2022 03 22

2022 10 25

2022 11 04

2023 01 16

2023 07 17

2023 09 19

2024 08 15

2024 12 01

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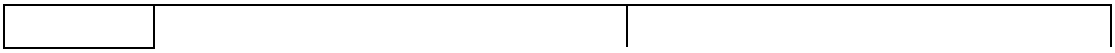
国家药品监督管理局

®



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3 HLX10-004-NSCLC303

P		
[redacted]		

3 1

48 6 12

6

HLX10-002-NSCLC301 636 214

210

212

61.0 27-75 73.1% 73.0% ECOG

1 78.0% PD-L1 66.8% 18.7%

72 34.3%

IRRC RECIST 1.1 PFS

OS RECIST 1.1

PFS IRRC ORR IRRC

DOR

2023 6 15

+

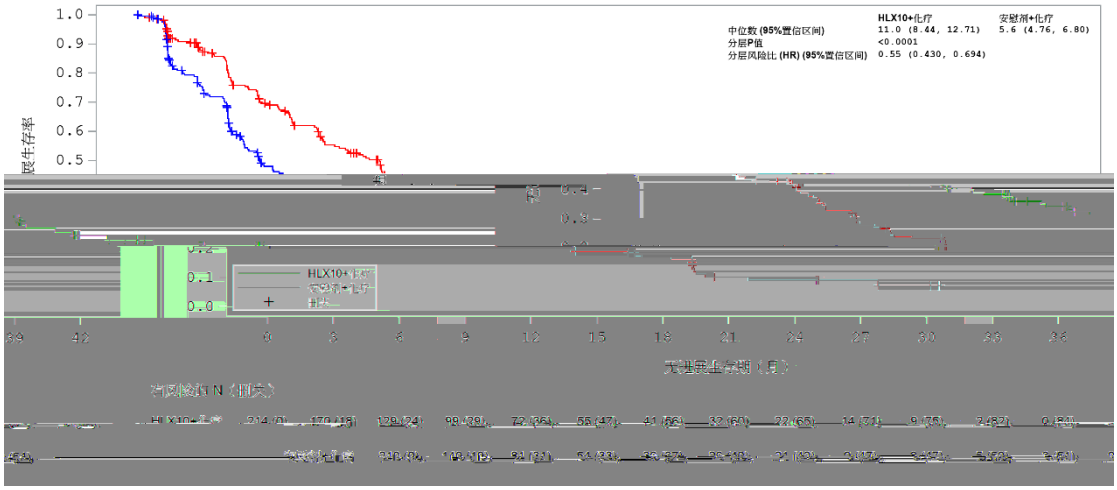
+ PFS OS

	+ +	
P		

	+ +	
P		
P		

P

3 HLX10-002-NSCLC301 **Kaplan-Meier**



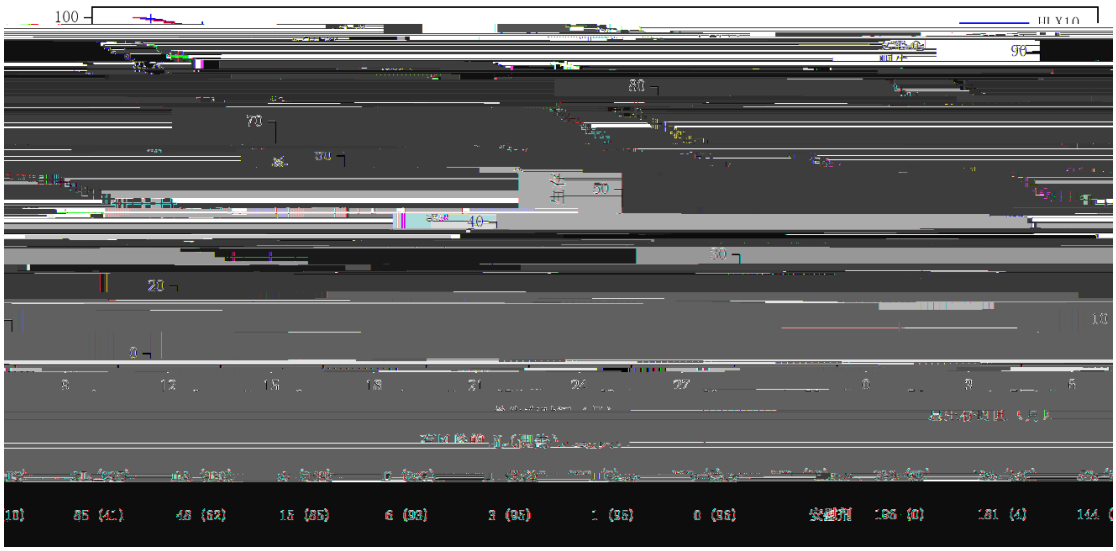
28-83 82.2% 68.5%

80.9%

5 HLX10-005-SCLC301

P		
P		
P		

4 HLX10-005-SCLC301 **Kaplan-Meier**



5 HLX10-005-SCLC301 **Kaplan-Meier**

/

HLX10-007-EC301 III

+5-FU +5-FU

/

/

PD-

L1 IRRC

RECIST 1.1 ECOG 0-1

PD-1/PD-L1

PD-L1 vs. <65

vs. 2:1

