

2007	02	15
2007	11	27
2007	12	26
2008	03	07
2008	10	13
2009	02	13
2010	04	07
2010	11	12
2011	10	12
2011	11	30
2012	03	12
2012	08	10
2013	01	25
2013	08	15
2013	10	17
2013	10	31
2015	08	31
2016	08	09
2016	11	07
2017	01	16
2017	06	16
2018	11	19
2018	12	24
2019	05	05
2020	02	18
2020	07	01
2021	01	19
2021	04	06
2021	06	16

警示语：严重感染和恶性肿瘤

严重感染

使用本品进行治疗的患者发生严重感染的风险增高，可导致住院或死亡。发生感染的多数患者正在合并使用免疫抑制剂，如甲氨蝶呤或糖皮质激素。

如果患者发生严重感染或脓毒症，应停用本品。

报告的感染包括：

- 活动性结核病，包括潜伏性结核病的复发。结核病患者经常伴随出现弥散性或肺外疾病。需在本品治疗前及治疗期间检测患者是否存在潜伏性结核病。如检查结果为阳性，则应在本品用药前对潜伏性结核病进行治疗。
- 侵袭性真菌感染，包括：组织胞浆菌病、球孢子菌病、念珠菌病、曲霉病、芽生菌病和肺囊虫病。组织胞浆菌病或其它侵袭性真菌感染患者多表现为弥散性，而非局灶性的疾病。在某些存在活动性感染的患者中，组织胞浆菌病的抗原和抗体检测结果可能是阴性的。若重度系统性疾病患者存在发生侵袭性真菌感染的危险，应考虑进行经验性的抗真菌治疗。
- 细菌、病毒及其它条件致病菌导致的感染，包括军团杆菌和李斯特菌。
对慢性或复发性感染患者治疗前，应慎重考虑本品治疗的风险和获益。
在本品治疗期间及治疗后，应密切监测患者是否出现感染的症状和体征，包括开始治疗前潜伏性结核病感染检测结果为阴性的患者。

恶性肿瘤

有报告显示，儿童和青少年患者使用包括本品在内的肿瘤坏死因子（ ）抑制剂治疗时，有淋巴瘤和其它恶性肿瘤的发生，其中有些是致命的。

本品上市后，已经有报告在接受包括本品在内的 抑制剂治疗的患者中出现了肝脾 细胞淋巴瘤（ ）病例，这是一种罕见的 细胞淋巴瘤。这些病例的病程呈侵袭性，可以导致死亡，绝大多数发生在克罗恩病或溃疡性结肠炎患者中，且大多数为青少年或青年男性。几乎上述所有患者均在接受 抑制剂时或之前短时间内接受过硫唑嘌呤或 巯基嘌呤的治疗。

®

Infliximab for Injection

Zhusheyong Yingfulixi Dankang

•

•

6

6

•

•

•

•

•

•

-

-

•

•

•

•

•

100mg/

	3mg/kg		2	6	8
10mg/kg /		4			
	5mg/kg		2	6	8
				10mg/kg	
	6	17			
	5mg/kg		2	6	8
			10		
				5mg/kg	8
		6			
			6		
	5mg/kg		2	6	6
	5mg/kg		2	6	8
		14	4		

	20				

8

5mg/kg

2

6

8

2

1~2

/

/

/

1.

100mg

2.

21

0.8mm

10ml

5

3. 0.9% 250ml 250ml 0.9%

0.4mg/ml 4mg/ml
 4. 3 2
 ≤1.2μm

5.

