SUSPECT ADVERSE REACTION REPORT

2025-AER-026145

## 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 | HONDURAS | Masked | Masked | Masked | 75 | Male | 03 | May | 2025 |

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

1) Food poisoning (Food poisoning (10016952), Food poisoning (10016952)) (03/May/2025 - 04/May/2025) - Recovered/Resolved

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..

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) Castration-resistant prostate cancer [10076506 - Castration-resistant prostate cancer]

18. THERAPY DATE(S) (from/to)

19. THERAPY DURATION

## 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-026145

24c. DATE RECEIVED BY MANUFACTURER

12/May/2025

24d. REPORT SOURCE ☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

20/May/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 report from study case was received by Astellas business partner Adium, on 12-May-2025, from a 75 Year(s) old Male patient in HONDURAS and received at Astellas from Adium on 13-May-2025, enrolled in post-marketing study: Enzalutamide Patient Support Program “ASOFARMA A TU LADO" who was on Xtandi (enzalutamide), Capsule (160 milligram(s), 1 every 1 Day). Indication for use was Castration-resistant prostate cancer.

Study No: Enzalutamide_Astellas PSP; Open-Label study.

The patient received enzalutamide for castration-resistant prostate cancer according to the following dosage regimen: (start date not provided) - (Ongoing): Oral 160mg once daily.

The patient received Eligard (leuprorelin acetate) Injection, powder, lyophilized, for suspension, extended release for prostate cancer according to the following dosage regimen: 20-May-2021 - (Ongoing): subcutaneous 45mg every 24 weeks.

Action taken with enzalutamide and leuprorelin acetate treatment in response to event was no change (ongoing).

The patient reported that last week, he had symptoms of food poisoning, nausea, dizziness, abdominal pain, abdominal distention. On 03-May-2025, the patient experienced food poisoning (intensity: mild). The patient referred that he thinks it was something he ingested during lunch (lettuce and chicken) he went to the family doctor, but he did not indicate treatment, only increase fluid intake. The patient recovered from food poisoning on 04-May-2025.

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 event with respect to enzalutamide and leuprorelin acetate:
- Food poisoning (seriousness: Non-Serious; causality: Not assessed)

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

No additional information was available.

Tracking of changes:
12-May-2025: Initial information was received.

Company Remarks (Sender's Comments) :

Event Information:
Food poisoning was assessed as Non Serious.

Non-Serious as event does not meet the ICH seriousness criteria.

Product: Enzalutamide
Astellas assessed Food poisoning as Not Related based on the information available, a reasonable possibility to suggest a relationship between the suspect drug and the event cannot be established and was due to something he ingested during lunch (lettuce and chicken).

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 |

Continuation Sheet for CIOMS report

Indications : 1) Castration-resistant prostate cancer [10076506 - Castration-resistant prostate cancer]
Action(s) Taken With Drug : Dose not changed

Causality

1) Food poisoning (Food poisoning - 10016952, Food poisoning - 10016952 )
Causality as per reporter : Not assessed
Causality as per Mfr : Not Related
DeChallenge : Not applicable
ReChallenge : Not Applicable

Labeling :

1) Food poisoning
CORE UnLabeled
IB UnLabeled

2) Drug : ELIGARD
Active Substance : 1) LEUPRORELIN ACETATE
Drug Characterization : Suspect
Form of Admin : 1) Injection
Lot Number : 1) L15276CUY
Daily Dose : 1) 0.267 milligram(s) (45 milligram(s), 1 in 24 Week)
Route of Admin : 1) Subcutaneous
Indications : 1) Prostate cancer [10060862 - Prostate cancer]
Therapy Dates : 1) From : 20/May/2021 To :Continuing
Action(s) Taken With Drug : Dose not changed

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

Dosage Text :

Drug 1 :Enzalutamide

1) 40 MG x 120 CAP x 30 FND Capsule, gelatin coated

Drug 2 :ELIGARD

1) Injection, powder, lyophilized, for suspension, extended release

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

Study # :Enzalutamide_Astellas PSP