

2019 12 26
2020 02 21
2020 06 22
2020 07 02

®

Guselkumab Injection

Gusaiqiyou Dankang Zhusheye

L-

L-

80

100 mg/1 mL/

—

0

4

100 mg

8

16

/

48 III 0.7%
156 0.5%

0.3%

52

7%
0.4%

II III
6%

156

III
9%

•
•
•

TB

TB
TB

12

2

30

“ ”

.

12

IgG

30

MRHD
MRHD 6 30

—

IgG

—

18

2636

65

160

65

13

75

65

—

CYP450

CYP450

IL-1 IL-6 IL-10

TNF

CYP3A4 CYP2C9 CYP2C19 CYP1A2
CYP2D6

CYP450

CYP450

987 mg 10 mg/kg
300 mg

3

III

VOYAGE 1 VOYAGE 2
VOYAGE 1 VOYAGE 2 1829
N=825
0 4 100 mg 8 q8w 48 VOYAGE 1
20 VOYAGE 2 N=582 0 80
mg 1 40 mg 40 mg q2w 48
VOYAGE 1 23 VOYAGE 2
N=422 16 20 8 100 mg
VOYAGE 1 0 52
8 28 VOYAGE 2 0
8 8 PASI 90
28 PASI 50%
4 8 0
PASI 90 28 32 8
VOYAGE 2 76
8
VOYAGE 1 2 BSA
22% 24% PASI 19 DLQI
14 14.5 25% 23% IGA
19% 18%
VOYAGE 1 2 32% 29%
54% 57% 62% 64%
21% 11% α
TNFα 10% IL-12/IL-23

VOYAGE 1 2 16 IGA
 IGA 0/1 PASI 90 2

16

24

48

2

2 VOYAGE 1 VOYAGE 2

	%					
	VOYAGE 1			VOYAGE 2		
	N=174	N=329	N=334	N=248	N=496	N=248
16						
PASI 75	10 (5.7)	300 (91.2) ^a	244 (73.1) ^b	20 (8.1)	428 (86.3) ^a	170 (68.5) ^b
PASI 90	5 (2.9)	241 (73.3) ^c	166 (49.7) ^b	6 (2.4)	347 (70.0) ^c	116 (46.8) ^b
PASI 100	1 (0.6)	123 (37.4) ^a	57 (17.1) ^d	2 (0.8)	169 (34.1) ^a	51 (20.6) ^d
IGA 0/1	12 (6.9)	280 (85.1) ^c	220 (65.9) ^b	21 (8.5)	417 (84.1) ^c	168 (67.7) ^b
IGA 0	2 (1.1)	157 (47.7) ^a	88 (26.3) ^d	2 (0.8)	215 (43.3) ^a	71 (28.6) ^d
24						
PASI 75	-	300 (91.2)	241 (72.2) ^e	-	442 (89.1)	176 (71.0) ^e
PASI 90	-	264 (80.2)	177 (53.0) ^b	-	373 (75.2)	136 (54.8) ^b
PASI 100	-	146 (44.4)	83 (24.9) ^e	-	219 (44.2)	66 (26.6) ^e
IGA 0/1	-	277 (84.2)	206 (61.7) ^b	-	414 (83.5)	161 (64.9) ^b
IGA 0	-	173 (52.6)	98 (29.3) ^b	-	257 (51.8)	78 (31.5) ^b
48						
PASI 75	-	289 (87.8)	209 (62.6) ^e	-	-	-
PASI 90	-	251 (76.3)	160 (47.9) ^b	-	-	-
PASI 100	-	156 (47.4)	78 (23.4) ^e	-	-	-
IGA 0/1	-	265 (80.5)	185 (55.4) ^b	-	-	-
IGA 0	-	166 (50.5)	86 (25.7) ^b	-	-	-

^a

p 0.001

^b

p 0.001

^c

p 0.001

^d

^e

p 0.001

0.001

8

2

PASI

p

PASI 90

20

VOYAGE 1 2

48

VOYAGE 1

1

2 48 VOYAGE 1 [NAPSI] p 0.001 3 24 VOYAGE 1
 p 0.05 24 [VOYAGE 2] 48 [VOYAGE 1]