ADR

25.3% 16.5%

HBV TNF CHF

/ T

HSTCL / Merkel

1

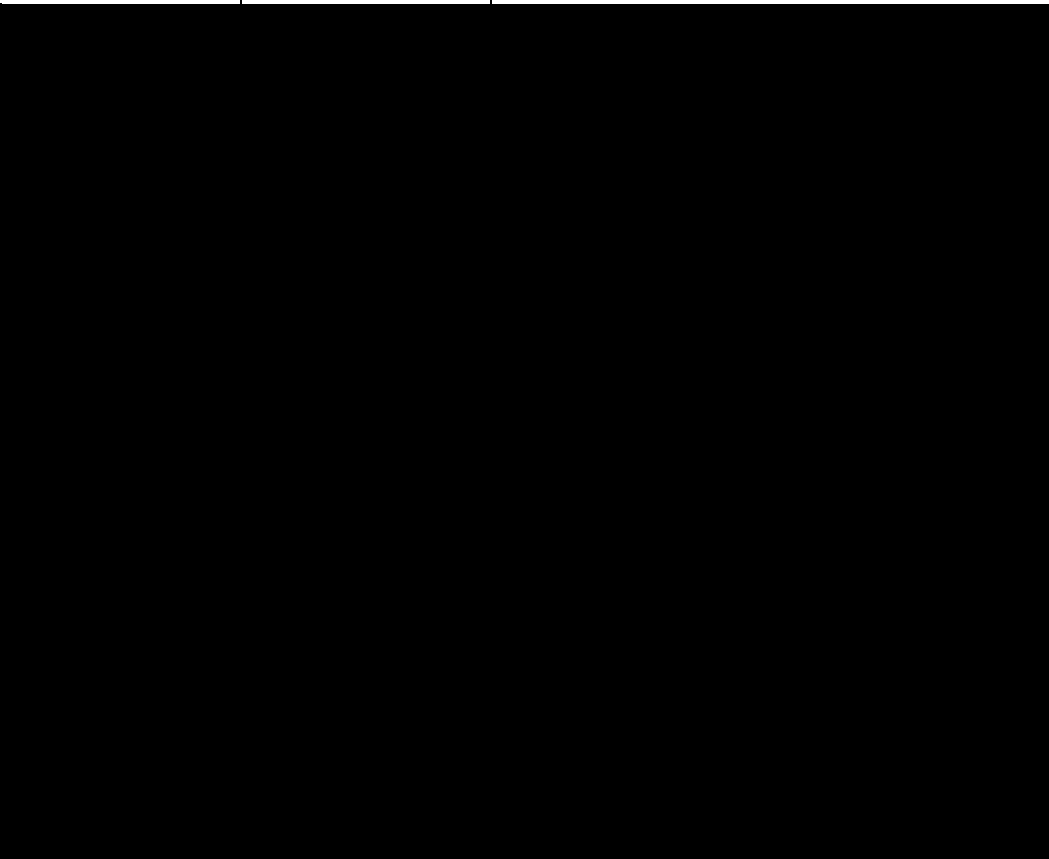
≥1/10 ≥1/100

<1/10 ≥1/1000 <1/100 ≥1/10000 <1/1000 <1/10000

1

	[]
	*
	T

	Merkel



2~3

ASPIRE 3 2

40 66% 1040

686 90 44% 1040

454 60

15% 74/494 0.4% 2/494

6mg/kg

SONIC

16.6% 27/163 AZA AZA

5% 9/179 5.6% 9/161

1 <1%

2

24 /

4 0 2 6 14

4% 8/219 <1% 1/222

0 2 6 14 4

2

2

/

1%

/ /

ACCENT I

2.4%

3 1~2

10% >16

191

MTX 5mg/kg 15%

6-

/ 6-MP/AZA MTX

II 5mg/kg 3mg/kg 5mg/kg 8

36% 3mg/kg 8

51% III SPIRIT

5mg/kg 3mg/kg 5mg/kg 0 2 6

20% 3mg/kg

27% I II 5mg/kg

8 III

5mg/kg 14.1%~23.0%

<1%

5%

36% 25%

6mg/kg

50%

ALT

ULN 5

ALT

AST 2

ALT 2

ALT AST

2 ALT

	1		2		ALT					
					>1	<3×ULN	≥3×ULN		≥5×ULN	
3	375	1087	58.1	58.3	24.0%	34.4%	3.2%	3.9%	0.8%	0.9%
4	324	1034	53.7	54.0	24.1%	34.9%	2.2%	4.9%	0.0%	1.5%
5	n/a	139	n/a	53.0	n/a	18.2%	n/a	4.4%	n/a	1.5%
6	242	482	30.1	30.8	12.4%	17.4%	1.2%	2.5%	0.4%	0.6%
7	n/a	60	n/a	49.4	n/a	16.7%	n/a	6.7%	n/a	1.7%
8	76	275	24.1	101.9	14.5%	51.1%	0.0%	9.5%	0.0%	3.6%
	98	191	18.1	39.1	16.3%	49.5%	0.0%	6.8%	0.0%	2.1%
9	281	1175	16.1	50.1	23.8%	49.4%	0.4%	7.7%	0.0%	3.4%

1	ALT										
2											
3											
4	2	3	C0168T21	C0168T26							5mg/kg
			ALT								
		1	3b	C0168T67							
5	2.5mg/kg/										
6			T23 T55 T47		53						
			C0168T37 C0168T46						30		
7	31										
	C0168T72										
8	C0168T51										
9	ALT	2	3	C0168T38	C0168T44						

5780 5494 - 5 26

1600 941 - 1

5 3210 6234 -

5 38

COPD

1 0.8 [5.7% 95%

2.65%~10.6%] 77 1 0.8 [

1.3% 95% 0.03%~7.0%]

60

T

ANA / dsDNA

ANA ANA

ANA 20%

dsDNA 17% 0%

[NYHAIII/IV

<35%] 150 10mg/kg 5mg/kg

0 2 6 10mg/kg

8 10mg/kg 5mg/kg 4

10mg/kg 5mg/kg

NYHA I/II

50

103		5mg/kg	54			
		385				10.7%
9.7%			8.7%	8.7%		7.8%
6.8%	6.8%			5.8%		5.8%
REACH		56.3%			ACCENTI	50.3%
	5mg/kg		REACH		8	
	12		73.6%	38.0%	8	
12		3	4			
				3		8
2	12		1	8	2	
		REACH	17.5%		1	
8	12			17.0%	18.0%	REACH
	2					
3	2.9%					
	≥65					
			65			65
			11.3%	4.6%	65	
65				5.2%	2.7%	

