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		9 Weeks	Male	2.95 kg	01	AUG	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
Fallecimiento (causa desconocida) [Death]	SYNAGIS	Yes	No	Not Applicable	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 01-AUG-2025
- ☐ 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) SYNAGIS (PALIVIZUMAB) Injection
(Continued on Additional Information Page)

15. DAILY DOSE(S)
#1) 44 milligram, q4w

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

17. INDICATION(S) FOR USE
#1) Respiratory syncytial virus (Prematuri
(Continued on Additional Information Page)

18. THERAPY DATES(from/to)
#1) 16-JUL-2025 / 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	

(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 #: CR-ASTRAZENECA-202508CAM010497CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00931200A

24b. MFR CONTROL NO.
202508CAM010497CR

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
13-AUG-2025

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

DATE OF THIS REPORT
15-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a male infant patient born in 2025 (age 9 weeks, weight 2.95 kg).

No medical history was reported.

No concomitant products were reported.

On 16-JUL-2025, the patient started treatment with Synagis (palivizumab) 44 milligram q4w, Intramuscular use, for respiratory syncytial virus (prematurity).

The dose of Synagis (palivizumab) was not changed.

The patient died (preferred term: Death) on 01-AUG-2025.

The patient died on 01-AUG-2025. It is not known whether an autopsy was performed. The cause of death was fallecimiento (causa desconocida).

The event was considered serious (Death).

The reporter did not assess causality for fallecimiento (causa desconocida).
The company physician considered that there was a reasonable possibility of a causal relationship between Synagis and the following event(s): fallecimiento (causa desconocida).

Company Clinical Comment: This case concerns a 9 week old male infant patient with fatal outcome in association with palivizumab. The cause of death was not further specified. Patient's young age could be confounding to patient's death. However, due to limited information on the exact cause of death, circumstances leading to death, possible underlying diseases, concurrent diseases, concomitant medication, medical and birth history, diagnostic workup prior fatal outcome, autopsy report (if performed), the evaluation did not find evidence to exclude a reasonable possibility of a causal relationship between fatal outcome and the suspect drug.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) SYNAGIS (PALIVIZUMAB) Injection; Regimen #1	44 milligram, q4w; Intramuscular use	Respiratory syncytial virus (Prematurity) (Respiratory syncytial virus infection)	16-JUL-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Respiratory syncytial virus infection (Respiratory syncytial virus infection);