3 VOYAGE 1 VOYAGE 2

	VOYAGE 1			VOYAGE 2		
ss-IGA (N)^a	145	277	286	202	408	194
ss-IGA 0/1 ^b , n (%)						
16	21 (14.5)	231 (83.4) ^c	201 (70.3) ^d	22 (10.9)	329 (80.6) ^c	130 (67.0) ^d
hf-PGA (N)^a	43	90	95	63	114	56
hf-PGA 0/1 ^b , n (%)						
16	6 (14.0)	66 (73.3) ^e	53 (55.8) ^d	9 (14.3)	88 (77.2) ^e	40 (71.4) ^d
f-PGA (N)^a	88	174	173	123	246	124
f-PGA 0/1, n (%)						
16	14 (15.9)	68 (39.1) ^e	88 (50.9) ^d	18 (14.6)	128 (52.0) ^e	74 (59.7) ^d
NAPSI (N)^a	99	194	191	140	280	140
SD						
16	-0.9 (57.9)	34.4 (42.4) ^e	38.0 (53.9) ^d	1.8 (53.8)	39.6 (45.6) ^e	46.9 (48.1) ^d

^a ss-IGA f-PGA hf-PGA 2 NAPSI 0
^b ss-IGA / hf-PGA 2
^c p 0.001
^d
^e p 0.001

VOYAGE 1 2 16 [DLQI]

4 VOYAGE 1 2 48 VOYAGE 1
 VOYAGE 1 156 5

4 16 VOYAGE 1 VOYAGE 2

	VOYAGE 1			VOYAGE 2		
DLQI	170	322	328	248	495	247
16	-0.6 (6.4)	-11.2 (7.2) ^c	-9.3 (7.8) ^b	-2.6 (6.9)	-11.3 (6.8) ^c	-9.7 (6.8) ^b

PSSD	0	129	248	273	198	410	200
	=0 n %						
16		1 (0.8)	67 (27.0) ^a	45 (16.5) ^b	0	112 (27.3) ^a	30 (15.0) ^b
PSSD	0	129	248	274	198	411	201
	=0 n %						
16		0	50 (20.2) ^a	32 (11.7) ^b	0	86 (20.9) ^a	21 (10.4) ^b

^a p 0.001

^b

^c

p 0.001

5 VOYAGE 1

		76	^a 156	^b 76	156
DLQI	>1 n	445	411	264	251
DLQI 0/1		337 (75.7%)	307 (74.7%)	198 (75.0%)	190 (75.7%)
PSSD	>0	347	319	227	214
	=0 n %	136 (39.2%)	129 (40.4%)	99 (43.6%)	96 (44.9%)
PSSD	>0	347	319	228	215
	=0 n %	102 (29.4%)	93 (29.2%)	71 (31.1%)	69 (32.1%)

VOYAGE 2 16

36 [SF-36]

[HADS]

[WLQ]

