

2022 03 22

2022 10 25

2022 11 04

XXXX XX XX

®

Serplulimab Injection

Siluli Dankang Zhusheye

DNA

1

80

MSI-H

•

•

•

NSCLC

ES-SCLC

100 mg 10 mL /

MSI-H

MSI-H

MSI-H

MSI-H

3 mg/kg

2 1

4.5 mg/kg

3 1

1

**1**

2

0-1

3 4 2

2 3

0-1

4

2

	3	4

5.0

NCI-CTCAE v5.0

\* 0-1

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

18

\_\_\_\_\_

65

●

●

0.9%

100 mL

●

●

0.2~5 μm

100 mL

25 /

30

±10



24

2~8

24

6



			3	HLX10-001	HLX10-010-	
MSI201	HLX10-004-NSCLC303					214
			77	76		
8				6	4	
	3			2		
1	3 mg/kg	2		4.5 mg/kg	3	
	207		50.72%			6
19.32%			12			
	3 mg/kg	2		4.5 mg/kg	3	
	207			79.7%		10%
			3			
30.0%	1%					
	-					

2

HLX10-004-NSCLC303

-

HLX10-005-SCLC301

-

747

389

357

1

4.5 mg/kg

3

41.50%

6

9.77%

12

747

69.5%

10%

3

34.1%

1%

2

214

747

1/10

1/100

<1/10

1/1000

<1/100

1/10000

<1/1000

<1/10000

2

\*

	a	d a
		b c
	b	e
	c d	
	e	
	f g	
		f
		g
		/
		h

i h  
j j  
k  
l  
l m k  
m  
n  
n o p

	/	
	u	u
	v	w v
	x	x
		y z
		aa
	bb	/
	cc dd	bb cc dd
	ee	ee
	ff gg	ff gg
		/
	hh	hh
	/	
	/	

	<p style="text-align: center;">ii -</p> <p style="text-align: center;">jj</p> <p style="text-align: center;">D-</p> <p style="text-align: center;">kk</p> <p style="text-align: center;">N</p> <p style="text-align: right;">ll</p>	<p style="text-align: center;">ii</p> <p style="text-align: center;">-</p> <p style="text-align: center;">jj ll</p> <p style="text-align: center;">kk</p>
	<p>C</p> <p style="text-align: center;">A</p>	<p style="text-align: right;">mm</p> <p style="text-align: center;">-</p> <p style="text-align: center;">N</p> <p style="text-align: center;">D-</p> <p>C</p>

\* 2

- a.
- b.
- c.
- d.
- e.
- f.
- g.
- h.
- i.
- j.
- k.
- l.
- m.
- n.
- o.
- p.
- q.
- r.

2

T-

1

1

s.  
t.  
u.  
v.  
w.  
x.  
  
y.  
z.  
aa.  
bb.  
cc.  
dd.  
  
ee.  
ff.  
gg.  
hh.  
ii.

jj. MB  
kk. T QT QT  
ll.  
mm. I T

214 4 961  
747

---

35 3.6% 1  
6 0.6% 2 16 1.7% 3 10 1.0% 4 1  
0.1% 5 2 0.2%  
2.76 0.03-16.72

		2.46			0.26-13.34		10	1.0%		
	20	2.1%				20	2.1%			
		40 mg							75.0 mg/	
		35.0-150.0 mg/				1.35			0.16-9.99	
	2021	10	22	6						
	1.86		0.30-4.17							
<hr/>										
					15	1.6%				
1	7	0.7%	2	5	0.5%	3	3	0.3%	5	0.5%
						2	4	0.4%	5	1
	0.1%	1	0.1%		3			1	0.1%	
	2									
						3.22			0.03-7.95	
		0.38			0.03-1.05		2	0.2%		
	1	0.1%				12	1.2%			
2	0.2%						40 mg			
		150.0 mg/			50.0-250.0 mg/					
0.12		0.03-0.20			2021	10	22		10	
			0.38					0.03-1.05		
								3.19	0.95-5.65	
			1.41		0.49-3.68		1	0.1%		
			3	0.3%			4			
		40 mg						63.33 mg/	50.0-	
100 mg/					0.51			0.26-3.58	2021	
	10	22	3					0.99		
0.49-1.84										
					3.68			4.07		
								100.0 mg/		
	1.48									
					0.10			0.20		

