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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
Z	CHINA	06	OCT	1952	58 Years	Female	54.00 kg	16	FEB	2011	

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

Facial palsy [VIIth nerve paralysis]

Case Description: Case reference number 2011-00787, received on 17-FEB-2011 is a company supported investigator initiated report from study 26866138-MMY-2074, A phase II study to evaluate the effect of PAD followed by ASCT on the concentrations of bone metabolites in patients with newly diagnosed multiple myeloma.

This case was reported by a physician and refers to a 58 year old female patient (004002 / ZXQI) who was diagnosed with multiple myeloma on an unknown

(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) VELCADE (BORTEZOMIB) Injection {Lot # not reported}

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

15. DAILY DOSE(S)
#1) 1.3 mg/m2, UNK

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

17. INDICATION(S) FOR USE
#1) multiple myeloma (Multiple myeloma)

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

18. THERAPY DATES(from/to)
#1) 24-JAN-2011 / Unknown

19. THERAPY DURATION
#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
Unknown	Indication	Multiple myeloma (Multiple myeloma)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Millennium Pharmaceuticals, Inc.
Veronique F. Kugener, MD
40 Landsdowne Street
Cambridge, MA 02139 UNITED STATES
Phone: 01 617-551-2972

26. REMARKS

24b. MFR CONTROL NO.
2011-00787

24c. DATE RECEIVED BY MANUFACTURER
17-FEB-2011

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

DATE OF THIS REPORT
25-FEB-2011

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
Qiu Lugui
REF: MMY-2074-CHN-1
No.288 Nanjing Road
Heping District
Tianjin city

CHINA

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

date. The patient's medical history and concomitant medications were not reported.

The patient began treatment with bortezomib (VELCADE) 1.3mg/M2 intravenously on 24-JAN-2011 for multiple myeloma. On 16-FEB-2011 (16:00hrs) the patient experienced right facial palsy. This patient experienced a disappearance of the right nasolabial fold and developed a forehead wrinkle. The patient also experienced difficulty in swallowing and lolling that affected her ability to eat and drink. The patient was admitted to hospital on 17-FEB-2011 where the patient underwent examination. A brain magnetic resonance imaging (MRI) scan showed no abnormalities. The patients treatment included acupuncture and an unspecified injection for the nutritis. VELCADE therapy was interrupted. The event was ongoing at the time of the report.

The investigator assessed the event of facial palsy as possibly related to VELCADE. The investigator confirmed that the event was not related to the trial procedure.

13. Relevant Tests

??-FEB-2011 MRI Brain Scan: normal results