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	GUATEMALA		PRIVACY		72 Years	Female	Unk		JAN	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
Patient reports that he fainted on 02/18/2025 [Syncope]	CALQUENCE	Yes	No	Not Applicable	Related
He has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025 [Asthenia]	CALQUENCE	No	Yes	Not Applicable	Related
Headache [Headache]	CALQUENCE	No	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) CALQUENCE (ACALABRUTINIB) Film-coated tablet

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

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) 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	
Unknown to Ongoing	Indication	Chronic lymphocytic leukemia (Chronic lymphocytic leukaemia)

(Continued on Additional Information Page)

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 #: GT-ASTRAZENECA-202502CAM024066GT
Study ID: DMS
Case References: GT-AstraZeneca-CH-00817074A

24b. MFR CONTROL NO.
202502CAM024066GT

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

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

DATE OF THIS REPORT
08-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 concerning a female elderly patient born in 1952 (age 72 years).

No medical history and no concomitant products were reported.

On an unknown date, the patient started treatment with Calquence (acalabrutinib) 100 milligram q12h, Oral use, for chronic lymphocytic leukemia.

During 15-JAN-25, the patient experienced headache (preferred term: Headache). On 18-FEB-25, the patient experienced patient reports that he fainted on 02/18/2025 (preferred term: Syncope). On 26-FEB-25, the patient experienced he has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025 (preferred term: Asthenia).

The dose of Calquence (acalabrutinib) was not changed.

The patient recovered from the event(s) headache on an unspecified date. The outcome of the event(s) of he has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025 and patient reports that he fainted on 02/18/2025 was unknown.

The following event(s) were considered serious due to medically significant:patient reports that he fainted on 02/18/2025.

The following events were considered non-serious:he has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025 and headache.

The reporter did not assess causality for he has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025 and patient reports that he fainted on 02/18/2025.The reporter considered that there was a reasonable possibility of a causal relationship between Calquence and the following event(s): headache.
The company physician considered that there was a reasonable possibility of a causal relationship between Calquence and the following event(s): he has felt very weak, he has not wanted to go to the doctor because he does not want to worry his family, until his appointment on 02/10/2025, headache and patient reports that he fainted on 02/18/2025.

Summary of significant follow-up information received by AstraZeneca on 05-MAY-2025 from Consumer via Patient Support Program. Event added. Narrative updated.

Company Clinical Comment: Syncope is not listed in the company core data sheet of Acalabrutinib. Underlying Chronic lymphocytic leukaemia could be confounding to the event. Advanced age could be considered as a risk factor. Due to limited information on detailed medical history, family history, circumstances surrounding the event, concomitant medications, start date of suspect drug, complete etiologic and diagnostic workup, the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between the event and suspect drug.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Chronic lymphocytic leukaemia (Chronic lymphocytic leukaemia);