia)

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	CLL (Chronic lymphocytic leukaemia)

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-2024A156670
Study ID: PSP-23269
Case References: CR-AstraZeneca-2024A156670

24b. MFR CONTROL NO.
2024A156670

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

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

DATE OF THIS REPORT
02-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
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 patient born in 1944.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Acalabrutinib (acalabrutinib) 100 milligram bid, Oral use, on an unknown date for cll.

During 15-MAY-25, the patient experienced pneumonia (preferred term: Pneumonia). On an unknown date, the patient experienced dizziness (preferred term: Dizziness), headache (preferred term: Headache), general malaise (preferred term: Malaise) and stomach pain (preferred term: Abdominal pain upper).

Treatment with Acalabrutinib (acalabrutinib) was temporarily Withdrawn.

The outcome of the event(s) of pneumonia was unknown. At the time of reporting, the event dizziness, general malaise, headache and stomach pain was ongoing.

The following event(s) were considered serious due to medically significant and hospitalized:pneumonia.

The following events were considered non-serious:dizziness, general malaise, headache and stomach pain.

The reporter considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event (s): dizziness, general malaise, headache, pneumonia and stomach pain.
The company physician considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): dizziness, general malaise, headache, pneumonia and stomach pain.

Follow-up of insignificant information received by AstraZeneca/MedImmune on 30-Jul-2024 from health professional via solicited source. New consumer reporter was added. Narrative updated.

All required follow-up attempts have been completed to obtain the Lot / Batch number for Calquence, however the Lot / Batch number was not received.

Summary of follow-up information received by AstraZeneca/MedImmune on 17-Sep-2024 via marketing company: Summary of unsuccessful Lot/Batch number attempts added. Narrative updated.

Summary of follow up information received by AstraZeneca on 28-MAY-2025 from Other Health Professional via Patient Support Program: Primary reporter added. Suspect Calquence action taken updated to temporarily withdrawn. New event Pneumonia added. Study ID added. Narrative updated.