2025 5 13

Anrikefon Injection

Anruikefen Zhusheye

7- D- -D- -D- -D- -2-

-2 7- [3.5]

$C_{39}H_{57}N_7O_5$

703.93

1.

2.

1ml 0.1mg

2

0.16 mL 1.888μg

13

I 3.375μg/kg

66.7% 4/6 33.3% 2/6

16.7% 1/6

C-QT QTc

0.2~3.375 μg/kg

2 min 15 min 1μg/kg

, C_{max} 10.2 ng/mL 8.13 ng/mL

AUC_{0-t} 10.13 ng*h/mL 9.89 ng*h/mL 2 min

15 min

3 0.3 μg/kg

0.2~3.375 μg/kg ,

227~274 mL/kg

3 0.3 μg/kg 1.3 L/kg

0.46~0.54 [^{14}C]

14.3%

[^{14}C]

≤1.07%

0.2~3.375 μg/kg

$t_{1/2}$ 1.39~2.24 h

46.30±12.02% 35.60±5.66%

3 0.3μg/kg

$t_{1/2}$ 26.3 h

74.7±13.2% 0.621±0.871%

0.119±0.292%

N=159

(N=13) N=281 AUC

7.88% 73.8% C_{max}

1 μg/kg

90≤GFR<130 mL/min, N=8 60≤GFR<90 mL/min,

N=8 30≤GFR<60 mL/min N=8 15≤GFR<30 mL/min N=9

$AUC_{0-\infty}$ 27.02% 62.79% 121.64% C_{max}

N=43

(N=11) (N=15) N=447

AUC 13.6% 51.2% 30.5%

AUC AUC

AUC 33% 78%

PK

≥65

65 AUC 38.5%

≥65 65 AUC 4%

III ASA I-

II 18-70 271

136 135

8h 3

1.0μg/kg 2min

FAS 0-

24h SPID $SPID_{0-24h}$ -39.1 *h

-27.4 *h 95% CI -11.7 (-17.0

-6.5) FAS

22.0 h vs 20.3 h 9.0 vs 8.4

8.9 vs 7.8

0-24h 33.1% vs 46.7%

2.3 mg vs 2.9 mg PPS

FAS

7 $SPID_{0-24h}$ -FAS

$SPID_{0-24h}$ *h	**N=136**	**N=135**
	-39.1	-27.4
95%	-11.7 (-17.0, -6.5)	/
P	<0.0001	/

/ III ASA

I-II 18-70

387 129

129 129 8h

3 1.0μg/kg 2min

FAS $SPID_{0-24h}$

-64.0 * h -62.9 * h -45.9 * h

$SPID_{0-24h}$ 95% CI -18.1(-24.4 -11.9) * h

$SPID_{0-24h}$ 95% CI -17.0 (-23.2 -10.7)

* h $SPID_{0-24h}$ 95% CI -1.1(-

7.4 5.1) * h FAS

21.04 h 21.32 h 18.18 h

8.7 8.5 8.2 8.6 8.4

7.6 0-24h 40.3% 35.7%

71.3% 0-24h 29.8mg 29.3mg 61.6mg

8 $SPID_{0-24h}$ -FAS

$SPID_{0-24h}$ *h	**N=129**	**N=129**	**N=129**
	-64.0	-62.9	-45.9

95%	-18.1 (-24.4, -11.9)	-17.0 (-23.2, -10.7)	/
P	<0.0001	<0.0001	/
95%	-1.1 (-7.4, 5.1)	/	/
P *	0.0001	/	/

* -11.03 *h

HSK21542

≥18 3

3 6

sp Kt/V ≥ 1.2 URR ≥ 65% sp Kt/V

≥ 1.2 URR ≥ 65% NRS 5

1:1 HSK21542 0.3μg/kg 1 3

12 12

NRS WI-NRS ≥4

12 WI-NRS ≥4

95%CI 37.2%(31.253%, 43.169%)

