

2016 11 23

2019 04 11

2020 06 19

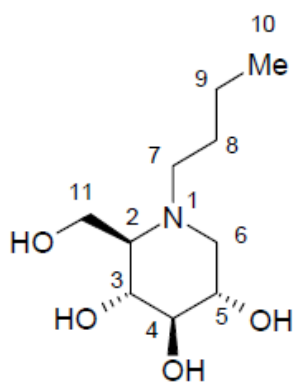
2021 01 22

® Zavesca®

Miglustat Capsules

Maigesita Jiaonang

(2R,3R,4R,5S)-1- -2- -3,4,5-



$C_{10}H_{21}NO_4$

219.28

C

0.1g

C

12

0.2g

12

(m <sup>2</sup> )	
>1.25	0.2g
>0.88- 1.25	0.2g
>0.73- 0.88	0.1g
>0.47- 0.73	0.1g
≤0.47	0.1g

4 C

70

50-70 ml/min/1.73 m<sup>2</sup>

0.2g

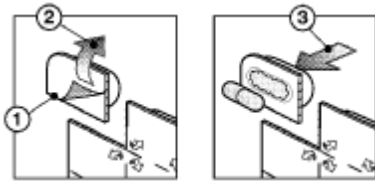
12

30-50 ml/min/1.73 m<sup>2</sup>

0.1g

12

< 30 ml/min/1.73 m<sup>2</sup>



- 1.
- 2.
- 3.

