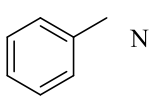
2007	01	24
2009	12	31
2011	06	26
2012	07	02
2014	11	19
2017	10	13
2020	09	10
2021	01	19
2022	06	28

Pemetrexed Disodium for Injection

Zhusheyong Peimeiqusai ’erna

N-{4-[2-(2- -4,7- -4 -1H- [2,3-d] -5-)] }-L-



$C_{20}H_{19}N_5Na_2O_6 \cdot 2\frac{1}{2}H_2O$

516.41

EGFR

ALK

EGFR

ALK NSCLC

4

0.2g

“ ”

500mg/m^2 BSA 10 21

1

500mg/m^2 BSA 10 21

1

75mg/m^2 BSA 2

21 1 30 /

500mg/m^2 BSA

10 21 1

350~1000μg 7 5

21

B_{12} 1000μg 3

B_{12}

4mg

WCC

ANC ≥1500 /mm^3 ≥100,000 /mm^3

≥45mL/min ≤1.5 AP

AST SGOT ALT SGPT ≤3

AST ALT≤5

1-3

1-3

1

<500/mm^3 ≥ 50,000/mm^3	75%
<50,000/mm^3	75%
<50,000/mm^3 [a]	50%

[a] NCI CTCAE CTCAE v2.0 NCI 1998 ≥ CTCAE 2 CTCAE=

≥ 3

2

2 [a,b]

	mg/m²	**mg/m²**
3 4	75%	75%
3 4	75%	75%
3 4	50%	100%

[a] NCI CTCAE

1.

2.

≥20%

≥20%

/

NSCLC

KEYNOTE-189

JMDB

ثم

4 JMDB

[a] + **(N=839)**

— GGT

—

JMEN 4

NSCLC 2:1

21 500mg/m^2

B_{12}

JMEN ECOG PS 2

45mL/min

B_{12}

JMEN 438 61

26-83 73% 65% 31% 2.9%

<2% 39% ECOG PS 0 5

96% 48% 6 21

23% 10 21

5 JMEN 438 ≥5%

5 JMEN

[a]	**(N=438)**		**(N=218)**	
	(%)	**3-4 (%)**	**(%)**	**3-4 (%)**
	66	16	37	4
	15	3	6	1
	6	3	0	0
ALT	10	0	4	0
AST	8	0	4	0
	25	5	11	1
	19	1	6	1
	19	2	5	0
	9	0	1	0

/	7	1	2	0
	5	1	3	0
	5	2	2	0

PARAMOUNT 333 61

32 83 58% 94% 4.8% <1%

36% ECOG PS 0 4

3.3% 0.6% 22%

16%

6 PARAMOUNT 333 ≥5%

6 PARAMOUNT

[a]	**(N=333)**		**(N=167)**	
	(%)	**3-4 (%)**	**(%)**	**3-4 (%)**
	53	17	34	4.8
	15	4.8	4.8	0.6
	9	3.9	0.6	0
	18	4.5	11	0.6
	12	0.3	2.4	0
	6	0	1.8	0
/	5	0.3	2.4	0
	5	0	3.6	0

[a] NCI CTCAE 3.0

13% vs. 4.8% 1.5% vs. 0.6%

12% vs. 7% 6% vs. 0%

3 4

1% <5%

/ —

—

<1%

—

—

—

—

—

—

JMEI 1:1

21 1

500mg/m^2 75mg/m^2

B_{12}

JMEI ECOG PS 3

45mL/min

B_{12}

JMEI 265 58

22 87 73% 70% 24% 2.6%

1.8% <2% 19% ECOG PS 0

7 JMEI 265 ≥5%

JMEI 7

7 JMEI

	16	2	12	1
/	15	1	17	1
	13	0	24	3
	6	0	4	0
	34	5	36	5
	8	0	8	0
/				
/	14	0	6	0
	7	0	2	0
	6	1	38	2

