SUSPECT ADVERSE REACTION REPORT

SV-Tolmar-TLM-2025-03410

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Years		Day	Month	Year	
GAM	EL Cont..	18	Jan	1955		Male				

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Death (Death (10011906), Death (10011906))
(- 19/Apr/2025) - Fatal

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- [x] PATIENT DIED
- [ ] LIFE THREATENING
- [ ] INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- [ ] RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- [ ] CONGENITAL ANOMALY
- [ ] OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Eligard® (Leuprolide acetate, Leuprolide acetate) (Suspect) (45 Milligram, Injection)(Unknown)

Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? [ ] YES [ ] NO [x] NA

15. DAILY DOSE(S)

1) (45 milligram(s), 1 in 6 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

21. DID EVENT REAPPEAR AFTER REINTRODUCTION [ ] YES [ ] NO [x] NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (07/Jun/2024 -)	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

1) PROSTATE CANCER (10060862, Prostate cancer) (//2024 -) (Continuing: Yes)

Cont..

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Tolmar, Inc
701 Centre Avenue
Fort Collins, CO, 80526, UNITED STATES OF AMERICA
Anjan.Chatterjee@tolmar.comand+1--9702124900

Study Information
Study Name: NA
EudraCT Number:
Protocol No.: NA
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
[ ] YES [ ] NO	SV-Tolmar-TLM-2025-03410
24c. DATE RECEIVED BY MANUFACTURER: 07/Jul/2025	24d. REPORT SOURCE: [x] STUDY [ ] LITERATURE [ ] HEALTH PROFESSIONAL
DATE OF THIS REPORT: 10/Jul/2025	25a. REPORT TYPE: [ ] INITIAL [x] FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

EL SALVADOR

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

This study report from EL SALVADOR was received by Adium Pharma S.A through the Jazz Safety tool of the Patient Support Program “ASOFARMA A TU LA" (reference number: SV-ADIUM-SV-0007-20250613) on 13-Jun-2025, from a consumer (caregiver) (non-healthcare professional) regarding an elderly male patient who experienced serious event of “death" (Death) during Eligard (leuprolide acetate) 45 mg therapy for prostate cancer. The needle component of the constituent device was not identified in the report. The report was sent to Tolmar on 13-Jun-2025.

The patient's medical history was unknown and current condition included prostate cancer.

Concomitant medications were unknown.

On 07-Jun-2024, the patient began receiving Eligard 45 mg every 6 months via subcutaneous route for prostate cancer (Lot numbers and expiration dates were unknown).

On 19-Apr-2025, the patient died due to unknown cause of death. The patient was 70 years old at the time of his death. It was unknown if an autopsy was performed. No further details were provided.

Action taken with Eligard in response to event was not applicable. De-challenge and Re-challenge were not applicable.

The outcome of death was fatal.

The reporter assesses the seriousness of death as serious (death).

The reporter did not provide the causality of death in relationship to Eligard and Eligard Unspecified Device.

No further query was raised.

On 24-Jun-2025, an attempt was made to contact the notifier following a request from the health authority.

On 25-Jun-2025, an attempt was made to contact the notifier following a request from the health authority.

On 03-Jul-2025, an attempt was made to contact the notifier following a request from the health authority.

On 07-Jul-2025, all three attempts were failed, and no further information was obtained.

On 07-Jul-2025, follow-up information from EL SALVADOR was received by Adium Pharma S.A through the Jazz Safety tool of the Patient Support Program "ASOFARMA A TU LA" (Reference number: SV-ADIUM-SV-0007-20250613) from a consumer (non-healthcare professional) and sent to Tolmar on 08-Jul-2025. New information included: Updated the patient's medical history (bone metastasis and high antigen levels), lab data (laboratory test abnormal) and narrative was updated.

The patient's medical history included bone metastasis and high antigen levels.

No further queries were raised.

Listedness:
Death>Eligard>Unlisted as per CCDS>07-Nov-2024
Death>Eligard>Unlisted as per USPI>Feb-2025
Death>Eligard unspecified device>Unlisted as per USPI>Feb-2025
Death>Eligard>Unlisted as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator Comment (Tolmar): This is regarding 70-year-old elderly male patient who reportedly died (Death) while on Eligard(Leuprolide acetate) 45mg therapy for prostate cancer. Tolmar assessed death as serious due to fatal outcome. Causal role of Eligard (drug component) in the patient's death was not assessable as lack of information regarding cause of death, events or circumstances preceding patient's death, autopsy report, relevant medical history, supportive investigations that could indicate cause of death, concomitant medications received by the patient precludes meaningful medical assessment of the report. However, advanced age of the patient and underlying prostate cancer were pre-existing risk factors for the patient's death. Death was assessed as not related to the device component of Eligard.

14.SUSPECT DRUG(S) (Continuation...)

Continuation Sheet for CIOMS report

Product-Reaction Level

1) Drug : Eligard® (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form Strength : 1) 45 Milligram
Form of Admin : 1) Injection
Lot Number : 1) Unknown
Daily Dose : (45 milligram(s), 1 in 6 Month)
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 07/Jun/2024 To :Not applicable
Action(s) Taken With Drug : Not applicable

Causality

1) Death (Death - 10011906, Death - 10011906)
Causality as per reporter : Not Related
Causality as per Mfr : Not assessable
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Death
CORE UnLabeled

2) Drug : Eligard® Unspecified Device (Leuprolide acetate)
Active Substance : 1) Leuprolide acetate
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) Unknown
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Action(s) Taken With Drug : Not applicable

Causality

1) Death (Death - 10011906, Death - 10011906)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Death
CORE

23. OTHER RELEVANT HISTORY (Continuation...)

2) BONE METASTASES (10005993 , Bone metastases) (Continuing : Unknown)

3) HIGH ANTIGEN LEVELS (10023547 , Laboratory test abnormal) (Continuing : Unknown)