2021 10 22

0.20

---

					11	1.1%				5
		2				2		2		
1		1		2	1	0.1%	3	7	0.7%	4
	2	0.2%	5	1	0.1%					

0.72		0.43-6.60				1.94			0.85-15.31
	5	0.5%				5	0.5%		

5					40 mg				
100 mg/		50.0-250.0 mg/				0.92			
0.56-1.25		2				8.18			
1.05-15.31									

---

					4	0.4%				
1	1	0.1%	2	2	0.2%	3	1	0.1%	9	0.9%
					1	2	0.2%	2	4	0.4%
3	2	0.2%	4	1	0.1%					

						4.67			1.05-7.72
		2.23				2.07-2.40	2		
		2.23				2.07-2.40			
						5.36			0.46-9.50
		2.41				0.46-4.37	2		

	2				2021	10	22	1	
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	0.46								
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					87	9.1%			
1	37	3.9%	2	49	5.1%	3	1	0.1%	
				3.84					0.89-12.68

3.88		0.69-7.49		7	0.7%			54
5.6%						2021	10	22
						2.43		0.69-7.49
				51	5.3%			
1	43	4.5%	2	8	0.8%			
	1.61			0.85-8.21				1.49
0.07-2.83			4	0.4%				8
						2021	10	22
						1.49		0.07-2.83
				14				6
	0.6%	1	1	0.1%	2	5	0.5%	1
								0.1%
	2			2	2			1
	0.1%	1			1	0.1%	1	
1	0.1%	2					1	0.1%
		1	0.1%	1				
					5.65			1.94-13.50
								1
0.1%				1	0.1%			
	80 mg/				0.26		2021	10
							22	1
					0.56			0.23
	0.16			2021	10	22		
	0.16							
						6.34		5.75-6.93
								1
0.1%				2	0.2%			
					6.01			
				13.08		0.69		2021
							10	22
					0.69			
	6.47							5.59

1.48			2021	10	22					
			1.48						6.77	
						4	0.4%		1	1
0.1%	2	2	0.2%	3	1	0.1%	2	0.2%		2
						7.11		6.97-7.59		
2.43		1	0.1%					2	0.2%	
	1		0.1%					40 mg		
		12.50 mg/					1.31	4		
							5.83		5.38-6.28	
				1	0.1%				40 mg	
				100		mg/			6.34	2
0.2%				1	0.1%					
						10	1.0%			
1	2	0.2%	2	1	0.1%	3	7	0.7%		/
			4.71				2.30-11.10	4	0.4%	
		1	0.1%					6	0.6%	
			8	0.8%						
<hr/>										
						74	7.7%			
1	35	3.6%	2	31	3.2%	3	8	0.8%		
						2.10		0.03-10.55		
		0.69			0.07-6.77		14	1.5%		
4	0.4%						13	1.4%		
	40 mg							50 mg/		5-80 mg/
			0.39				0.03-4.67		2021	10

22 35 0.53 0.07-  
5.85

---

2 0.2%  
1 0.1% 4 1 0.1% 5  
1.03 0.59-1.48  
0.43 0.16-0.69 2  
2 40 mg  
125 mg/ 100-150 mg/ 0.18  
0.03-0.33

---

3 0.3%  
2 1 0.1% 3 1 0.1% 5 1 0.1%  
0.46 0.26-6.37  
2.79 1.02-4.57 1 0.1%  
40 mg 75 mg/ 2.04  
1 0.1% 2 0.2%

---

4 0.4% 1 3 2 1 2  
0.2% 1 1 3 1 2 0.2% 1 1 3 1  
2 0.2% 1 1 2 1 1 0.1%  
1 1 0.1% 2  
14 1.5% 1 11 2 1  
3 2 8 0.8% 1 5 2 2 5 1 8  
0.8% 1 7 2 1 1  
0.1% 1 1 0.1% 2  
5 0.5% 1 4 2 1  
2 0.2% 1 1 4 1 2 0.2% 3 1  
4 1 2 0.2% 1 1 3 1

2 0.2% 1  
 1 0.1% 2 1 0.1% 1  
 1 0.1% 3 1  
 0.1% 4  
 4 0.4% 1 3 2 1  
 3 0.3% 1 3 0.3% 1  
 2 0.2% 1 1 2 1 2 0.2% 3 1  
 5 1 1 0.1%  
 1 1 0.1% 5 3  
 5 0.5% 1 3 2 2  
 3 0.3% 1 2 0.2% 1 1 2 1  
 2 0.2% 1 1 2 1 1  
 0.1% 1 1 0.1% 2  
 2 0.2% 1 2  
 0.2% 5 1 0.1% 1  
 1 0.1% 2  
 3 0.3% 3 2 0.2% 1  
 1 2 1 2 0.2% 2 1 3 1  
 1 0.1% 2 1  
 0.1% 3  
 2 0.2% 1 1 4 1  
 1 0.1% 2  
 1 0.1% 5  
 15 1.6% 1 4 2 4  
 3 1 4 5 5 1 12 1.2% 1 4 2 6 3

