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	GUATEMALA		PRIVACY		14 Years	Female	Unk	29	FEB	2024

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

Other Serious Criteria: Medically Significant
Scoliosis [Scoliosis]

Case Description: Initial information received on 08-May-2025 regarding a solicited valid serious case received from a consumer/non-healthcare professional, in the scope of post-marketing sponsored study "PP-000229".

This case to be linked to case id- GT-SA-2024SA385049 (same patient)

Study Title: Colores de Vida.

(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) IMIGLUCERASE (IMIGLUCERASE) Powder for concentrate for solution for infusion

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 4 DF, QOW	#1) IV drip

17. INDICATION(S) FOR USE
#1) Gaucher disease (Gaucher's disease)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 01-DEC-2014 / Ongoing	#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

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Sanofi-Aventis R&D
82 Avenue Raspail
Gentilly Cedex, 94250 FRANCE
Phone: 33 141247000

26. REMARKS
Medically Confirmed: No
Patient ID: G-CNM005-GT
Study ID: PP-000229

24b. MFR CONTROL NO.
2025SA137699

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

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

DATE OF THIS REPORT
15-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This case involves a 14 years old female patient who had scoliosis while being treated with Imiglucerase [Cerezyme].

The patient's past medical history, medical treatment(s), concomitant medication(s), vaccination(s) and family history were not provided.

On 01-Dec-2014, the patient started taking Imiglucerase Powder for concentrate for solution for infusion, strength 400 iu, at a dose of 4 DF QOW iv (intravenous) drip for Gaucher's disease. It was unknown whether 0.2 micron filter was used for infusion or not. It was unknown whether infusion was done in home settings or not. Last date of infusion was unknown.

On 29-Feb-2024 the patient developed scoliosis (scoliosis) (latency: 9 years 2 months 28 days) (unknown batch number and expiry date) (Seriousness criteria: Medically significant). Reason for which the doctors had evaluated the patient evolution and made the decision to perform corrective surgery in the following weeks (date not provided). No further information was provided by the informant.

Action taken: No Action taken for the event.

Corrective treatment: Surgery to be done for the event (Scoliosis).

At time of reporting, the outcome was Not Recovered / Not Resolved for the event scoliosis.

Reporter Causality: Related

Company Causality: Not reportable