

结
国家药品监督管理局
药品批准证明文件
附件骑缝章

4 4 4 4 80 3
 1 1
 3
 1 1
 RA
 DMARDs
 3 MTX DMARDs 3
 sJIA
 NSAIDs 2 2
 sJIA
 3
 CRS
 2 CAR T
 CRS 3
 1 1
 200mg/10mL
 1 1
 3
 RA
 8mg/kg 4 1 MTX DMARDs 3
 4 4 4mg/kg 3
 0.9% 100mL 3
 1 3
 >100 kg 800mg 1 1
 3
 sJIA
 3 sJIA 2 1
 1 3

2	
30 kg	12 mg/kg
≥ 30 kg	8 mg/kg

1 4

1 100mL 0.9%

1 <30 kg sJIA 0.9%

50mL

CRS

CRS 1 100mL

1 12 mg/kg 12 mg/kg 8 mg/kg <30 kg

1 100 mL 0.9%

1 50mL 0.9%

1 3 800 mg/ 3

1 800 mg/ 3 4 ALT

AST CRS 4 ALT

r *A*

RA

> 1 3 ULN	DMARDs 4mg/kg 4mg/kg 8mg/kg 100mL
> 3 5 ULN ()	<3 ULN >1~3 ULN >3 ULN 100mL
> 5 ULN	100mL

ANC

×10 ⁹ /L	
---------------------	--

ANC > 1	⏏
ANC 0.5 ~ 1	ANC >1×10 ⁹ /L 4mg/kg 8mg/kg⏏
ANC < 0.5	⏏

×10 ³ /μL	
50 ~ 100	>100×10 ³ /L 4mg/kg 8mg/kg⏏
< 50	⏏

sJIA

<2×10 ⁹ /L	<100×10 ³ /L	ALT	AST	1.5
ULN	⏏			
	⏏			
/			⏏	
	⏏			

> 1 ~ 3× ULN	MTX ALT AST ⏏
> 3-5×ULN	MTX < 3×ULN > 1-3×ULN ⏏
> 5×ULN	⏏

ANC

$\times 10^9/L$	
ANC > 1	

ANC 0.5-1

ANC

>1×

(0.4mL/kg)

100mL

100mL

Ш

<30kg

(0.6mL/kg)

50mL

50mL

Ш

“ ”

Ш

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0.9%

30°C

24

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Ш

2~8°C

24

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Д

1Ч

Ш

MedDRA

1

ADR

Ш

ADR

0.1

Ш

0.1

1

1

MTX

DMARDs

		Ч	Ч
		Ч	Ч
		Ч	Ч
		Ч	
			Ч
		Ч	
		Ч	

3778	6	4mg/kg	8mg/kg
Ш3778			13
4		0.3%	Ш
2	5	<i>r</i>	<i>A</i>
		Ш	
6	2876	Ш	46
	5	30	1.1%
Ш			
24	15	8	Ш
1.32	/100	+DMARD	1.37
		/100	
Ш			
	24	Ш	

1a _____

<u>MedDRA</u>	<u>4</u>	_____

<u>1.2</u>	_____	_____

<u>3</u>	_____	_____

_____	<u>1.3/100</u>	_____

_____	<u>0.027/100</u>	_____
_____	<u>0.035/100</u>	_____
_____	<u>0.004/100</u>	_____
<u>3</u>	_____	_____

1 “ ”

2 “ ”