2				10	1.0%	1	2	2	5	3	1	4		
2				7	0.7%	1	1	2	1	3	3	4		
2														
							17	1.8%	1	11	2	1	3	
5							14	1.5%	1	10	2	2	3	
2							14	1.5%	1	13	2	1	-	
				10	1.0%	1	6	2	2	3	2			
	7	0.7%		1					7	0.7%	1	6	2	
1							5	0.5%	1	2	2	1	3	2
				5	0.5%	1	3	2	1	3	1			
4	0.4%			1					3	0.3%		1		
									3	0.3%		1	2	2
1							3	0.3%	1	2	3	1		
	2	0.2%		2										
2	0.2%			1	N									
PR				QT					QT			T		
				T										
	MB			1	0.1%		1	-						
											1	0.1%		
2				1	0.1%	3				1	0.1%	4		
						2	0.2%		2				1	
0.1%		1					1	0.1%		2			1	
0.1%	3													

---

PD-1/PD-L1 1%

- -

Vogt-Koyanagi-Harada syndrome



3 4 2  
1-2 mg/kg/  
1 1  
3 12 2  
3 0-1 12  
10 mg/

2 3

4

---

2-3

2-3

---

2-3

2-3

4

---

2

1

1

4 1

1 2

3

4

SJS

TEN

3

4

2

3

4

3

0-1

4

2

0-1

3

4

1%

PD-1/PD-L1



IgG

PD-1  
IgG4

IgG

6

6

18

65

37.5%

71.9% 71.7% 3

35.0% 32.1%

26.7% 25.1%

6.7% 5.5%

P450 CYP

7

746

—

—

5.61 L

—

CL<sub>0</sub> 0.219 L/  
0.697

125

17.9

23.0

—————

—————

—————

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HLX10-010-MSI201

II

IRRC RECIST 1.1  
 ECOG 1  
 T 2  
 HIV HBsAg HBcAb HCV  
 3 mg/kg 2 1  
 CT MRI  
 48 6 48 12 IRRC  
 RECIST v1.1 ORR  
 ORR IRRC DoR  
 PFS DCR OS  
 108  
 MSI-H  
 42 42 53.5 28.0-68.0  
 45.2% 64.3% ECOG 1 0 100%  
 IV 3.0 1-5  
 57.1% 3  
 2021 07 10 1 12 42  
 13.14 IRRC 3  
 4

**3 HLX10-010-MSI201 IRRC**

		(N=42)
		n (%)
<b>ORR</b>	<b>IRRC</b>	<b>RECIST v1.1</b>
ORR	95% CI	31.0% (17.6%- 47.1%)
	CR	2 (4.8)

		PR			11 (26.2)
		SD			10 (23.8)
		PD			16 (38.1)
		NE			3 (7.1)
<b>DoR</b>	<b>IRRC</b>	<b>RECIST v1.1</b>			
					NA (4.2, NA)
6	DoR	%	95%CI		82.5% (46.1%-95.3%)
12	DoR	%	95%CI		82.5% (46.1%-95.3%)
		<b>PFS</b>	<b>IRRC</b>	<b>RECIST v1.1</b>	
					4.2 (2.2, NA)
6	PFS	%	95%CI		49.7% 33.4%-64.1%
12	PFS	%	95%CI		46.8% 30.6%-61.4%
		<b>OS</b>			
					NA (17.7, NA)
6	OS	%	95%CI		90.5% 76.6%-96.3%
12	OS	%	95%CI		67.9% 51.2%-80.0%

ECOG 1 IRRC RECIST 1.1

1

/ PD-1 PD-L1 CTLA-4

3

PD-L1 TPS<1%, 1% TPS<50%, TPS 50% NSCLC

B, C vs.

