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		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
25-JUN-2025

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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.

Mfr. Control Number: 2024A156670

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
This medicine does not do its job. [Drug ineffective]	ACALABRUTINIB	No	No	Not Applicable	Not Applicable
Disease progression [Malignant neoplasm progression]	ACALABRUTINIB	Yes	Yes	Related	Not Related
Excessive sweating [Hyperhidrosis]	ACALABRUTINIB	No	No	Related	Related
Ganglia in the throat and neck. [Synovial cyst]	ACALABRUTINIB	No	No	Related	Related
Patient in great pain [Pain]	ACALABRUTINIB	No	No	Related	Related
Patient downfall with depression [Depressed mood]	ACALABRUTINIB	No	No	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female patient born in 1944.

No medical history and concomitant products were reported.

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

During 15-MAY-25, the patient experienced pneumonia (preferred term: Pneumonia). On an unknown date, the patient experienced dizziness (preferred term: Dizziness), patient downfall with depression (preferred term: Depressed mood), patient in great pain (preferred term: Pain), ganglia in the throat and neck. (preferred term: Synovial cyst), excessive sweating (preferred term: Hyperhidrosis), disease progression (preferred term: Malignant neoplasm progression), this medicine does not do its job. (preferred term: Drug ineffective), headache (preferred term: Headache), general malaise (preferred term: Malaise) and stomach pain (preferred term: Abdominal pain upper).

The report described lack of effect for Acalabrutinib. The reported term was "this medicine does not do its job." (preferred term: Drug ineffective).

Treatment with Acalabrutinib was temporarily Withdrawn.

At the time of reporting, the event disease progression, dizziness, excessive sweating, ganglia in the throat and neck., general malaise, headache, patient downfall with depression, patient in great pain and stomach pain was ongoing. The outcome of the event (s) of pneumonia and this medicine does not do its job. was unknown.

The reporter assessed events of pneumonia and disease progression were serious due to hospitalized and medically significant criteria.

The reporter assessed events of dizziness, excessive sweating, ganglia in the throat and neck., general malaise, headache, patient downfall with depression, patient in great pain, stomach pain and this medicine does not do its job were non-serious.

The reporter did not assess causality for this medicine does not do its job..The reporter considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): disease progression, dizziness, excessive sweating, ganglia in the throat and neck., general malaise, headache, patient downfall with depression, patient in great pain, pneumonia and stomach pain.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): disease progression. The company physician considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): dizziness, excessive sweating, ganglia in the throat and neck., general malaise, headache, patient downfall with depression, patient in great pain, 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.

Summary of follow-up information received by AstraZeneca 25-Jun-2025: Events This medicine does not do its job, Disease progression, Excessive sweating, Ganglia in the throat and neck., Patient in great pain, Patient downfall with depression added. Narrative updated.