

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

3 mg/kg 2 1

4.5 mg/kg 3 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 mL25 /

30 ±10

MSI201	HLX10-004-NSCLC303	HLX10-001	HLX10-010-214
24	6	2~8	24
3	3	77	76
8	3	6	4
1	2	2	3
3 mg/kg	4.5 mg/kg		
207	50.72%		≥6
19.32%	≥12		
3 mg/kg	4.5 mg/kg	3	
207	79.7%		≥10%
	3		
30.0%	≥1%		
γ-			

-

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

	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
	/	
	/	

	ii Y- jj D- kk N ll	ii Y- jj ll kk
	C A	mm - N C D-

* 2

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

2

1

1

T-

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					
						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		
		0.46								

					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	18
					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	0.8%
				2021	10	22	34	
				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
		1	0.1%	1				
				5.65			1.94-13.50	1
0.1%			1	0.1%				
	80 mg/			0.26		2021	10	22
				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
					0.69			22
	6.47						5.59	

[illegible]

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

2 0.2% 1

 1 0.1% 1

 1 0.1% 2 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 0.1% 3

 1 0.1% 5

 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

 0.1% 3 1 0.1% 5

 2 0.2% 4 1 0.1%

 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	α-						
										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

0.13	0.03-0.23	2			1
			0.03		
2	0.2%		1	1	2
	0.72		0.03-1.41		1
	0.03-0.16	2			
	0.10		0.03-0.16		
1	0.1%	3			
	0.03		0.20		
			0.20		
					ADA
			ADA		
		961			
					ADA
				21	2.2%
1	ADA				ADA

[illegible]

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

2

3

4

2-3

2-3

2-3

2-3

4

2

1

1

4 1

TEN

1 2

3

4 SJS

3

3 4 2

4

3

0-1

4

2

0-1

3 4

1%

PD-1/PD-L1

2 3

3

4

- -

1

2

3

PD-1

IgG

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

CL₀ 0.219 L/
 0.697

125

17.9

23.0

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	
		IV				3.0	
57.1%				≥3			
2021		07		10		1	
		13.14		IRRC		12	
						42	
						3	
4							

IRRC			
ORR	95% CI	31.0% (17.6%- 47.1%)	
CR		2 (4.8)	

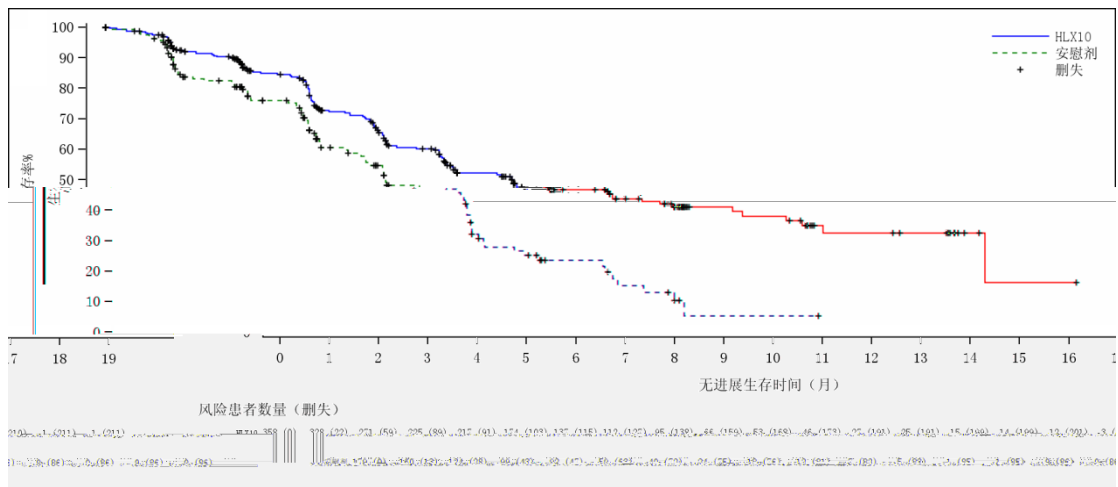
		PR			11 (26.2)
		SD			10 (23.8)
		PD			16 (38.1)
					3 (7.1)
					NA (4.2, NA)
≥ 6	DoR	%	95%CI		82.5% (46.1%-95.3%)
≥ 12	DoR	%	95%CI		82.5% (46.1%-95.3%)
					4.2 (2.2, NA)
6	PFS	%	95%CI		49.7% 33.4%-64.1%
12	PFS	%	95%CI		46.8% 30.6%-61.4%
					NA (17.7, NA)
6	OS	%	95%CI		90.5% 76.6%-96.3%
12	OS	%	95%CI		67.9% 51.2%-80.0%