3.0 mg/kg +5-FU

+5-FU

iCPD iRECIST

HLX10-007-EC301 551 368

183

64 34-75 470 85.3% 73.5%

ECOG PS 1 0 476

86.4%

OS IRRC RECIST 1.1 PFS

IRRC iRECIST PFS RECIST 1.1

iRECIST PFS IRRC RECIST 1.1 iRECIST

ORR IRRC RECIST 1.1 iRECIST

DOR

2022 4 15

5-FU 5-FU OS PFS

6 6 7

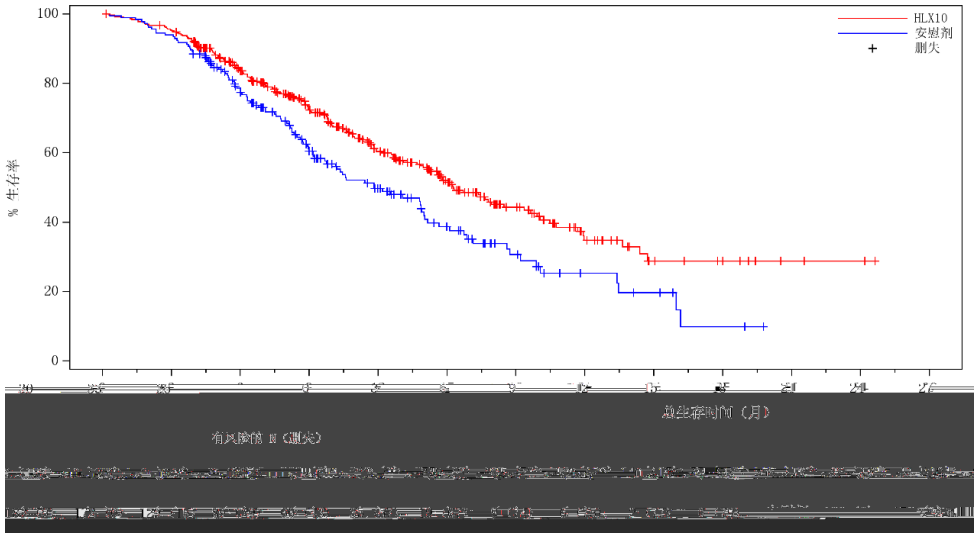
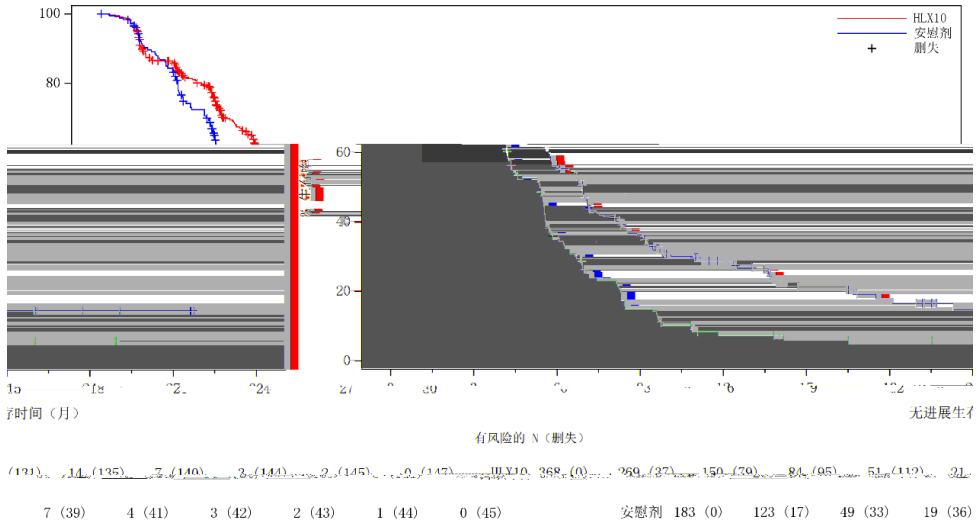
6 HLX10-007-EC301

	+ + **N=368**	+ + **N=183**
OS		
%	163 44.3%	104 56.8%
95% CI	15.3 13.96 18.63	11.8 9.69 14.03
* 95% CI	0.68 0.529 0.871	
P	0.0020	
PFS IRRC RECIST 1.1		
%	219 59.5%	129 70.5%
95% CI	5.8 5.68 6.93	5.3 4.30 5.55
* 95% CI	0.60 0.476 0.747	
P	0.0001	
ORR IRRC RECIST 1.1		
ORR n %	242 65.8%	92 50.3%
95% CI	60.7% 70.6%	42.8% 57.7%

	+ + **N=368**	+ + **N=183**
DOR IRRC RECIST 1.1		
95% CI	5.8 5.32 7.29	4.2 3.88 5.09
* 95% CI	0.54 0.401 0.740	
P	0.0001	

* Cox

6 HLX10-007-EC301 Kaplan-Meier



7 HLX10-007-EC301 Kaplan-Meier