2022 03 22

2022 10 25

2022 11 04

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2023 07 17

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国家药品监督管理局

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**3 HLX10-004-NSCLC303**

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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

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+ PFS OS

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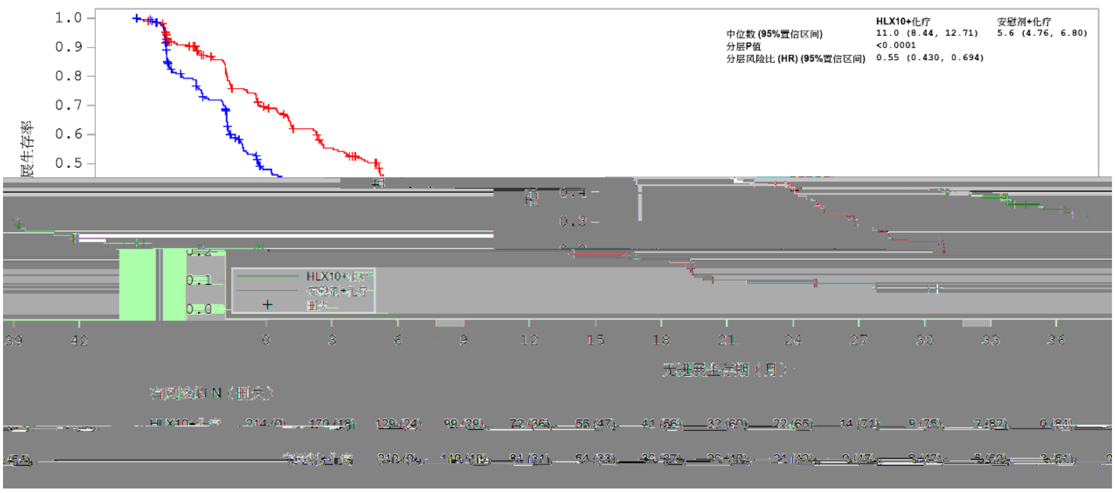
**3 HLX10-002-NSCLC301 Kaplan-Meier**



28-83 82.2% 68.5%

80.9%

**5 HLX10-005-SCLC301**

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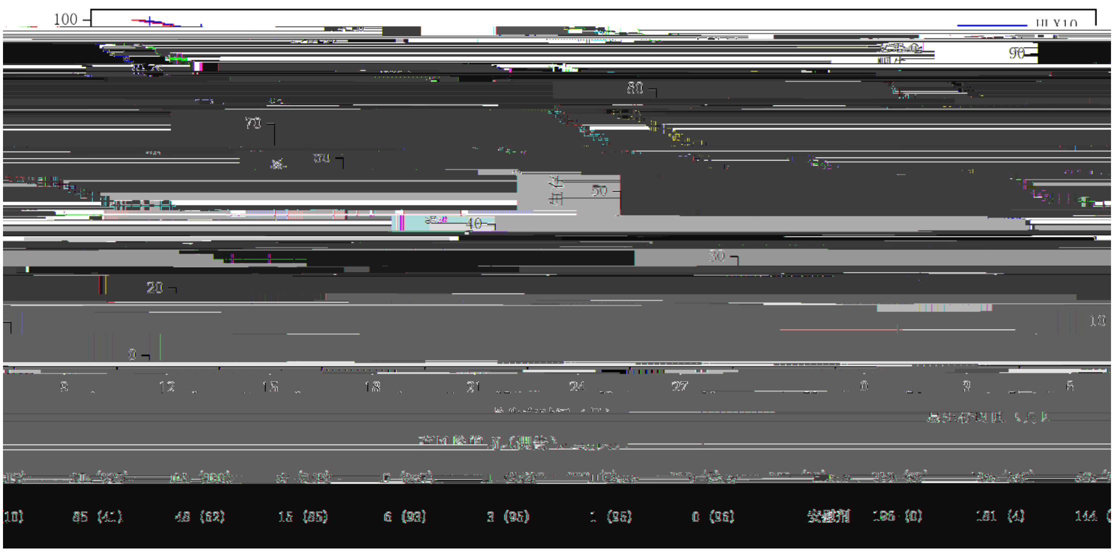
**4 HLX10-005-SCLC301 Kaplan-Meier**



**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

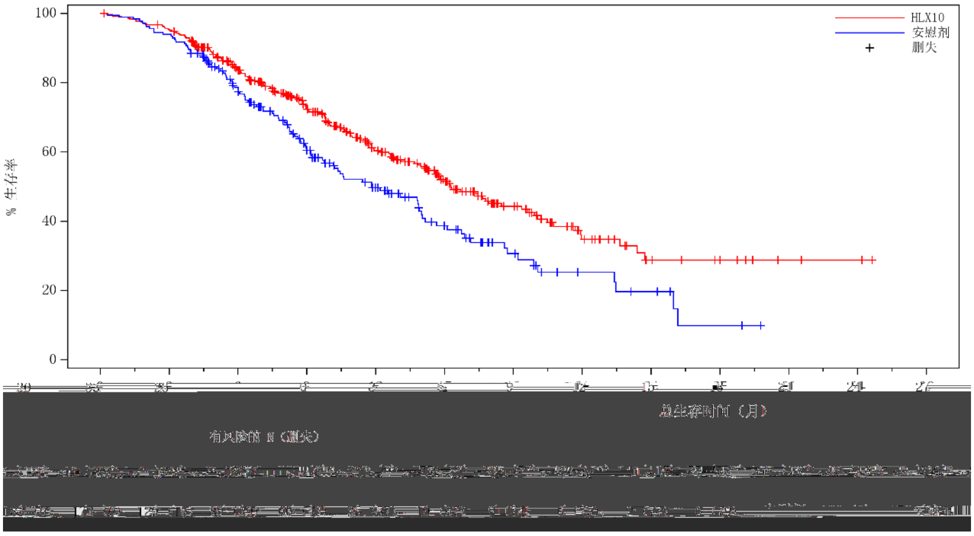
**6 HLX10-007-EC301**

| | + + <br>**N=368** | + + <br>**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**