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	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
The patient underwent a biopsy on the neck 4 months ago, does not provide exact dates. [Biopsy]	ACALABRUTINIB	No	No	Not Related	Not Related
Patient presents lymph nodes in the neck, for the past 22 days. Does not provide exact dates./ Patient has been presenting lymph nodes in the chest for 22 days. Does not provide exact dates./ Patient presents lymph nodes on the back, for the past 22 d [Lymphadenopathy]	ACALABRUTINIB	No	No	Not Related	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) ACALABRUTINIB (ACALABRUTINIB) Film-coated tablet

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

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

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

18. THERAPY DATES(from/to)
#1) 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	Chronic lymphocytic leukemia (Chronic lymphocytic leukemia)
Unknown	Historical Condition	Tumor (Neoplasm)

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-202507CAM001463CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00903357A

24b. MFR CONTROL NO.
202507CAM001463CR

24c. DATE RECEIVED BY MANUFACTURER
02-JUL-2025

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

DATE OF THIS REPORT
04-JUL-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
The patient showed a little depression. [Depression]	ACALABRUTINIB	No	No	Not Related	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a male patient born in 1952.

The patient's past and current medical history included tumor (dates not reported).

No concomitant products were reported.

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

On an unknown date, the patient experienced the patient underwent a biopsy on the neck 4 months ago, does not provide exact dates. (preferred term: Biopsy), the patient showed a little depression. (preferred term: Depression) and patient presents lymph nodes in the neck, for the past 22 days. does not provide exact dates./ patient has been presenting lymph nodes in the chest for 22 days. does not provide exact dates./patient presents lymph nodes on the back, for the past 22 d (preferred term: Lymphadenopathy).

The dose of Acalabrutinib (acalabrutinib) was not changed.

The patient recovered from the event(s) the patient showed a little depression. and the patient underwent a biopsy on the neck 4 months ago, does not provide exact dates. on an unspecified date. At the time of reporting, the event patient presents lymph nodes in the neck, for the past 22 days. does not provide exact dates./ patient has been presenting lymph nodes in the chest for 22 days. does not provide exact dates./patient presents lymph nodes on the back, for the past 22 d was ongoing.

The events were considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): patient presents lymph nodes in the neck, for the past 22 days. does not provide exact dates./ patient has been presenting lymph nodes in the chest for 22 days. does not provide exact dates./patient presents lymph nodes on the back, for the past 22 d, the patient showed a little depression. and the patient underwent a biopsy on the neck 4 months ago, does not provide exact dates..
The company physician did not consider that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): patient presents lymph nodes in the neck, for the past 22 days. does not provide exact dates./ patient has been presenting lymph nodes in the chest for 22 days. does not provide exact dates./patient presents lymph nodes on the back, for the past 22 d, the patient showed a little depression. and the patient underwent a biopsy on the neck 4 months ago, does not provide exact dates..

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Computerised tomogram Unknown		