2:1 4.5 mg/kg +

+

IRRC RECIST 1.1

24 RECIST 1.1

6

48

12

PFS IRRC RECIST 1.1

537

358

179

63.0

35-86 90.9% 66.9% 82.9%

ECOG 1 82.9% 71.7% IV 37.8%

PD-L1 TPS<1%

HLX10-004-NSCLC303

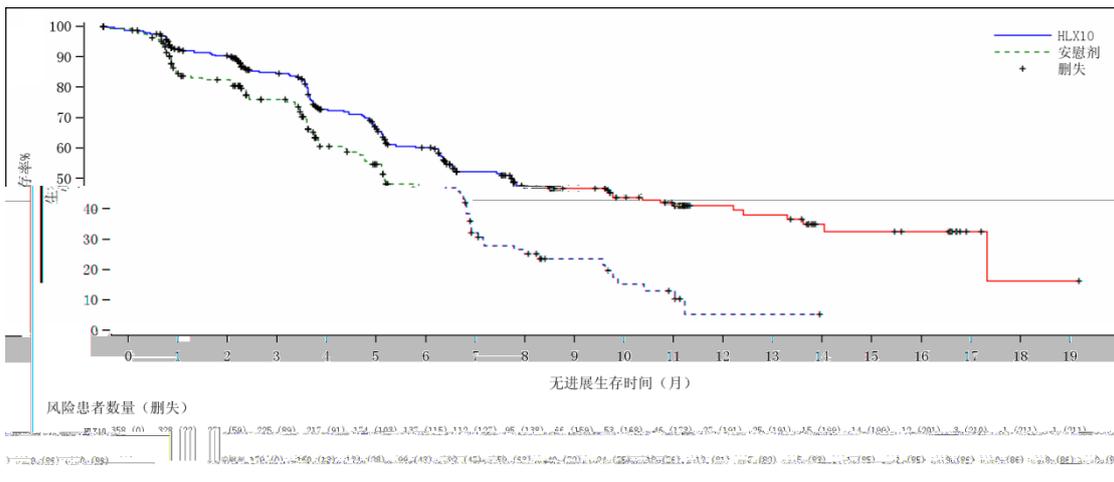
PFS V

	+ + N=358	+ + N=179
<b>PFS</b>		
%	146 (40.8%)	93 (52.0%)
95% CI	8.28 (6.90,10.38)	5.72 (5.22,6.83)
* 95% CI	0.55 (0.42,0.73)	
<i>P</i>	<0.001	
<b>OS</b>		
%	76 (21.2%)	44 (24.6%)
95% CI	- (17.35,-)	- (13.11,-)
* 95% CI	0.75 (0.52,1.10)	
<i>P</i>	0.138	
	230 (64.2%)	80 (44.7%)
95% CI	(59.0%,69.2%)	(37.3%,52.3%)
	9.43 (0.0,17.8)	5.36 (0.0,12.6)
6	62.1%	34.0%

