CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

2025-AER-030001

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	86	Male	12	May	2025

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

1) Difficulty in breathing (Difficulty breathing (10012791), Dyspnoea (10013968))
(12/May/2025 -) - 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..

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) (02/Oct/2020 -)	

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-030001
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
30/May/2025	☑ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
06/Jun/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 :

This case was received by Astellas business partner, Adium, from an 86 year(s) old male patient in PANAMA on 30-May-2025, and was received at Astellas from Adium on 02-Jun-2025, via an electronic form through the Jazz Safety tool of the "ASOFARMA A TU LADO", 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 02-Oct-2020.

Study no: Enzalutamide_Astellas PSP: Open label study.

The patient received enzalutamide for prostate cancer according to the following dosage regimen: 02-Oct-2020 - (stop date not provided): 160 mg, oral, once daily. Action taken with enzalutamide was reported as unknown.

On 12-May-2025, the patient experienced difficulty in breathing (moderate), for which the treating physician advised him to administer oxygen at home when these episodes occur. The outcome of the event was recovering/resolving.

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:
- Difficulty in breathing (seriousness: Non-Serious; causality: Not Related)

No further information was available.

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

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

Company Remarks (Sender's Comments) :

Event Information:
Difficulty breathing was assessed as Serious due to Other Medically Important Condition.

Other Medically Important Condition is based on nature of event and treatment with oxygen.

Difficulty in breathing was coded as Difficulty breathing due to closest available MedDRA term.

Product: Enzalutamide
Astellas assessed Difficulty breathing 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. The confounders include elderly age of patient and underlying malignancy.

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

Product-Reaction Level

1) Drug	:	Enzalutamide (Enzalutamide)
Active Substance	:	Enzalutamide
Coding Class	:	Verum
Drug Characterization	:	Suspect
Form Strength	:	40 Milligram
Form of Admin	:	Capsule
Lot Number	:	Unknown
Daily Dose	:	160.0 milligram(s) (160 milligram(s), 1 in 1 Day)
Route of Admin	:	Oral
Indications	:	Prostate cancer [10060862 - Prostate cancer]
Therapy Dates	:	From : 02/Oct/2020 To :Unknown
Action(s) Taken With Drug	:	Unknown

Causality

Continuation Sheet for CIOMS report

1) Difficulty in breathing (Difficulty breathing - 10012791, Dyspnoea - 10013968)

Causality as per reporter	: Not Related
Causality as per Mfr	: Not Related
DeChallenge	: Not applicable

Labeling :

1) Difficulty in breathing

CORE	UnLabeled
IB	UnLabeled

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

Study # :Enzalutamide_Astellas PSP