28

SF 36 HADS WLQ 48

156

NAVIGATE

NAVIGATE 16

IGA 2

N=871 0

4

45 mg 100 mg 90 mg 100 mg

16

268 IGA 2

N=133 12

16 20

N=135 8

VOYAGE 1 2

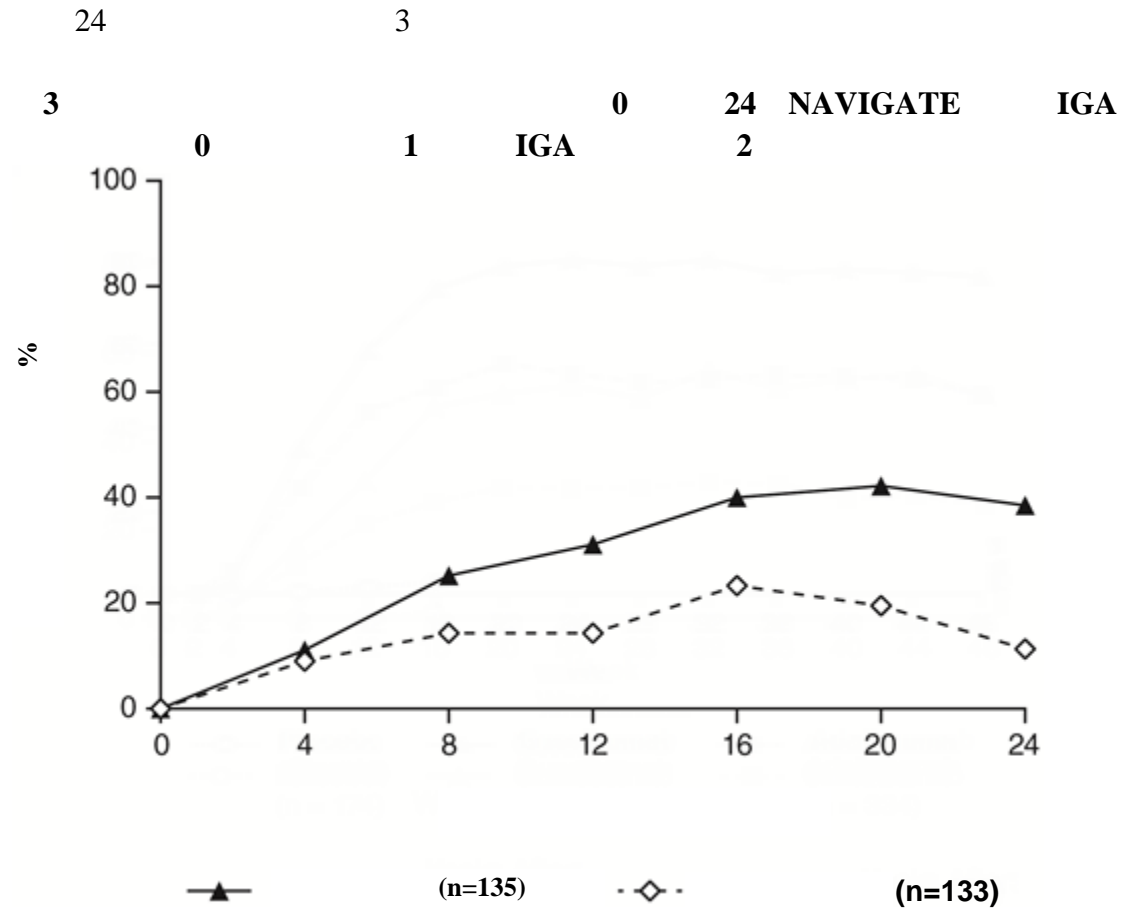
12 24 IGA 0/1

2

12-24 IGA 0/1 2 2

IGA 0/1 2 2

1.5 vs 0.7 p 0.001
 IGA 0/1 2 31.1% 14.3% p=0.001 PASI 90 48%
 23% p 0.001 4 11.1% 9.0%



ECLIPSE

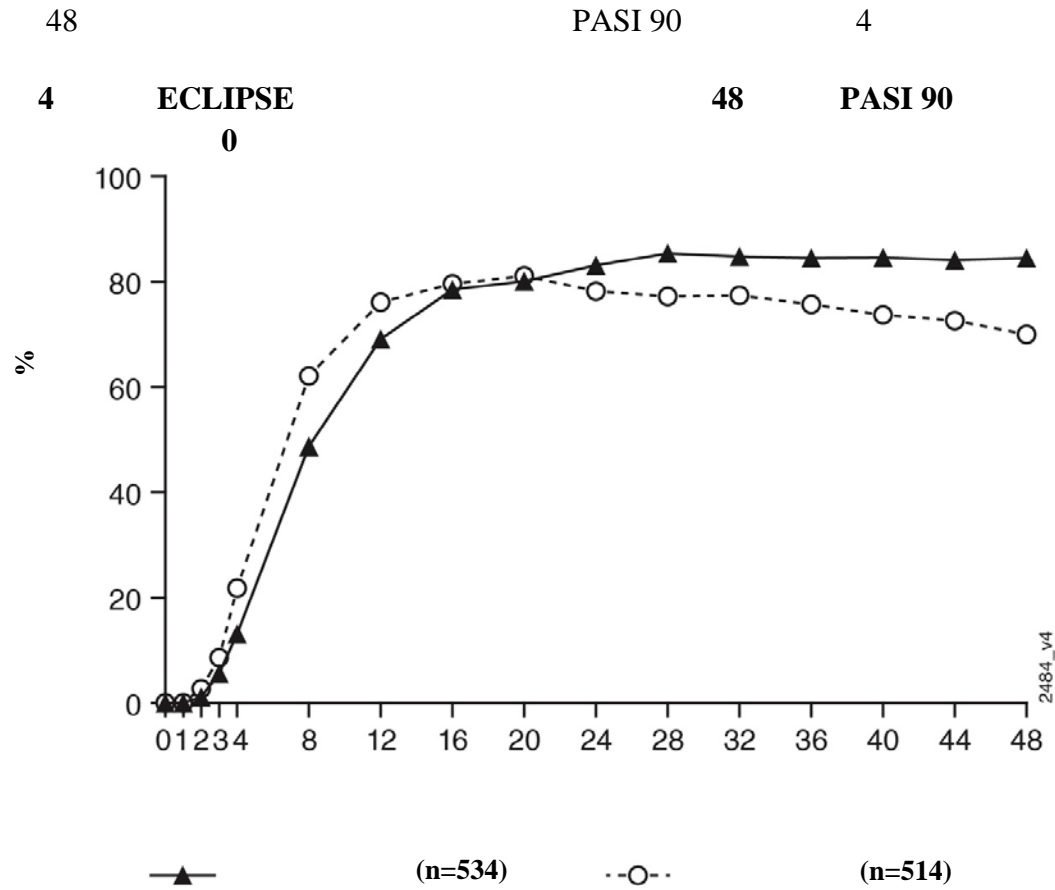
N=514 0 1 2 3 4 N=534 0 4 100 mg 8
 44 300 mg 4