11  
50 - 200mg

247  
2.1      132    1

40    C

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

---



---



---



---

\_\_\_\_\_

/

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

55%

6 12

/

37% 1

58% C

1

1-3

80%

-

/

< 30 ml/min/1.73 m<sup>2</sup>

C

6 C

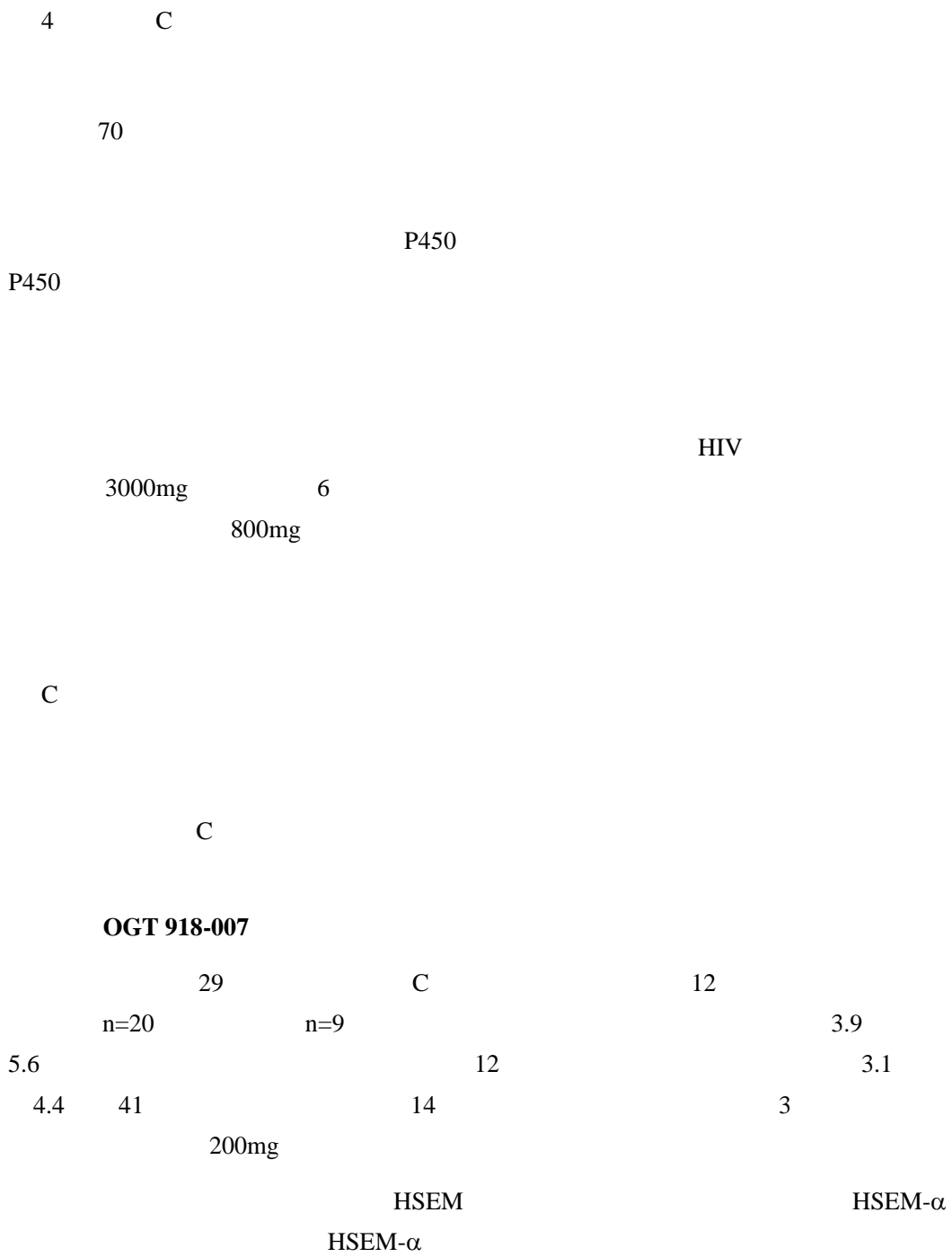
1

C

40 - 50%

C

/



**1 OGT 918-007 12 HSEM-α**

		(95% CI) /		(95% CI)	(95% CI)
		(n=8)	n=18		(n=10)

<b>HSEM-<math>\alpha</math></b> ANCOVA)	a	-0.050 (-0.608, 0.509)	-0.376 (-0.746, -0.005)	-0.326 (-1.000, 0.348) p = 0.327	-0.465 (-0.752, -0.178)
<b>HSEM-<math>\alpha</math></b> ANCOVA)	a	0.055 (-0.443, 0.553)	-0.463 (-0.796, -0.129)	-0.518 (-1.125, 0.089) p = 0.091	

a 12 CI =

HSEM =

12 0.4 [95% CI 0.13

1.22 p = 0.17] 80% / 24

SAI /

12 SAI

0.087 [95% CI -0.287 0.461] 0.802

[95% CI 0.220 1.385] ANCOVA -0.715 [95%

CI -1.438 0.007 p = 0.052] /

/ Folstein MMSE

12

1.219 [95% CI -0.060 2.498] -0.352 [95% CI -2.213 1.510]

ANCOVA -1.571 [95% CI -0.692 3.834 p = 0.165]

C

### Stage I Survey

66 C

1.5 3.1

1 43 C

/ /

6 C

1

C

C

4		180 840 4200mg/kg/	>180mg/kg/
	6		
52		180 420 840 1680mg/kg/	>180mg/kg/
AUC	4		
2		85 165 495 825mg/kg/	>495mg/kg/
	50		
4		35 70 105 140mg/kg/	105 mg/kg/
	10		
52		750 2000mg/kg/	>750 mg/kg/ AUC
	4		
2		85 165 495 825mg/kg/	≥85mg/kg/
		26	300 600 1200mg/kg/
1200 mg/kg/	AUC		7
	52	750 2000mg/kg/	≥750 mg/kg/
AUC		6	

Ames

14

20 60 180mg/kg/ 20mg/kg/

14

20 mg/kg/

mg/m<sup>2</sup>



6 60mg/kg/  
 2  
 14 17 20  
 60 180mg/kg/  
 $\geq 2$   
 6 ~18 15 30 45mg/kg/ 15mg/kg  
 6 20  
 20 60 180mg/kg/  $\geq 2$   
 $>20\text{mg/kg/}$

CD-1 104 210 420 500mg/kg/  
 3 6 7  
 CD-1

SD 100 30 60 180 mg/kg/  
 1 2 5

:

C 3 1 HIV

2  
 C<sub>max</sub> 36% t<sub>max</sub> 2  
 AUC 14%

83L

(CL/F) 230 ± 39ml/ 70% - 80%  
 100mg <sup>14</sup>C 6 - 7 83% 12%

5%

150

1

C

—

3 - 15 3

5-16 C

200mg

C<sub>max</sub> AUC<sub>τ</sub>

100mg

1

2

6 3

31.4% -67.2%

—

CL/F

CL/F

40% 60%

18 - 29 ml/min

CL/F

70%

—

BMI

—

> 70

30°C

84 /

60

JX20130040

H20160635

Janssen-Cilag International NV

Turnhoutseweg 30, B-2340 Beerse, Belgium

Almac Pharma Services Limited

Seagoe Industrial Estate, Craigavon, Co. Armagh BT63 5UA, United

Kingdom

6 5 517

200131

400-860-0673