Merkel

T

/

2

24

/

-
-
-

III/IV

TNF

65

/

-
-
-

•

•

T

CT

T cell enzyme-linked immune-spot assay T-SPOT. TB

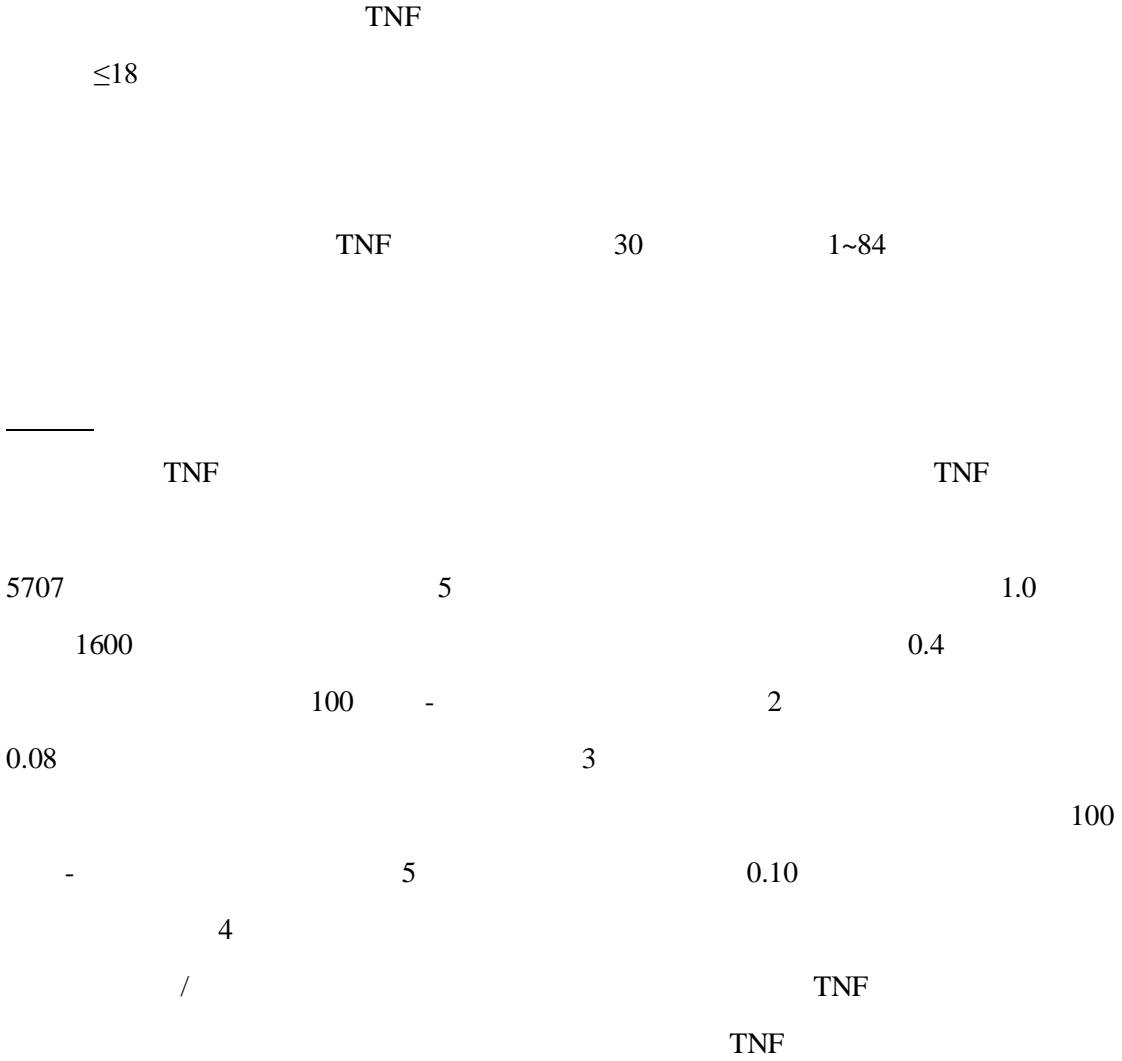
TNF

BCG

5 mm

/

/



TNF

2

TNF

≤18

JIA

22

6-

TNF

T- HSTCL

TNF

T-

HSTCL

T-

TNF

6-

HSTCL

TNF

TNF

HSTCL

6-

HSTCL

TNF

Merkel

60

60

TNF

TNF

[

NMSC]

14

1

0.4

0.11/100 -

4019

NMSC

1597

0.52/100 -

0.5

COPD

COPD

NMSCs

NMSCs

TNF

TNF

TNF

TNF

HBV

HBV

HBV

TNF

HBV

HBV

TNF
HBV
TNF
TNF
TNF

HBV
HBV
TNF
HBV

2

5

/

ALT AST

10mg/kg NYHA III/IV
5mg/kg 10mg/kg

50

/

2

/

/

/

0 2 6

-

TNF

/

-

TNF α

TNF α

TNF α

TNF α

/
TNF

12

12

6

450

230

TNF α

TNF α

12

12

6

III

REACH

6-

6

21

6 17

5mg/kg

6 17

65

65

181

75

65

65

65

65

18~65

65

65

65

TNF α

TNF α

TNF α

DMARDs

TNF

MTX

MTX

MTX

NSAIDs

/

6-MP/AZA

MTX

NSAIDs

MTX

P450

CYP450

CYP450

[

TNF α

-1 IL-

1

-6 IL-6

-10 IL-10

IFN]

