SUSPECT ADVERSE REACTION REPORT

2025-AER-015148

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	
Masked	PANAMA	Masked	Masked	Masked	85	Male		Feb	2025	

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

1) Frequent urination at night (Nocturnal urinary frequency (10079321), Nocturia (10029446)) (/Feb/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) Enzalutamide (Enzalutamide, Enzalutamide) (Suspect) (Verum) (40 Milligram, Capsule)(Unknown)

Cont..

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

15. DAILY DOSE(S)

1) 160.0 milligram(s) (160 milligram(s), 1 in 1 Day)

16. ROUTE(S) OF ADMINISTRATION

1) Oral

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) (11/Sep/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.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : Astellas Pharma Global Development, Inc.
2375 Waterview Drive
Northbrook, IL, 60062-6111, UNITED STATES OF AMERICA

Study Information
Study Name: Enzalutamide Patient Support Progr (Cont..)
EudraCT Number:
Protocol No.: Enzalutamide_Astellas PSP
Center No.:
Subject Id :

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-AER-015148
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
21/Apr/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
28/Apr/2025	☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

Information was received by Astellas business partner, Adium (Asofarma) from a patient on 13-Mar-2025 and was received at Astellas from Adium (Asofarma) on 14-Mar-2025, in PANAMA concerning a 85 Year(s) old Male patient, enrolled in post-marketing study: Enzalutamide Patient Support Program who was on Xtandi (enzalutamide), Capsule (160 milligram(s), 1 every 1 Day). Indication for use was Prostate cancer. The patient initiated treatment on 11-Sep-2024.

Study ID: Enzalutamide_Astellas PSP; Open-Label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimen 11-Sep-2024 - (ongoing): Oral, 160 mg, once daily.

Action taken with enzalutamide was dose not changed (ongoing).

The patient received leuprolide acetate (Eligard) for prostate cancer according to the following dosage regimen: 11-Sep-2024 - (ongoing): subcutaneous, 45 mg, every 6 month.

Action taken with leuprolide acetate was dose not changed (ongoing).

The patient reports that since Feb-2025, he has been experiencing frequent urination at night and has had to get up 4 to 5 times in the middle of the night to urinate. The physician was aware of the situation. The outcome of event was not recovered/ not resolved (still ongoing).

Medical history was not reported.

Past medications were not reported.

Concomitant medications were not reported.

No relevant lab data was reported.

The patient assessed the following events with respect to enzalutamide and leuprolide acetate:
- Frequent urination at night (seriousness: Non-Serious; causality: Not Assessed)

Consent to contact Patient for follow-up information was provided.

Tracking of changes:
13-Mar-2025: Initial information was received.

Follow up was received by Astellas business partner, Adium (Asofarma) from a patient on 21-Apr-2025 and was received at Astellas from Adium (Asofarma) on 22-Apr-2025, from patient with following updates: Enzalutamide route, Eligard lot and expiry and narrative was updated.

Company Remarks (Sender's Comments) :

Event Information:
Nocturnal urinary frequency was assessed as Non Serious.

Non-Serious is based on event not meeting ICH seriousness criteria.

Frequent urination at night was coded as Nocturnal urinary frequency due to closest available MedDRA term.

Product: Enzalutamide
Astellas assessed Nocturnal urinary frequency as Not Related based on available information for this case, a reasonable possibility to suggest a relationship between the suspect therapy and the reported event cannot be established. Underlying prostate cancer would be risk factor in this elderly aged patient. With the available information medical assessment has been done, however, upon receiving further information case will be reassessed.

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

Product-Reaction Level

1) Drug	: Enzalutamide (Enzalutamide)
Active Substance	: 1) Enzalutamide
Coding Class	: Verum
Drug Characterization	: Suspect
Form Strength	: 1) 40 Milligram
Form of Admin	: 1) Capsule

Continuation Sheet for CIOMS report

Lot Number	:	1) Unknown
Daily Dose	:	1) 160.0 milligram(s) (160 milligram(s), 1 in 1 Day)
Route of Admin	:	1) Oral
Indications	:	1) PROSTATE CANCER [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 11/Sep/2024 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

Causality

1) Frequent urination at night (Nocturnal urinary frequency - 10079321, Nocturia - 10029446)

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

Labeling :

1) Frequent urination at night

CORE	UnLabeled
IB	UnLabeled

2) Drug	:	ELIGARD
Active Substance	:	1) LEUPRORELIN ACETATE
Drug Characterization	:	Suspect
Form Strength	:	1) 45 Milligram
Form of Admin	:	1) Injection
Lot Number	:	1) 15276CUY
Daily Dose	:	1) 0.25 milligram(s) (45 milligram(s), 1 in 6 Month)
Route of Admin	:	1) Subcutaneous
Indications	:	1) prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	1) From : 11/Sep/2024 To :Continuing
Action(s) Taken With Drug	:	Dose not changed

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 2 :ELIGARD

1) lyophilized injectable suspension

24a. NAME AND ADDRESS OF MANUFACTURER (Continuation...)

Study # :Enzalutamide_Astellas PSP