\* Cox

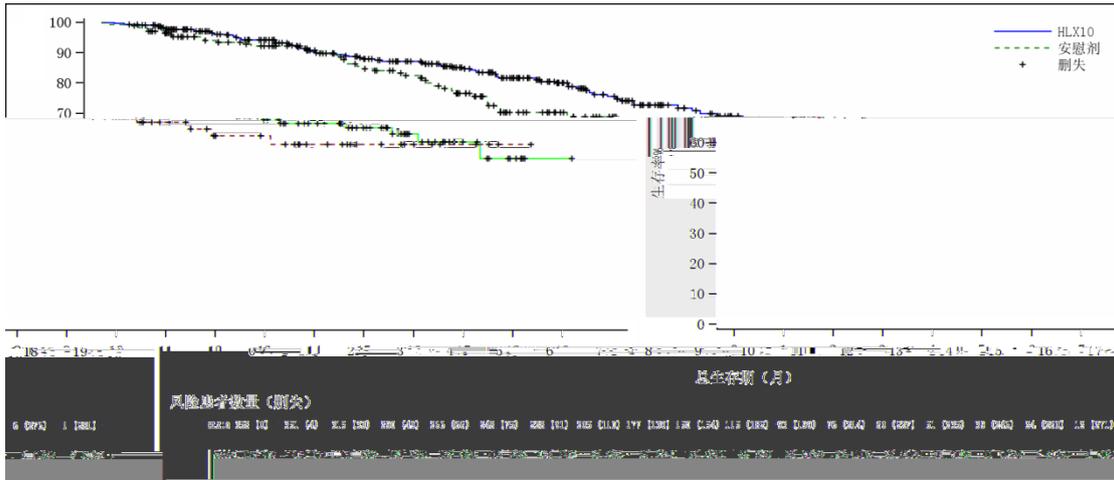
## 1 HLX10-004-NSCLC303

## Kaplan-Meier



## 2 HLX10-004-NSCLC303

## Kaplan-Meier



HLX10-005-SCLC301

ES-SCLC

ECOG 1

IRRC RECIST 1.1

/

PD-1 PD-L1 CTLA-4 3

PD-L1 TPS<1% TPS 1% /

vs. 65 vs. <65

2:1 4.5 mg/kg +

+

6

48 12 RECIST 1.1

PD

NCCN ESMO

PD

HLX10-005-SCLC301 585 389

196 **<0.001**

62.0 28-83 82.2% 68.5%

80.9% IV 80.2% PD-L1

@ ^ Q 9q 14.66300011 1

TPS<1%

OS IRRC

RECIST 1.1 PFS iRECIST PFS

RECIST 1.1 PFS2 IRRC RECIST 1.1 ORR IRRC

RECIST 1.1 DOR

2021 10 22 HLX10-005-SCLC301

OS PFS 6

3 4

**6 HLX10-005-SCLC301**

+ + + +

N=389 N=196

**OS**

% 146 37.5% 100 51.0%

95% CI 15.38 13.273 NA 10.91 9.955 14.324

\* 95% CI 0.63 0.489 0.818

*P* <0.001

**PFS IRRC RECIST 1.1**

% 223 57.3% 151 77.0%

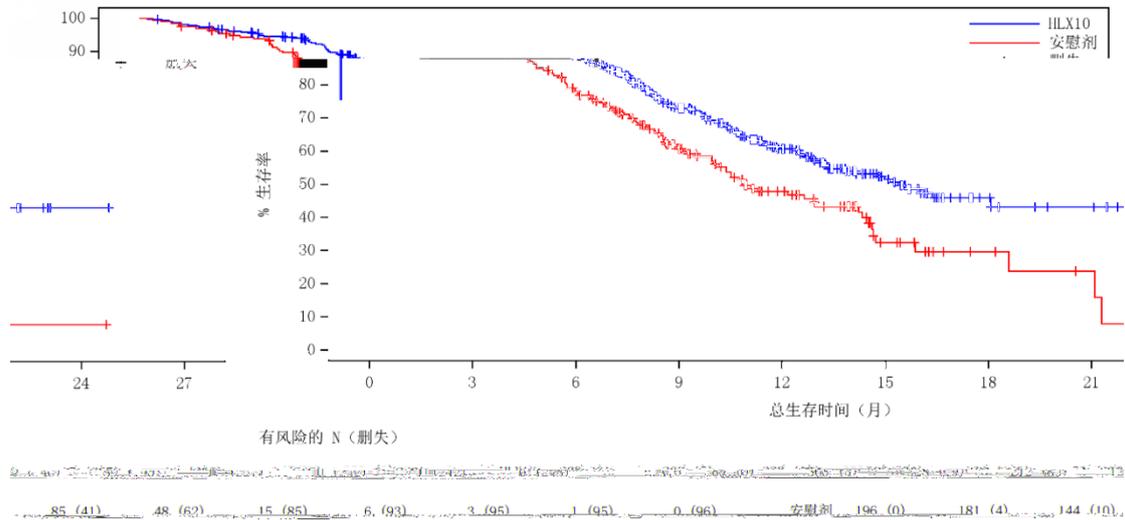
95% CI 5.72 5.520 6.899 4.34 4.205 4.501

	+ +		+ +	
	N=389		N=196	
95% CI	75.89	84.05	63.49	76.70
<b>DOR IRRC RECIST 1.1</b>				
95% CI	5.55	4.238	6.801	3.22 2.924 4.172
* 95% CI	0.48 0.369 0.616			
<i>P</i>	<0.001			