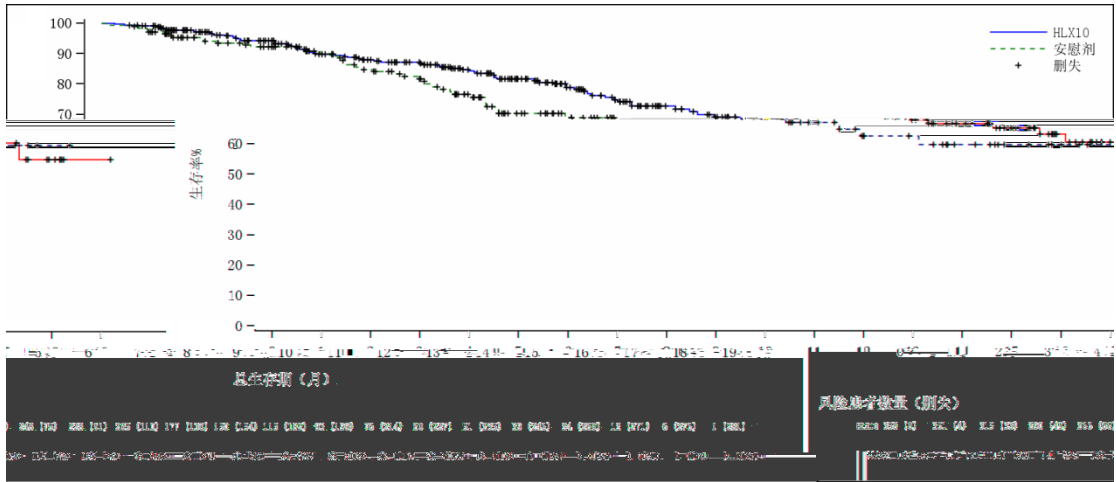
ECOG	≤1		IRRC	RECIST	1.1
	1				
		/	PD-1	PD-L1	CTLA-4
3					
	PD-L1	TPS<1%, 1%≤TPS<50%, TPS≥50%		NSCLC	
B, C		vs.			
2:1		4.5 mg/kg		+	
		+			
			IRRC	RECIST	1.1
		24		RECIST	1.1
6			48	12	
			PFS	IRRC	RECIST 1.1
		537		358	
	179				63.0
	35-86	90.9%	66.9%		82.9%
ECOG	1	82.9%	71.7%	IV	37.8%
	PD-L1	TPS<1%			
HLX10-004-NSCLC303					

PFS flQ q 1 ÆG†023/098 cm ÉŠ<@n1H 1695

%	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	
%	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