CYP450

CYP450

/

12

20mg/kg

ATTRACT

TNF

ASPIRE

≤10mg/ /

ACR

428

ATTRACT

30 54 102

54

8.4

20 31 50%

III

3mg/kg

10mg/kg

0 2 6

4 8

6

15mg/

ASPIRE

1004

<3

54

51

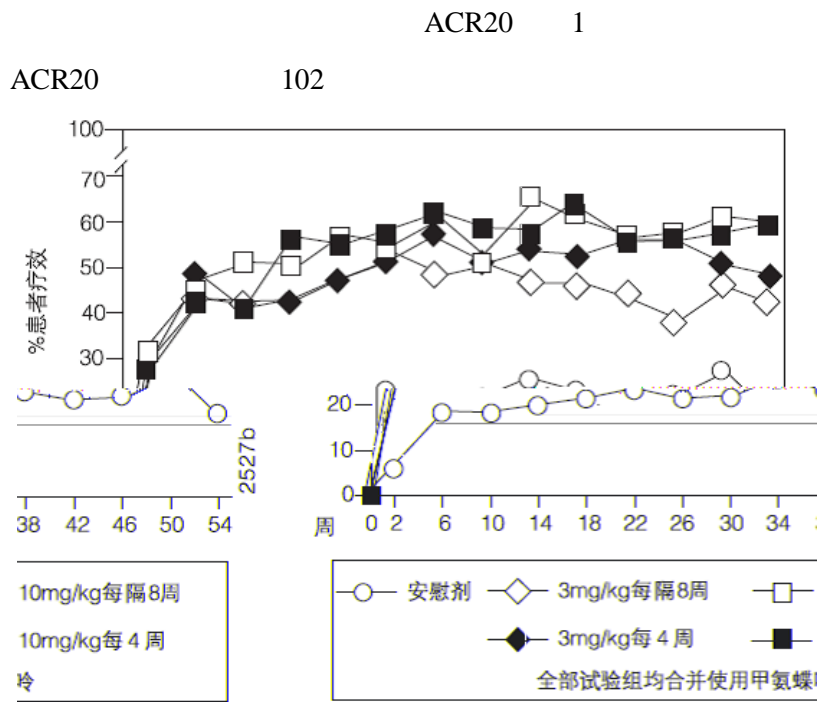
0.6

19 31

0 2 6

8

3mg/kg 6mg/kg 8
 20mg/ 3 2
 40
 5 3 20%
 ACR20 5 /
 ESR C- CRP
 ATTRACT 54



1 ACR20

ATTRACT 3 10%
 ACR50 6 0%
 ACR70 6 0%
 p<0.018

3 ATTRACT ACR

	+	+			
		3mg/kg* 8	3mg/kg* 4	10mg/kg* 8	10mg/kg* 4
	(n=88)	(n=86)	(n=86)	(n=87)	(n=81)
ACR50					
30	5%	27%	29%	31%	26%
54	9%	21%	34%	40%	38%
102	6%	21%	30%	36%	20%

ACR70					
30	0%	8%	11%	18%	11%
54	2%	11%	18%	26%	19%
102	1%	10%	21%	20%	10%
* p<0.05					

ASPIRE 54 ACR20 ACR50
 ACR70 4
 15% 8% p=0.003

4 ASPIRE ACR

	(n=274)	+	
		3mg/kg 8 (n=351)	6mg/kg 8 (n=355)
ACR20			
54	54%	62% ^a	66% ^b
ACR50			
54	32%	46% ^b	50% ^b
ACR70			
54	21%	33% ^c	37% ^b
^a p<0.05 ^b p<0.001 ^c p=0.002			

54
 van der Heijde-modified Sharp /

ATTRACT 80% 5 54
 102

5 ATTRACT 54

(10 90)	+	+				p *
		3mg/kg 8 (n=71)	3mg/kg 4 (n=71)	10mg/kg 8 (n=77)	10mg/kg 4 (n=66)	
54	(n=64)	(n=71)	(n=71)	(n=77)	(n=66)	
	55 (14 188)	57 (15 187)	45 (8 162)	56 (6 143)	43 (7 178)	
	4.0 (-1.0 19.0)	0.5 (-3.0 5.5)	0.1 (-5.2 9.0)	0.5 (-4.8 5.0)	-0.5 (-5.7 4.0)	p<0.001

	25 (8 110)	29 (9 100)	22 (3 91)	22 (3 80)	26 (4 104)	
	2.0 (-1.0 9.7)	0.0 (-3.0 4.3)	-0.3 (-3.1 2.5)	0.5 (-3.0 2.5)	-0.5 (-2.7 2.5)	p<0.001
JSN						
	26 (3 88)	29 (4 80)	20 (3 83)	24 (1 79)	25 (3 77)	
	1.5 (-0.8 8.0)	0.0 (-2.5 4.5)	0.0 (-3.4 5.0)	0.0 (-3.0 2.5)	0.0 (-3.0 3.5)	p≤0.001
*						

ASPIRE 90% 2 30
 54 6 +
 97% 86% 7 +
 79% 57% 8
 + 47% 59%

6 ASPIRE 54

(10 90)		+		p *
		3mg/kg 8	6mg/kg 8	
54	(n=279)	(n=355)	(n=360)	
	5.05 (1.40 14.50)	5.15 (1.75 15.05)	5.25 (1.75 14.20)	
	0.43 (0.00 4.53)	0.00 (-0.75 1.25)	0.00 (-1.00 1.25)	p<0.001
	3.00 (0.50 10.50)	3.75 (1.00 11.00)	3.75 (1.00 10.75)	
	0.25 (0.00 3.75)	0.00 (-0.75 1.25)	0.00 (-1.00 1.00)	p<0.001
JSN				
	1.00 (0.00 3.90)	1.00 (0.00 3.80)	1.00 (0.00 3.80)	
	0.00 (0.00 0.40)	0.00 (0.00 0.00)	0.00 (0.00 0.20)	p=0.004
* +				

7 ASPIRE 54

	(n=282)	+		(n=722)
		3mg/kg 8 (n=359)	6mg/kg 8 (n=363)	
0 ^a	40	50	48	98

54	0	23 (57%)	39 (78%)	38 (79%)	77 (79%)
p			0.037	0.028	0.012

8 ASPIRE

54

	(n=282)	+		
		3mg/kg 8 (n=359)	6mg/kg 8 (n=363)	(n=722)
≥1	227	306	306	612
	93 (41%)	155 (51%)	168 (55%)	323 (53%)
p		0.027	0.001	0.002

