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MedDRA		

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PNH

y

		AUC	
MRHD	200mg	8.5	5.8

PNH PNH

“ ”

18

CYP2C8

CYP2C8 C_{max} $AUC_{0\text{-}inf}$

7% 85% CYP2C8

CYP2C8

CYP2C8 PBPK

CYP2C8 C_{max} $AUC_{0\text{-}inf}$ 0.107%

65.5%

CYP2C8

PNH

200mg 4 AP

88.11% 24 AP 76.98%

PNH 200mg

1 Hb Hb

24 Hb 128 g/L 1

1 LDH

2 LDH >85% 18

24 4 3 ULN

92%

C-QT 7230 ng/mL QTcF 90% CI

10ms QTc

50~600 mg

T_{max} 3.50~4.00 h 200mg 7

C_{max} AUC 1.64 1.84

C_{max} AUC_{0-t} AUC_{0-}

108.05% 98.73% 97.86% C_{max} AUC

200mg

102 L 0.646~0.851

CYP2C8

N- M13

12.7% 6.26% M3-2

M2-2 36.8% 15.8% 9.70%

200 mg

65kg 5^{th}

	(N=37)	(N=36)
( )[1]		
( )[2]		
(g/L)[2]		
LDH U/L [2]		
10^9/L [2]		
PNH % [2]		
n%		
12 n%		
6 n%		
12 MAVE n%		

3 HSK39297-301 PNH 24

	(N=37) 95%CI	(N=36) 95%CI	95%CI P

	(N=37) 95%CI	(N=36) 95%CI	95%CI P

Ames

50

150 450 mg/kg/ 28 14

14 GD7 450 mg/kg [

mg/m^2 MRHD 21.6]

- GD6-17

30 100 300 mg/kg/ 300 mg/kg AUC MRHD

8.5 /

/ - GD6~19

60 120 300 mg/kg/ AUC MRHD 5.8

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GD6-PND21

50 100 300 mg/kg/ 300 mg/kg AUC

MRHD 6.2 F1

rasH2 26 60 120

300 mg/kg/ AUC MRHD 6

/ / 14 /

2 / 1 /