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

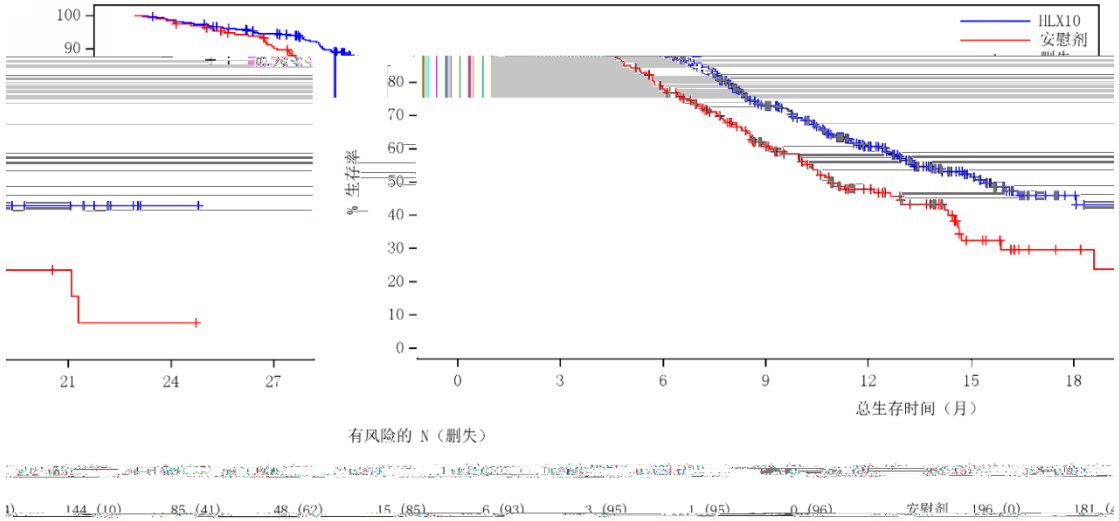
PD										
HLX10-005-SCLC301					585			389		
196										
62.0		28-83		82.2%		68.5%				
80.9%		IV		80.2%		PD-L1				
TPS<1%										
OS					IRRC					
RECIST		1.1		PFS		iRECIST		PFS		
RECIST 1.1		PFS2		IRRC		RECIST 1.1		ORR		IRRC
RECIST 1.1				DOR						
				2021		10		22		HLX10-005-SCLC301
						OS		PFS		6
3		4								

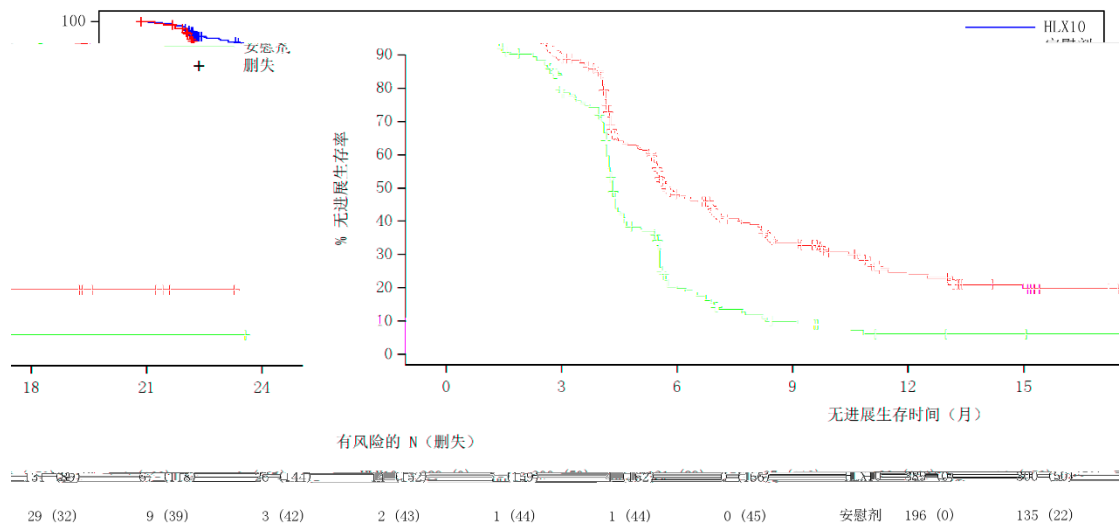
	%	146	37.5%		100	51.0%	
	95% CI	15.38	13.273	NA	10.91	9.955	14.324
*	95% CI		0.63	0.489	0.818		
<i>P</i>				<0.001			

		%		223		57.3%		151		77.0%	
		95% CI		5.72		5.520		6.899		4.34	
										4.205	
										4.501	

95% CI	75.89 84.05	63.49 76.70
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





T PD-1 PD-L1 PD-L2 T

PD-1

T

PD-1 G4

IgG4 PD-1 PD-L1 PD-L2

PD-1

13 31

PD-1/PD-L1

PD-L1

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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24

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