SUSPECT ADVERSE REACTION REPORT

EUDRACT Number: 2019-000831-26

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
5.1.2.e	5.1.2.e			5.1.2.e	5.1.2.e	5.1.2.e	5.1.1.d	23	DEC	2019	

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

Other Serious Criteria: 5.1.1.d

Case Description: 5.1.1.d

(Continued on Additional Information Page)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) RDN-929 (RDN-929) Capsule

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

15. DAILY DOSE(S)
#1) 50 milligram, qd

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

17. INDICATION(S) FOR USE
#1) Dementia Alzheimer's type (Dementia Alzheimer's type)

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

18. THERAPY DATES(from/to)
#1) 20-NOV-2019 / 17-DEC-2019

19. THERAPY DURATION
#1) 27 days

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
5.1.2.e	5.1.2.e	5.1.2.e

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Rodin Therapeutics, Inc.
852 Winter Street
Waltham, MA 02451 UNITED STATES
Phone: +1 5.1.2.e

26. REMARKS
Patient ID: 5.1.2.e
Study ID: RDN-929-103
Center ID: 5.1.2.e

24b. MFR CONTROL NO.
5.1.1.c

25b. NAME AND ADDRESS OF REPORTER
5.1.2.e

24c. DATE RECEIVED BY MANUFACTURER
24-DEC-2019

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

DATE OF THIS REPORT
07-JAN-2020

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Study sponsor determined the event to be serious based on medical importance on 24-DEC-2019. SAE reports with initial and follow-up information was received on 03-JAN-2020 and 06-JAN-2020.

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

5.1.1.d

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d
5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d
5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d
5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d	5.1.1.d

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	

13. Relevant Tests

[redacted]

Mfr. Control Number: NL-MMS-20-ROD-00001

ADDITIONAL INFORMATION

13. Relevant Tests

5.1.1.d

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
5.1.1.d	5.1.1.d	5.1.1.d
5.1.1.d	5.1.1.d	5.1.1.d
	5.1.1.d	
5.1.1.d	5.1.1.d	5.1.1.d
5.1.1.d	5.1.1.d	5.1.1.d
	5.1.1.d	