SUSPECT ADVERSE REACTION REPORT

DO-Tolmar-TLM-2025-04273

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	
O-G	DOMINICAN Cont..	09	Nov	1965	59	Male			2025	

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

1) Bone metastasis (Bone metastases (10005993), Metastases to bone (10027452)) (//2025 -) - Not Recovered/Not Resolved/Ongoing

- ☐ 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) (22.5 Milligram, Injection)(Unknown) Cont..

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)

1) (22.5 milligram(s), 1 in 3 Month)

16. ROUTE(S) OF ADMINISTRATION

1) Subcutaneous

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ 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) (//2023 - Ongoing)	

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) (Continuing: Yes)

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	DO-Tolmar-TLM-2025-04273
24c. DATE RECEIVED BY MANUFACTURER: 01/Jul/2025	24d. REPORT SOURCE: ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 04/Jul/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

1a. COUNTRY

DOMINICAN REPUBLIC

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

Event Description :

This study report from Dominican Republic was received by Adium via the 'ASOFARMA A TU LADO' Patient Support Program (reference number: DO-ADIUM-DO-0069-20250701) on 01-Jul-2025 from a consumer or other non-health professional regarding an Adult 59-year-old male patient who experienced a serious (medically significant) event of ''Bone metastasis'' (metastases to bone) during Eligard (leuprolide acetate) 22.5 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 02-Jul-2025.

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

Concomitant medication was Apalutamide.

On an unknown date and month in year 2023, the patient began receiving Eligard 22.5 mg every 3 months, via subcutaneous route, for prostate cancer (Lot numbers and Expiration dates were not provided).

On an unknown date and month in year 2025, the patient was diagnosed with bone metastasis following an unspecified imaging study.

Corrective treatment was unknown.

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

The outcome of metastases to bone was not resolved.

The reporter assessed the seriousness of metastases to bone as serious (medically significant).

The reporter provides the causality of metastases to bone in relationship to Eligard and Eligard unspecified device as not related.

No further information is expected as the reporter does not consent to be contacted for follow up.

Metastases to bone>Eligard>Listed as per CCDS>07-Nov-2024
Metastases to bone>Eligard>Listed as per USPI>Feb-2025
Metastases to bone>Eligard unspecified device>Listed as per USPI>Feb-2025
Metastases to bone>Eligard>Listed as per Canadian monograph>02-Apr-2025

Company Remarks (Sender's Comments) :

Evaluator comment (Tolmar): The case is regarding an adult 59-year-old male patient who experienced a serious (medically significant) event of metastases to bone (bone metastasis) during Eligard (leuprolide acetate) 22.5 mg therapy for prostate cancer. Tolmar assessed the reported event as serious since it meets the ICH seriousness criteria and is an IME event. The causality for the reported event metastases to bone is assessed as not related to Eligard (drug and device) components as the event can be explained by the natural progression of underlying prostate cancer through metastases, rather due to product.

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

Product-Reaction Level

1) Drug	:	Eligard® (Leuprolide acetate)
Active Substance	:	1) Leuprolide acetate
Drug Characterization	:	Suspect
Form Strength	:	1) 22.5 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) Unknown
Daily Dose	:	(22.5 milligram(s), 1 in 3 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : //2023 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Bone metastasis (Bone metastases - 10005993, Metastases to bone - 10027452)
Causality as per reporter : Not Related

Continuation Sheet for CIOMS report

Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Bone metastasis
CORE Labeled

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) Bone metastasis (Bone metastases - 10005993, Metastases to bone - 10027452)
Causality as per reporter : Not Related
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Bone metastasis
CORE