**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)

| Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) | Product | Serious | Listed | Reporter Causality | Company Causality |
|---|---|---|---|---|---|
| MOUTH LESIONS LIKE BLOOD-FILLED BLISTERS [Oral blood blister] | ACALABRUTINIB | 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 ) 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 ) CLL (Chronic lymphocytic leukaemia)

18. THERAPY DATES(from/to)
#1 ) 01-AUG-2023 / 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 | 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-202505CAM024601CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00880115A

24b. MFR CONTROL NO.
**202505CAM024601CR**

24c. DATE RECEIVED BY MANUFACTURER
28-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.

## 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 1965.

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

The patient started treatment with Acalabrutinib (acalabrutinib) 100 milligram q12h, Oral use, on 01-AUG-2023 for cll.

During 15-MAY-25, the patient experienced mouth lesions like blood-filled blisters (preferred term: Oral blood blister).

The dose of Acalabrutinib (acalabrutinib) was not changed. At the time of reporting, the event mouth lesions like blood-filled blisters was ongoing.

The event was considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event (s): mouth lesions like blood-filled blisters.
The company physician considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): mouth lesions like blood-filled blisters.