ATTRACT 102 + /
 + SF-36
 SF-36 8 2
 102 + / +
 9

9 ATTRACT 102

	+	+				p *
		3mg/kg 8	3mg/kg 4	10mg/kg 8	10mg/kg 4	
	88	86	85	87	81	
	0.1	0.4	0.4	0.4	0.3	≤0.006
	(0.0 0.4)	(0.1 0.6)	(0.1 0.7)	(0.2 0.9)	(0.1 0.5)	
SF-36						
	88	84	86	86	79	
	2.8	4.6	6.8	6.9	6.7	≤0.011
	(0.5 5.8)	(1.3 9.5)	(3.1 15.7)	(1.8 14.8)	(2.8 11.4)	
*						

ASPIRE 54
 10 0.7 0.6
 p<0.001 SF-36

10 ASPIRE 54

		+	
		3mg/kg 8	6mg/kg 8
	275	354	358
	0.57	0.64	0.76
	(0.16 0.90)	(0.29 1.07)	(0.28 1.20)
p *		<0.001	<0.001
SF-36			
	226	303	302
	8.9	10.9	11.8
	(1.4 18.9)	(2.6 19.8)	(4.4 21.2)
p *		0.099	0.003
*			

2

653

[CDAI \geq 220 \leq 400]

/ 92% 1

108 16% 4/25 4

CDAI \geq 70 5mg/kg 81% 22/27 p<0.001

Fisher 4% 1/25 48% 13/27 5mg/kg

4 CDAI<150

I ACCENT I 545 0

5mg/kg 2

2 6 8 5mg/kg 2 6 8

5mg/kg 10mg/kg 2 6 5mg/kg 8

10mg/kg 2

6

2 57% 311/545 30

5mg/kg 10mg/kg 11

54 5mg/kg 10mg/kg

11

	5mg/kg ^a	3 ^b	
		8	
		5mg/kg	10mg/kg
30			
	25/102 25%	41/104 39%	48/105 46%
p ^c		0.022	0.001
54			
d	6/54 11%	14/56 25%	18/53 34%
p ^c		0.059	0.005
a	0		
b	0 2 6	5mg/kg	
c		p	
d			