18 24% IGA BSA 20% PASI
 48 PASI 90
 84.5% vs. 70.0% p<0.001 PASI 6

6 ECLIPSE PASI	%	
	N=534	N=514

48	PASI 90	451 (84.5%) ^a	360 (70.0%)
12	48 PASI 75	452 (84.6%) ^b	412 (80.2%)
12	PASI 75	477 (89.3%) ^c	471 (91.6%)
12	PASI 90	369 (69.1%) ^c	391 (76.1%)
48	PASI 100	311 (58.2%) ^c	249 (48.4%)

^a p<0.001
^b p < 0.001 p=0.062
^c



IL-23 IgG1λ IL-23 23 IL-23 p19

IL-17A IL-17F IL-22

mg/kg 2
100 mg/kg MRHD 15 25 mg/kg
mg/kg 2
MRHD 60

MRHD 6 30 3 1 10 mg/kg 50mg/kg mg/kg
6
28

SD 100 mg 5.5 ±
C_{max} 8.09 ± 3.68 mcg/mL ±

0 4 8 100 mg 20
III ± SD
1.15 ± 0.73 mcg/mL 1.23 ± 0.84 mcg/mL

100 mg
49%

10 L V_z 7-

IgG IgG mAb

0.479 L/

15-18

CL
T_{1/2}

0.288 -
17

/

10 mg - 300 mg

C_{max} AUC

1384

65

70

65

65

4

75

CL/F

/

IgG mAb

IgG mAb

2 8°C

100 mg

1 mL

1 /

24

JS20190043

S20190044

Janssen-Cilag International NV
Turnhoutseweg 30, B-2340 Beerse,

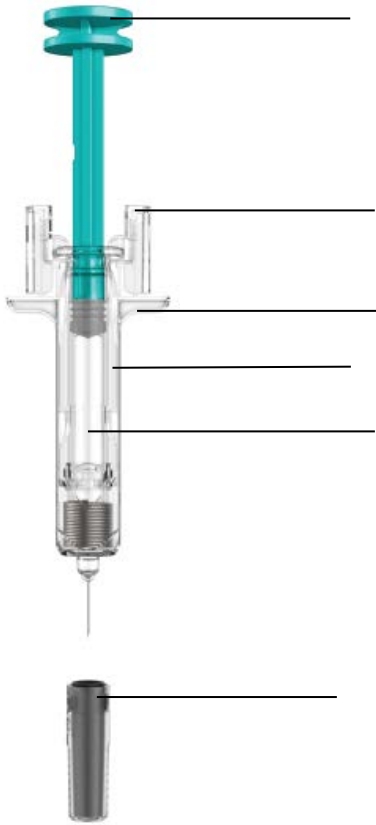
: Cilag AG
: Hochstrasse 201, 8200 Schaffhausen,

:
:
: 710304
: 400 888 9988
: (029) 8257 6616
: <http://www.xian-janssen.com.cn>

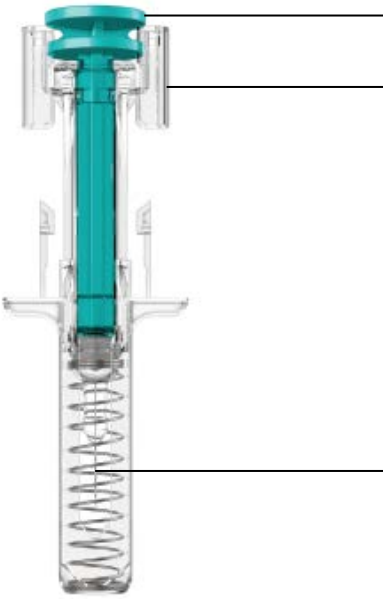
19



2°C-8°C

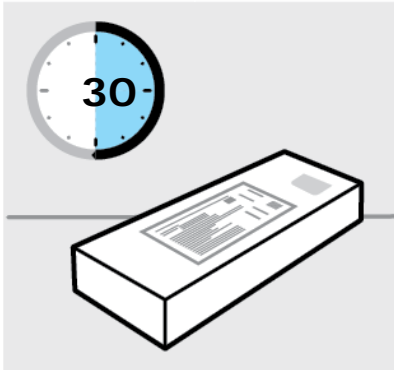


2



- 1
 - 1
 - 1
 - 1
- 3

1.