\* Cox

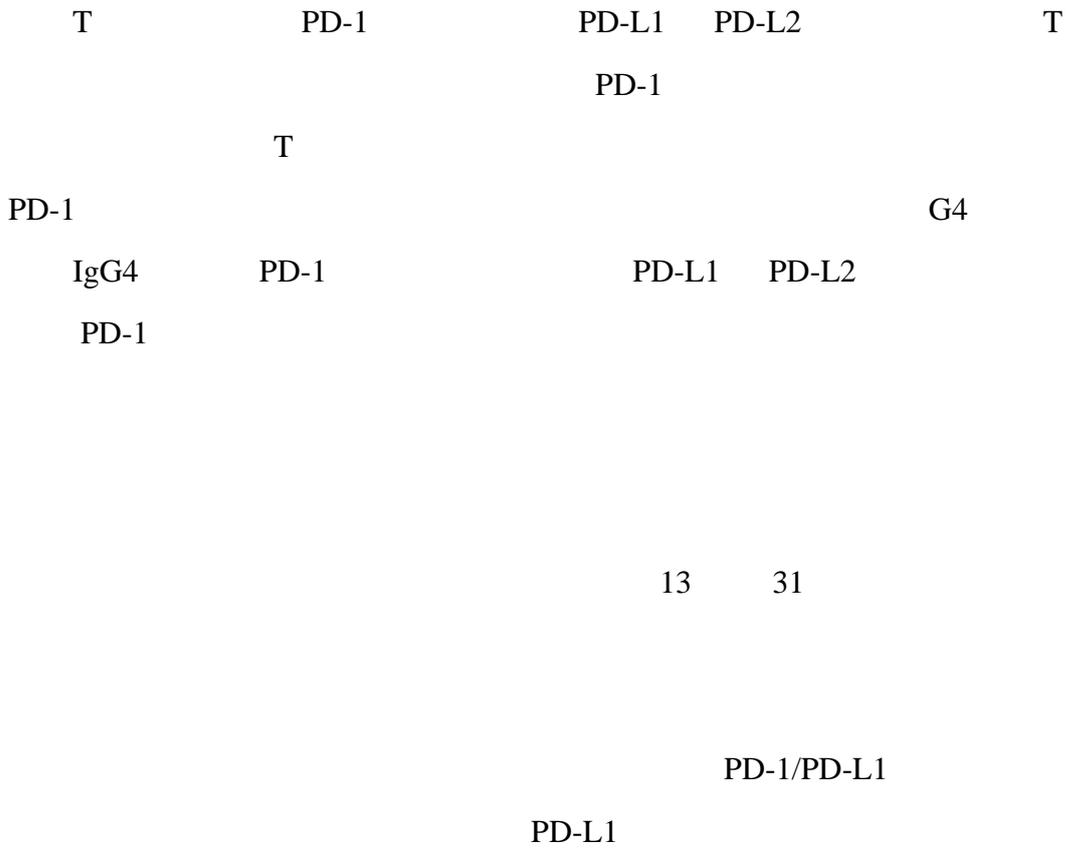
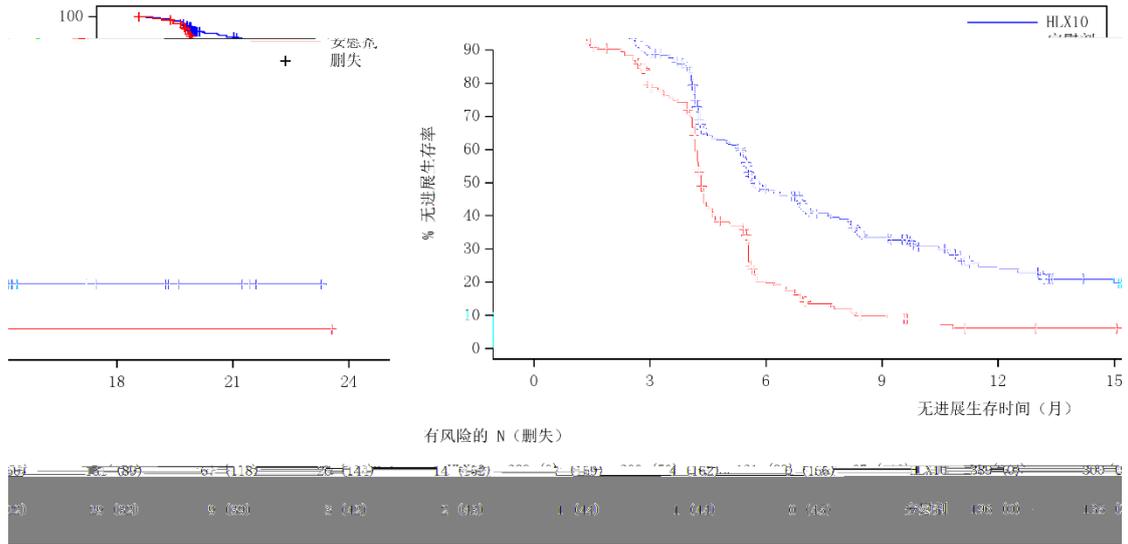
### 3 HLX10-005-SCLC301

### Kaplan-Meier



4 HLX10-005-SCLC301

Kaplan-Meier



PD-1

PD-1

PD-1

PD-1

2-8

10 mL 1 /

36

YBS00282022

S20220013

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200233

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