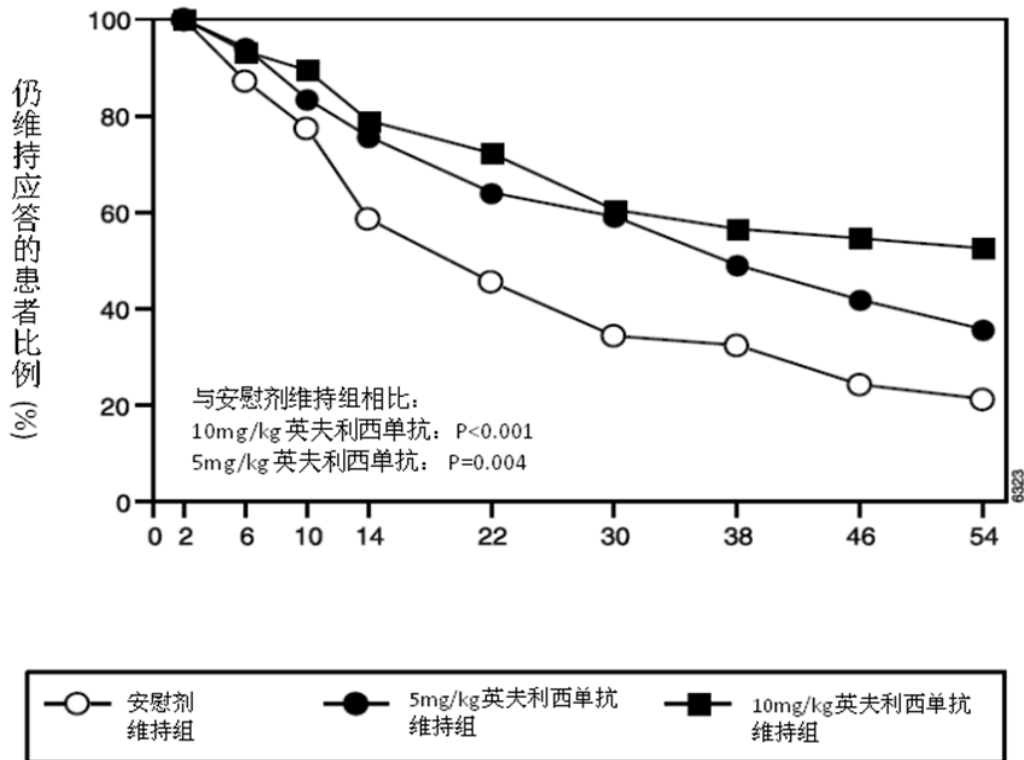
5mg/kg 10mg/kg

2

30 54 5mg/kg 10mg/kg

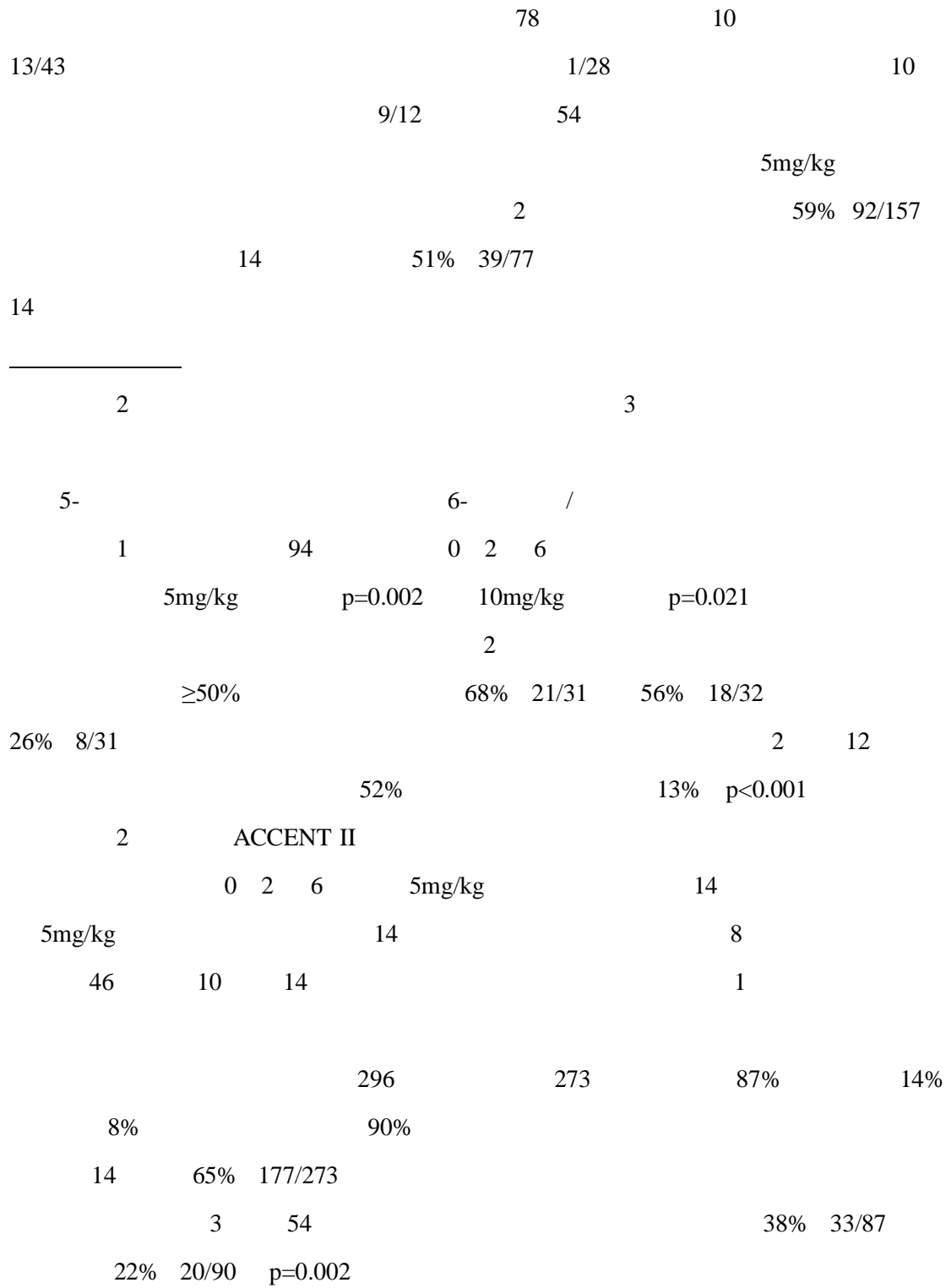
IBDQ

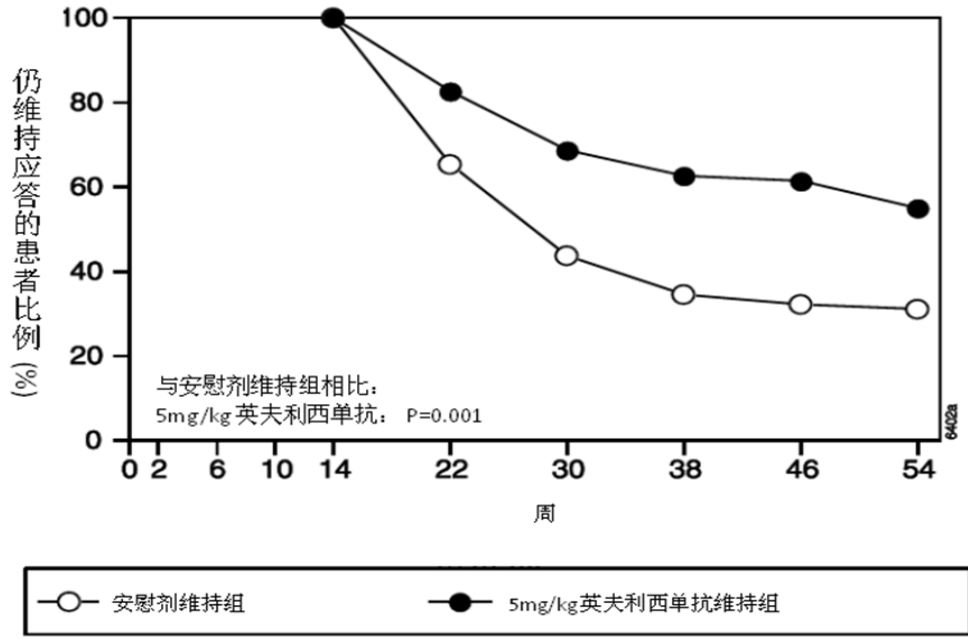
SF-36



2 54

Kaplan-Meier





3 54

5mg/kg

5mg/kg

66% 25/38

57% 12/21

10mg/kg

14

17%

15%

REACH

112 6 17

CDAI

40

6-MP

AZA

MTX

35

0 2 6

5mg/kg

10

8

12 5mg/kg

10mg/kg /

8

10

88.4% 99/112

10

58.9% 66/112 30

8

59.6%, 31/52

12

35.3%, 18/51 p=0.013

54

8

12

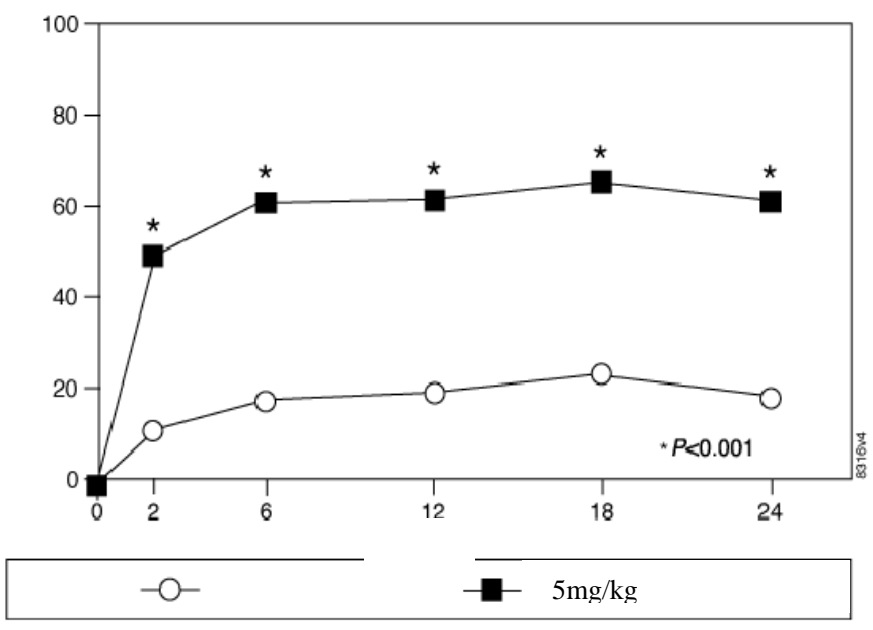
55.8% 29/52

23.5% 12/51 p<0.001

30

8

8 45.8% 12 33.3% 54
 16.7% 45.8% 12
 279
 18~74
 Bath BASDAI
 >4 >4[VAS 0~10] 0
 DMARDs
 2 6 12 18 5mg/kg ASAS 20
 24 ASAS20
 60% 18% p<0.001 2 24 4
 12



4 ASAS20
 24 ASAS50 ASAS70 44% 28%
 9% 4% p<0.001 22% [4
 ASAS <20 0~100mm] 1% p<0.001
 12

	n=78		5mg/kg n=201		p
		24		24	
ASAS20					
a	6.6	6.0	6.8	3.8	<0.001
a	7.3	6.5	7.6	4.0	<0.001
BASFI ^b	5.8	5.6	5.7	3.6	<0.001
c	6.9	5.8	6.9	3.4	<0.001
CRP					
d mg/dL	1.7	1.5	1.5	0.4	<0.001
cm					