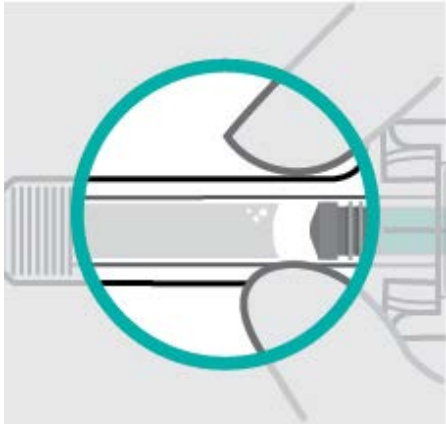
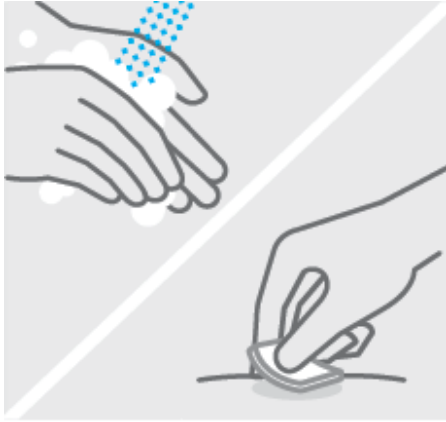
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“EXP”

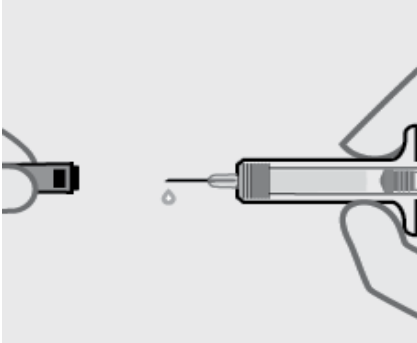


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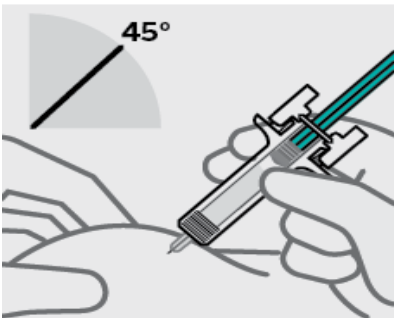
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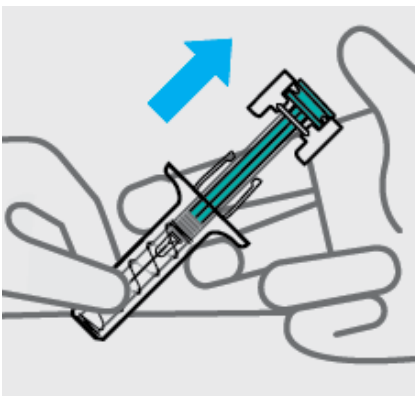
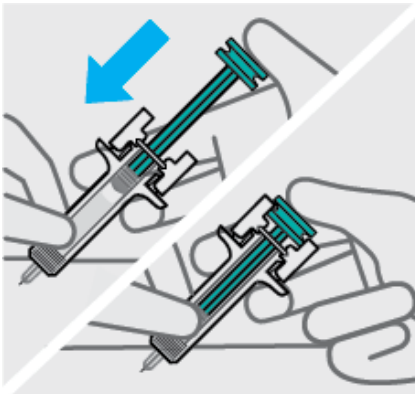
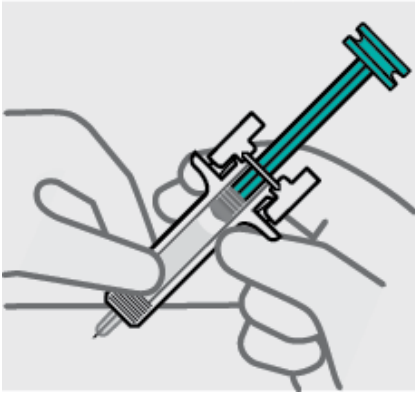
2.



5



45



3.

