CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Female	Unk		Unk	

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

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
The patient mentions that while taking Xigduo 5mg/1000mg she was diagnosed with a tumor in the pancreas [Pancreatic carcinoma]	XIGDUO	Yes	No	Not Applicable	Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown}

15. DAILY DOSE(S)
#1) 5 milligram with unknown frequency

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Diabetes (Diabetes mellitus)

18. THERAPY DATES(from/to)
#1) 2023 / FEB-2025

19. THERAPY DURATION
#1) Unknown

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

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: CR-ASTRAZENECA-202505CAM014830CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00872979A

24b. MFR CONTROL NO.
202505CAM014830CR

24c. DATE RECEIVED BY MANUFACTURER
19-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202505CAM014830CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program, concerning a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

In 2023, the patient started treatment with oral Xigduo (dapagliflozin, metformin) (batch number(s): Unknown) 5 milligram with unknown frequency, for diabetes.

On an unknown date, while taking Xigduo 5mg/1000mg the patient was diagnosed with a tumor in the pancreas (preferred term: Pancreatic carcinoma).

Treatment with Xigduo was discontinued during Feb-2025.
The prescription was changed to Forxiga 10mg which she was currently taking.

The outcome of the event of the patient mentions that while taking Xigduo 5mg/1000mg she was diagnosed with a tumor in the pancreas was unknown.

The event of the patient mentions that while taking Xigduo 5mg/1000mg she was diagnosed with a tumor in the pancreas was upgraded by the company physician from non-serious to serious due to Medically Significant criterion.

The reporter did not assess causality for the patient mentions that while taking Xigduo 5mg/1000mg she was diagnosed with a tumor in the pancreas.
The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event: the patient mentions that while taking Xigduo 5mg/1000mg she was diagnosed with a tumor in the pancreas.

Company Clinical Comment: Pancreatic carcinoma is not listed in the company core data sheet of dapagliflozin + metformin. Underlying diabetes could be possible risk factor. Due to limited information on circumstances leading to event, patient age, start date of suspect drug, event onset date and outcome, clinical course, treatment provided, relevant medical history, concurrent conditions, concomitant medications, detailed diagnostic and etiological workup. the evaluation did not find the evidence to exclude a causal relationship between the event and suspect drug.