[a] NCI CTCAE 2.0

1% 5%

— /

/ —

—

1%

JMCH 1:1

21 1

500mg/m^2 75mg/m^2 21 1 75mg/m^2

226 1

222 1 226

74% n=168

B_{12} 14% n=32 12% n=26

JMCH KPS 70

45mL/min

B_{12} 168

60 19 85 82% 92% 5%

3.0% <1% 54% KPS 90-100 /

6 / 2

93%

8 JMCH ≥5%

JMCH 8

8 JMCH / [a]

[b]	+ (N=168)		(N=163)	
	(%)	**3-4 (%)**	**(%)**	**3-4 (%)**
	56	23	13	3
	53	15	17	1
	26	4	10	0
	23	5	9	0
	11	1	10	1
	16	1	18	2
	5	0	1	0
	82	12	77	6
	57	11	50	4
/	23	3	6	0
	20	1	14	1
	17	4	8	0
	12	1	7	1
	5	1	1	0
	48	10	42	9
	7	4	1	1
	10	0	10	1
	8	0	6	0
/				
	16	1	5	0
	11	0	6	0

[a] JMCH 226 1 222 1
8 B_{12} 168
163 ADR

[b] NCI CTCAE 2.0

1% 5%

—

/ —

—

— AST ALT GGT

—

1%

—

—

—

Stevens-Johnson

ORIENT-11

≥20%

10 JMID 106

102 ≥2% CTCAE 3

4

10 JMID CTCAE 3 4

	(N=106) n (%)	**(N=102) n (%)**	**P** [a]
	22(20.8)	41 (40.2)	0.003
	7 (6.6%)	3 (2.9%)	0.333
	4 (3.8%)	21 (20.6%)	<0.001
/	5 (4.7%)	29 (28.4%)	<0.001
	7 (6.6%)	0 (0.0%)	0.014
	0 (0.0%)	5 (4.9%)	0.027
	3 (2.8%)	5 (4.9%)	0.492
	2 (1.9%)	4 (3.9%)	0.439

N= n= CTCAE=

[a] P Fisher 3 4

JMIL

252 AC 125
GC 127 AC
6 AC AC 3 4
GC 63 [50.4%] vs. 84 [66.1%] p=0.015 AC
43.2% ≥1 3 4 GC
55.9% p=0.045 AC 50 [40.0%] vs. 76 [59.8%] p=0.002
50 [40.0%] vs. 76 [59.8%] p=0.002 4 [3.2%] vs. 15 [11.8%]
p=0.015 GC
11 JMEN
5% CTCAE

11 JMEN 5%

a	b	(N=62)		(N=37)	
		(%)	3 4 (%)	(%)	3 4 (%)
		32.3	1.6	16.2	2.7
		30.6	1.6	13.5	0.0
	ALT SGPT	22.6	1.6	16.2	0.0
	/	17.7	0.0	5.4	0.0
	AST SGOT	16.1	0.0	16.2	0.0
		16.1	0.0	2.7	0.0
		14.5	0.0	2.7	0.0
	/	11.3	1.6	0.0	0.0
	-	11.3	0.0	0.0	0.0
		9.7	0.0	0.0	0.0
		8.1	0.0	0.0	0.0
	-	6.5	0.0	0.0	0.0
		6.5	0.0	0.0	0.0

ALT= AGC= ANC= AST=
CTCAE= CTCAE 3.0 NCI2003 G= N=
SGOT= SGPT= WBC=
a =≥10% =≥5% <10%
5%
b CTCAE 3.0 NCI2003

B_{12}

B_{12}

B_{12} 3/4

3/4

ANC ≥1500 /mm^3

≥100,000 /mm^3

ANC

<45mL/min

<45mL/min

-

- 45 79mL/min 2

2 NSAIDs 1.3g/

5 2

NSAIDs

6

31 2

/

0.2g 21.5mg

65 65 65

65

(NSAIDs)

≥80 mL/min NSAIDs

1600 mg/ ≥ 1.3 g/

≥ 80

mL/min NSAIDs

≥45-79 mL/min 2

2 NSAIDs

NSAIDs

NSAIDs 5

2 NSAIDs NSAIDs

P450

CYP3A CYP2D6 CYP2C9 CYP1A2

INR

/

TS

DHFR GARFT

TS GARFT

Ames

≥0.1 mg/kg/ 0.006

9

500mg/m^2 0.03

500mg/m^2 0.0012

426 0.2-

838 mg/m^2 10 9 L/m^2

81%

24 70%-90%

OAT3 3

90 mL/min) 91.8 mL/min

3.5 19.3%

AUC

26 80

B_{12}

22 4 18 12 13 9

400 2480 mg/m^2 AUC

Cmax 2.30 $L/h/m^2$

2.3

1 /

36

YBH13932020

H20051288

5

222069

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