Schober e	4.0	5.0	4.3	4.4	0.75
e	3.6	3.7	3.3	3.9	0.04
e	17.3	17.4	16.9	15.7	0.02
e	10.6	11.0	11.4	12.9	0.03
a VAS 0=" " 10=" " b BASFI 10 c 6 BASDAI 2 d CRP 0~1.0mg/dL e Schober >4cm >6cm <15cm >10cm					

SF-36

24

SF-36

10.2

0.8 p<0.001 SF-36

70

3

18 18

BSA ≥10%

PASI ≥12

10

I EXPRESS 378

0 2 6 5mg/kg

8

22

46 24 5mg/kg
 8 46
 8 5mg/kg PASI
 21 sPGA 52% 36%
 2% 75% BSA>20% 71% 82%

II EXPRESS II 835 3mg/kg 5mg/kg
 0 2 6 14
 8
 PRN 46 16
 5mg/kg 8 5mg/kg
 PASI 18 63% BSA>20% 55%
 64%

III SPIRIT 249 PUVA
 0 2 6 3 mg/kg
 5mg/kg 26 sPGA
 3 0~5
 PASI 19 sPGA 62% 22% 3%
 75% BSA >20% 114 46% 26

I II III 10 PASI75 PASI
 75% I III sPGA
 sPGA 6 5= 0=
 <5%
 II rPGA
 rPGA 6 6= 1=

13 I II III 10 PASI75
 “ ”

		3mg/kg		5mg/kg	
		I- PASI75 ^a	77 2 3%	---	---
sPGA	3 4%	---	---	242 80% *	
II- PASI75 ^a	208 4 2%	313 220 70% *	314 237 75% *		
rPGA	2 1%	217 69% *	234 75% *		
III- PASI75 ^a	51 3 6%	99 71 72% *	99 87 88% *		
sPGA	5 10%	71 72% *	89 90% *		
* p<0.001					
a	10				
b	10				