15.0% (10.631%, 19.354%) 95%CI 22.2% (14.872%,

29.565%) HSK21542 12 WI-NRS ≥4

1

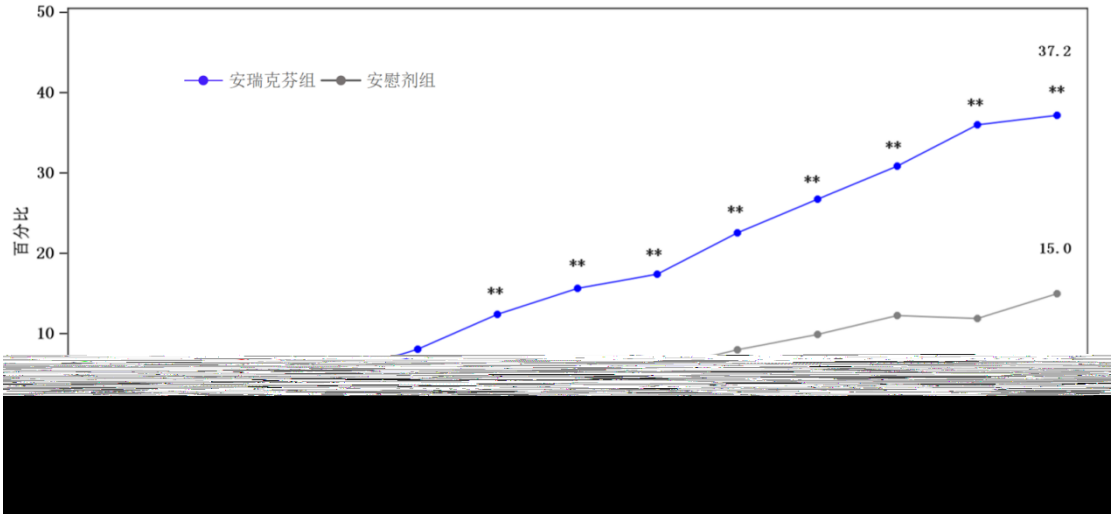
12

40

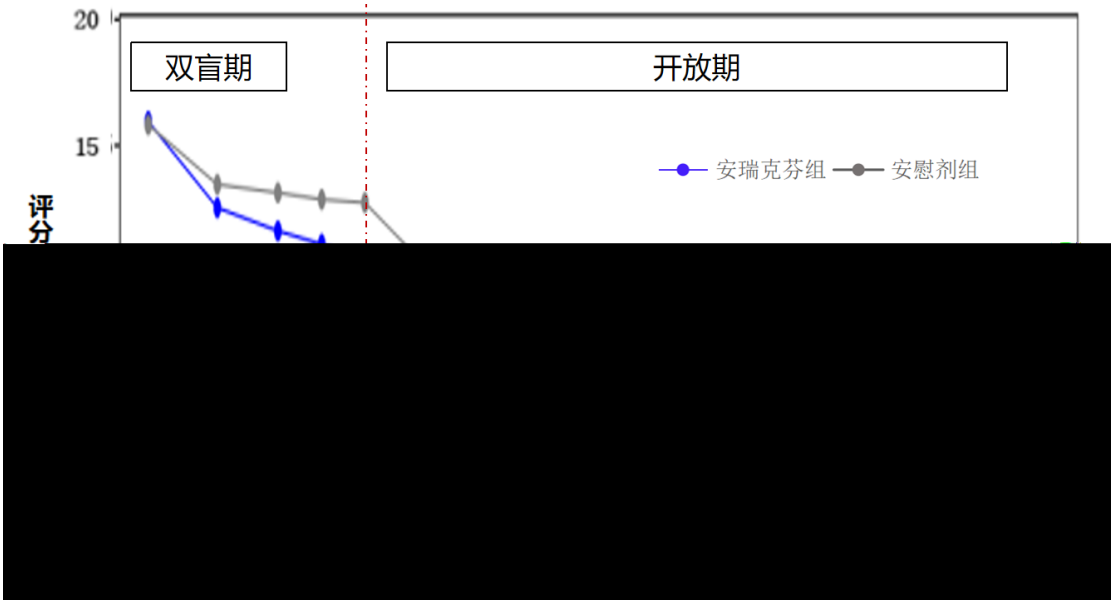
HSK21542 443 89.1%

52 5-D -7.7 (3.27)

HSK21542 2



1 WI-NRS ≥4



2 5-D

κ KOR

Ames

4

2 7 1 3 10 mg/kg/ ≥1 mg/kg/

/

- 6~17

0.2 1 4 mg/kg/ [AUC MRHD 1μg/kg

19 82 358] 4 mg/kg/

- NOAEL 1mg/kg/ 7~19

0.3 1 2 μg/kg/ AUC MRHD 0.1 0.3 0.8

2 μg/kg/

6 21

0.2 1 4 mg/kg/ AUC MRHD 17 59 250

1 0.1 0.5 2.5 mg/kg/ AUC

MRHD 16 107 1609 10 60 425 RasH2

1 6 0.4 2 10 mg/kg/ AUC

MRHD 31 142 669 23 112 593

25

4 /

36

YBH08362025

H20250014

17

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