3 _____ Ш

_____ 95% Ш

4 _____ Ш

Г Д

Ш

Г Д Ш

Г Д

Ш

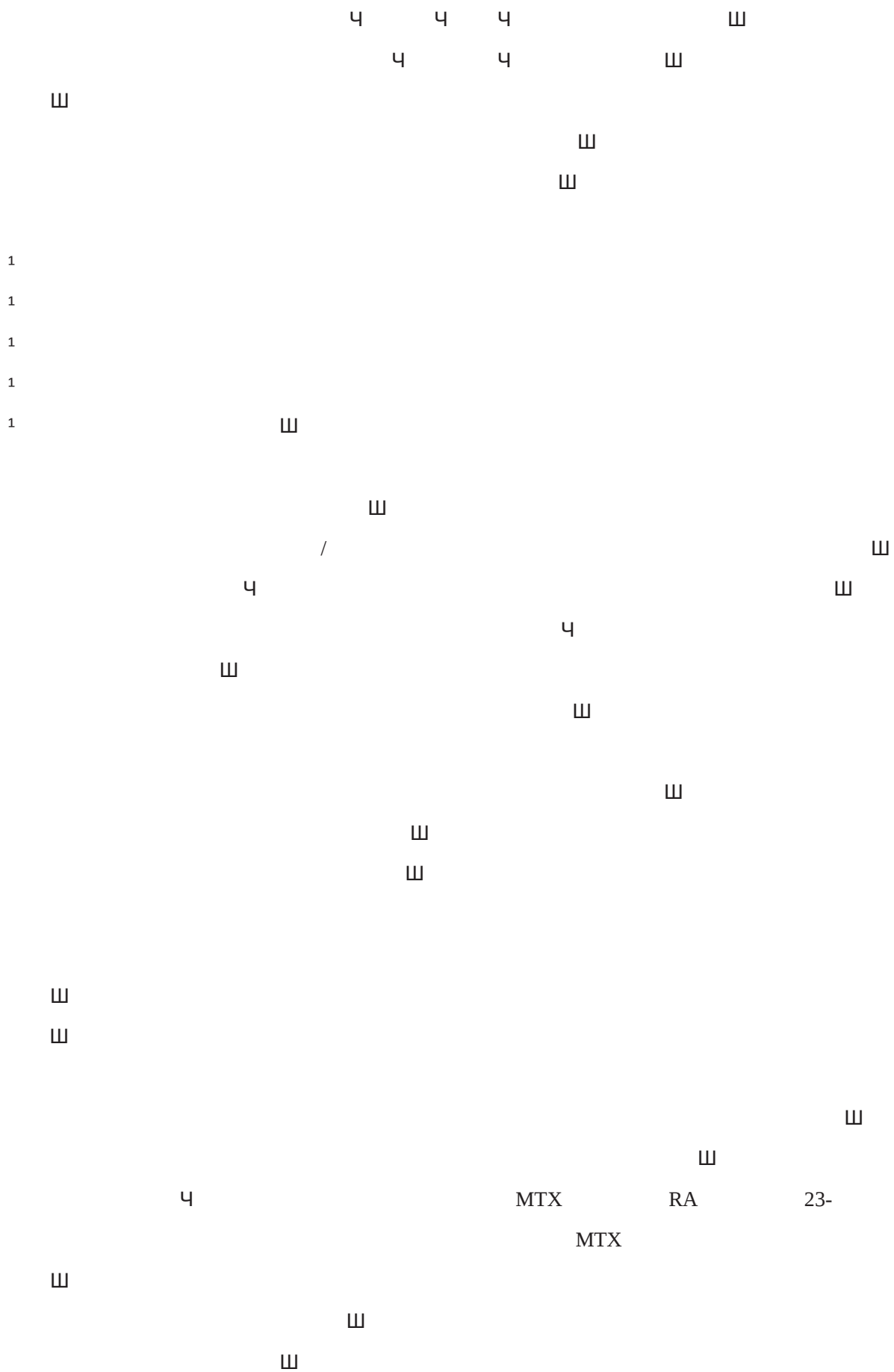
Ч Ч

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三

三

W

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Г Д Ш

W

4

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2 5 Ⅲ

MTX

Д Г Д Ш

W

ALT AST AS2

n



[illegible]

山	10mg/kg	57%	39%	
	山RA			山
RA			CYP3A4	
			山	
	CYP2C19	CYP3A4		山RA

MTX 10~25mg/ Ⅲ 24 ACR20 Ⅲ 52
MTX Ⅲ
η 623 MTX Ⅲ 4 8mg/kg
MTX 10~25mg/ Ⅲ Ⅳ 1220
DMARDsⅢ 8 mg/kg
DMARDⅢ 0 499 TNF
Ⅲ TNF Ⅲ 4 8mg/kg
MTX 10~25mg/ Ⅲ η ~ 0 24
ACR20 Ⅲ
η ~ 0 ACR20 Ⅳ ACR50 ACR70 2Ⅲ
2 MTX/ ACR

	MTX		MTX		MTX		DMARD		TNF	
	TCZ 8mg/kg N=286	MTX N=284	TCZ 8mg/kg +MTX N=398	+MTX N=393	TCZ 8mg/kg +MTX N=205	+MTX N=204	TCZ 8mg/k g +DMARD N=803	+DMARD N=413	TCZ 8mg/kg +MTX N=170	+MTX N=158
ACR20										
24	70%***	52%	56%***	27%	59%***	26%	61%***	24%	50%***	10%
52			56%***	25%						
ACR50										
24	44%**	33%	32%***	10%	44%***	11%	38%***	9%	29%***	4%
52			36%***	10%						
ACR70										
24	28%**	15%	13%***	2%	22%***	2%	21%***	3%	12%**	1%
52			20%***	4%						
52			7%	1%						
MCR†										

TCZ=

*p 0.05

**p 0.01

***p 0.0001

+MTX/DMARD

+MTX/DMARD

+MTX/DMARD

WA25204 4 4 4

RA CV 11 TNF [ETN]

RA RA CV 11

3,080 RA DMARDs 0.50

CV RA 11 1:1 IV TCZ 8 mg/kg Q4W SC ETN

50 mg QW 3.2 11

MACE 4 CV 11 ITT

161 CV TCZ 83/1538[5.4%] ETN 78/1542[5.1%]

11

TCZ ETN MACE 95%CI >1.80 TCZ

ETN 11 MACE 95%CI 1.43 TCZ ETN

[HR] =1.05 95% CI 0.77 1.43 11

sJIA

12 4 4 11

: =2:1 2 MTX 75

2 30 kg 8 mg/kg 30 kg

12 mg/kg 37 2 11 JIA ACR70 6

11 12

11

12 JIA ACR JIA ACR30 30%

7 0.37.5ΔC 11 JIA ACR 6

3 30% 4 50% 4 70% 1 30% 11

4 4 4 4

ESR -CHAQ 11 85% 64/75

24.3% 9/37 11 p<0.0001 11

JIA ACR 30,50,70 90 11 11

6 12 JIA ACR

	N=75	N=37
ACR 30	90.7%*	24.3%
ACR 50	85.3%*	10.8%
ACR 70	70.7%*	8.1%
ACR 90	37.3%*	5.4%

* p<0.0001, vs.

JIA ACR				sJIA ACR			
				44	JIA ACR		

Cockcroft-Gault

80mL/min

050mL/min

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г Д

2 8Ñ

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г Д

200mg/10mL 1 / 4 /

г Д

200mg/10mL 18

г Д

г Д

г Д

11 A6

г Д

155

400-9998703

<http://www.bio-thera.com/Ш>