SUSPECT ADVERSE REACTION REPORT

2025-AER-016363

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Masked	PANAMA	Masked	Masked	Masked	85	Male			

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

1) Ulcer on the right thigh (Leg ulcer (10068310), Skin ulcer (10040943))
Recovering/Resolving
2) Ulcer on the sacrum (Decubitus ulcer (10011985), Decubitus ulcer (10011985))
Recovering/Resolving
3) Deteriorated in a few weeks (General physical health deterioration (10049438), General physical health deterioration (10049438))
Recovering/Resolving

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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..

15. DAILY DOSE(S)

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

16. ROUTE(S) OF ADMINISTRATION

1) Oral

17. INDICATION(S) FOR USE

1) prostate cancer [10060862 - Prostate cancer]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (01/Dec/2023 -)	

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

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

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 ☐ YES ☐ NO

24b. MFR CONTROL NO.

2025-AER-016363

24c. DATE RECEIVED BY MANUFACTURER

24/Apr/2025

24d. REPORT SOURCE

☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

30/Apr/2025

25a. REPORT TYPE

☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

This case was received by Astellas business partner, Adium, on 18-Mar-2025 from a Patient and caregiver in PANAMA via email from the Patient Support Program "ASOFARMA A TU LADO" and was received at Astellas from Adium on 19-Mar-2025, 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 01-Dec-2023.

Study No.: Enzalutamide_Astellas PSP; Open-Label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimens: 01-Dec-2023 - (ongoing): Oral 160 mg once daily. Confirmed Unknown information about lot number and expiry date.

Action taken with enzalutamide was dose not changed.

The patient received Eligard (leuprorelin) for prostate cancer according to the following dosage regimens: 01-Dec-2023 - (ongoing): Subcutaneous 45 mg every 6 months.

Action taken with leuprorelin was dose not changed.

On an unknown date the patient was hospitalised due to an unknown reason.

On an unknown date the patient had ulcer on the right thigh, sacral ulcer.

The bedridden patient with caregiver at home since he has to perform all his care in bed. with two ulcers, one on the sacrum and the other on the right thigh. Caregiver refers that he has deteriorated in a few weeks.

Upon follow up on 24-Apr-2025, confirmed that events onset date was reported after hospitalization no exact date when events was occurred.

The outcome of the events [Ulcer on the right thigh, Ulcer on the sacrum and Deteriorated in a few weeks] was recovering.

Medical history was not reported.

Past medications were not reported.

Concomitant medications were not reported.

No relevant lab data was reported.

The patient and caregiver assessed the following events with respect to enzalutamide and leuprorelin:
- Ulcer on the right thigh (seriousness: Non-serious; causality: Not Assessed)
- Ulcer on the sacrum (seriousness: Non-serious; causality: Not Assessed)
- Deteriorated in a few weeks (seriousness: Non-serious; causality: Not Assessed)

No additional information was available.

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

Follow up was received by Astellas business partner, Adium, on 24-Apr-2025, from patient and caregiver via email from the Patient Support Program "ASOFARMA A TU LADO" and was received at Astellas from Adium on 25-Apr-2025: updated events outcome, confirmation about event onset dates and suspect drug lot details, updated narrative.

Company Remarks (Sender's Comments) :

Event Information:
Leg ulcer, Decubitus ulcer and General physical health deterioration were assessed as Non Serious.

Non Serious due to no patient jeopardy reported/ as event does not meet the ICH seriousness criteria.

All the events coded to closest available LLT per MEDDRA.

Product: Enzalutamide
Astellas assessed Leg ulcer, Decubitus ulcer and General physical health deterioration as Not Related based on the clinically relevant information currently available for this individual case and the evidence is not sufficient to suggest a relationship between the suspect therapy and the reported adverse event. Complication due to advance underlying metastatic cancer with elderly age constitutes a more plausible alternative explanation for the

Continuation Sheet for CIOMS report

reported event. Additionally, action taken with the suspect drugs in response to the events was no change. More information regarding current medical conditions, medical history, co suspect medications and concomitant medications will aid in comprehensive medical assessment.

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
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 : 01/Dec/2023 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Ulcer on the right thigh (Leg ulcer - 10068310, Skin ulcer - 10040943)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

2) Ulcer on the sacrum (Decubitus ulcer - 10011985, Decubitus ulcer - 10011985)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) Deteriorated in a few weeks (General physical health deterioration - 10049438, General physical health deterioration - 10049438)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Ulcer on the right thigh
CORE UnLabeled
IB UnLabeled
2) Ulcer on the sacrum
CORE UnLabeled
IB UnLabeled
3) Deteriorated in a few weeks
CORE UnLabeled
IB UnLabeled

2) Drug : ELIGARD
Active Substance : 1) LEUPRORELIN ACETATE
Drug Characterization : Suspect
Form Strength : 1) 45 Milligram
Form of Admin : 1) Suspension for 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 : 01/Dec/2023 To :Continuing
Action(s) Taken With Drug : Dose not changed

Causality

1) Ulcer on the right thigh (Leg ulcer - 10068310, Skin ulcer - 10040943)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Continuation Sheet for CIOMS report

2) Ulcer on the sacrum (Decubitus ulcer - 10011985, Decubitus ulcer - 10011985)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

3) Deteriorated in a few weeks (General physical health deterioration - 10049438, General physical health deterioration - 10049438)
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

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

Study # :Enzalutamide_Astellas PSP