I 5mg/kg
85% 10 PASI75 4%

II 3mg/kg
5mg/kg 72% 77% 10 PASI75
2% II 70% 78% 10

PASI75 2%
II 3mg/kg 5mg/kg 292 297
10 PASI

14 8
PRN 50 PASI75

8 5mg/kg 5
46 8 5mg/kg 54% PASI75
3mg/kg 36% 8 3mg/kg PASI75

5mg/kg 10
8 5mg/kg 8
8 5mg/kg I 50
II

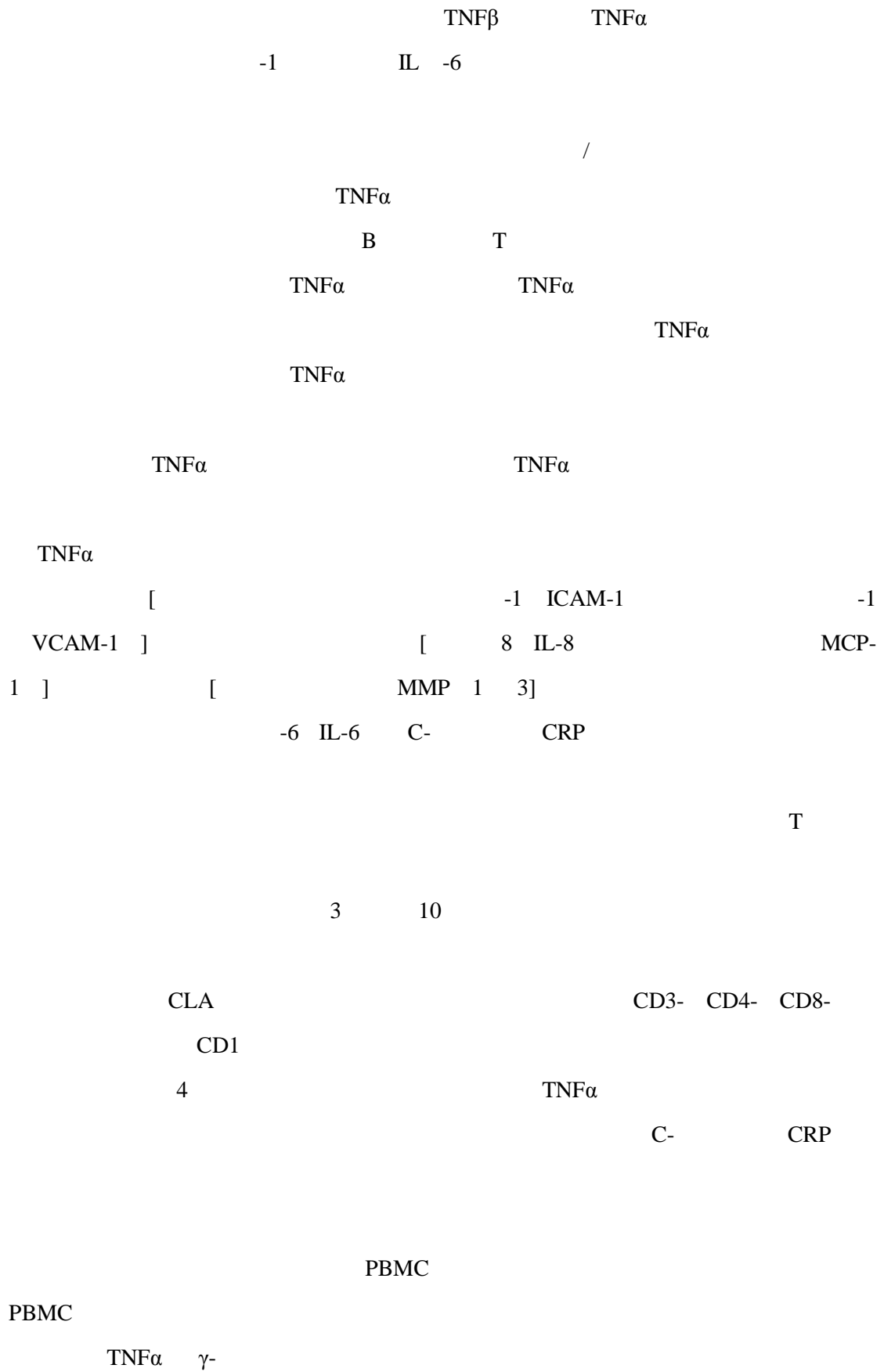
8	a	32.4%	61.2%	60.3%
30	a	27.5%	48.3%	52.9%
a		vs. p < 0.001		

ACT 1 54 54
 44.9% 19.8% p < 0.001
 34.6% vs. 16.5% p < 0.001 46.1% vs. 18.2% p < 0.001
 54
 37.9% vs. 14.0% p < 0.001 20.2% vs. 6.6% p < 0.001
 30 22.3% vs. 7.2% p < 0.001 ACT 1 ACT 2 54 21.0%
 vs. 8.9% p=0.022 ACT 1

54 ACT 1 ACT 2
 5mg/kg 10 mg/kg
 100 -
 21 19 vs. 40 p=0.019 p=0.007 5mg/kg 10
 mg/kg 100
 - 22 19 vs. 34 p=0.145 p=0.022
 ACT 1 ACT 2 54
 5mg/kg 28/242 11.6% []
 10 mg/kg 18/242 7.4% [p=0.011]
 36/244 14.8%

C0168Y06
 n=45
 5mg/kg
 3 29.2% vs. 66.7% p=0.017
 ACT 1 ACT 2 IBDQ 36 SF-36

- TNF α
 TNF α TNF TNF β α TNF α



8 HLA-DR CD3+

B

IL-2R IL-6 IL-8 ICAM

8 30

- Ames

cV1q

TNF α

cV1q

cV1q

TNF α

3

cV1q10mg/kg 40mg/kg

6

10mg/kg

40mg/kg

cV1q

3mg/kg 20mg/kg

3~10mg/kg

5mg/kg

3~5mg/kg

7.7~9.5

2 6

-

4

8

3mg/kg

10mg/kg

3~10mg/kg

8

0.5~6 μ g/ml

<0.1 μ g/ml

	6~17		5mg/kg	
	N=60	N=112	N=117	
N=16		2 17		
8	6 17			5mg/kg
	AUCss		20%	2 6
	AUCss	40%		-

2~8°C

1 /

36

JS20210018

SJ20171001

Janssen Biologics B.V.

Einsteinweg 101, 2333 CB Leiden,

Cilag AG

Hochstrasse 201, CH-8200 Schaffhausen

710304

400 888 9988

029 8257 6616

<http://www.xian-janssen.com.cn>