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
UNKNOWN	COSTA RICA	07	FEB	2001	24 Years	Female	56.00 kg		FEB	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Therapeutic abortion [Therapeutic abortion]
Pregnancy [Maternal exposure during pregnancy]

Case Description: This Costa Rica case is a solicited pregnancy report received on 24 Apr 2025 from a nurse from a patient support program via Ferrer. This 24 year old, 56 kg female patient began therapy with Remodulin (treprostinil sodium, concentration 2.5 mg/ml), on 19 Sep 2024 for an unknown indication. The current dose was reported as unknown (at 0.045 mg/ml), continuous via subcutaneous (SQ) route. On 16 Feb 2025, the patient had her last menstruation. The gestational age was 9 weeks and 3 days.

(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) Treprostinil sodium (SQ) (TREPROSTINIL SODIUM) Injection, 2.5 mg/ml

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK (0.045 mg/ml), continuing	#1) Subcutaneous use

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Ongoing	#1) Unknown

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
16-FEB-2025		Date of LMP for pregnancy
Unknown to Ongoing	Current Condition	Non-smoker (Non-tobacco user)
Unknown to Ongoing	Current Condition	Abstains from alcohol (Abstains from alcohol)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
United Therapeutics
55 T W Alexander Drive, P.O. Box 14186
Research Triangle Park, NC 27709 UNITED STATES
Phone: 1 (919) 485-8350

26. REMARKS
World Wide #: CR-UNITED THERAPEUTICS-UNT-2025-014448
Study ID: PSP_Remodulin_043

24b. MFR CONTROL NO.
UNT-2025-014448

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

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

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

(Continued on Additional Information Page)

DATE OF THIS REPORT
15-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: UNT-2025-014448

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

On an unreported date in Feb 2025, she was pregnant (maternal exposure during pregnancy). On 21 Apr 2025, the patient notified her pregnancy status to her treating physician. After the treating physician spoke with the patient, the patient accepted and authorized a therapeutic abortion (abortion induced, hospitalized). On an unreported date in Apr 2025, the patient was hospitalzied. On 24 Apr 2025, 7 months 6 days, after initiating SQ Remodulin, the therapeutic abortion was scheduled and was performed without any complications. The result of the reactions was reported as resolved. The patient was continued to be treated with SQ Remodulin and there was no interruption of it. The case was considered mild and the patient remained stable. The pharmacological history of the patient was not reported.

Action taken with SQ Remodulin was not applicable for the events of maternal exposure during pregnancy and abortion induced. At the time of reporting, the outcome of maternal exposure during pregnancy and abortion induced was resolved on 24 Apr 2025.

The reporter assessed the causal relationship between the SQ Remodulin, and the events of maternal exposure during pregnancy and abortion induced as not related.

Follow-up information was received on 06 May 2025 as a query response via Ferrer.

On 10 Mar 2025, pregnancy was confirmed through serum B-HCG. It was reported that the patient had not suffered from any infections, nor she had been exposed to unsafe or toxic environments. The patient had no previous pregnancies, miscarriage and abortions. She did not have history of smoking, and use of alcohol and illicit drug.

Case Comment/Senders Comment: The company has assessed the serious adverse event of abortion induced as not related to SQ treprostinil. The event was intentional and appears to have been a medical decision likely related to the high-risk nature of the pregnancy in the context of underlying PAH.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	10-MAR-2025	Human chorionic gonadotropin pregnancy		

13. Relevant Tests

Serum B-HCG (10-MAR-2025): pregnancy;

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Treprostinil sodium (SQ) (TREPROSTINIL SODIUM) Injection, 2.5 mg/ml; Regimen #1	UNK (0.045 mg/ml), continuing; Subcutaneous use	Drug use for unknown indication (Product used for unknown indication)	Ongoing; Unknown
#1) Treprostinil sodium (SQ) (TREPROSTINIL SODIUM) Injection, 2.5 mg/ml; Regimen #2	UNK, continuing; Subcutaneous use	Drug use for unknown indication (Product used for unknown indication)	19-SEP-2024 / Unknown; Unknown

25b. Name And Address of Reporters continued
COSTA RICA

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

Ferrer

COSTA RICA

Dr. Benjamín Ramírez

15-May-2025 21:44

ADDITIONAL INFORMATION

COSTA RICA

NAME AND ADDRESS WITHHELD.