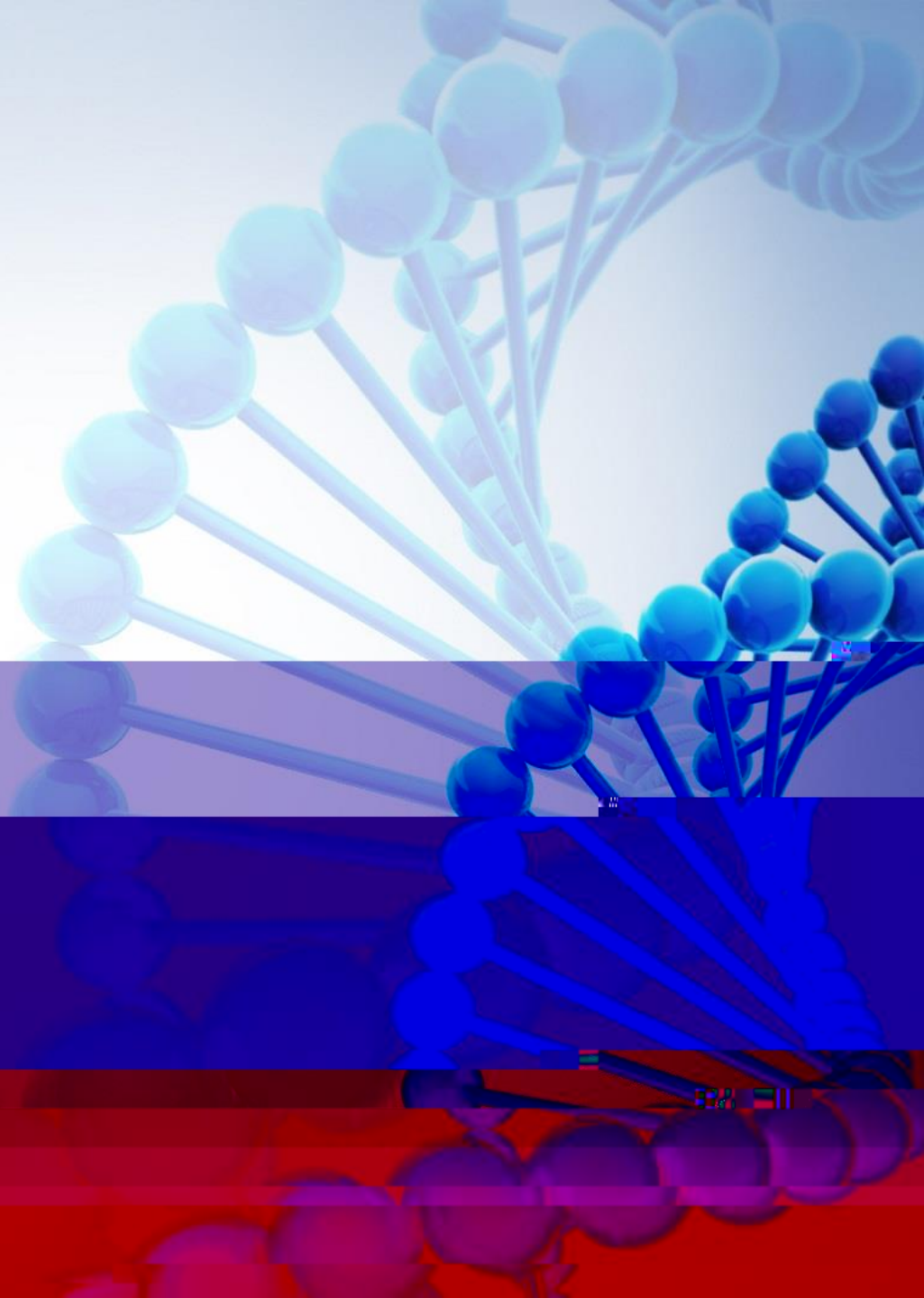
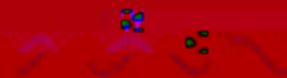


上

2022 8

宏·进·步





2.1

2.2

2.3

2.4

2.5







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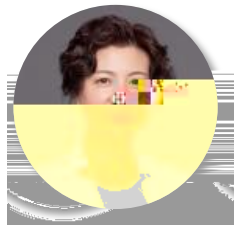
2.4
HLX10[®] FDA
NDA NMPA[®]
HLX10[®] NDA
MSI-H[®]





2019 3

30



MBA

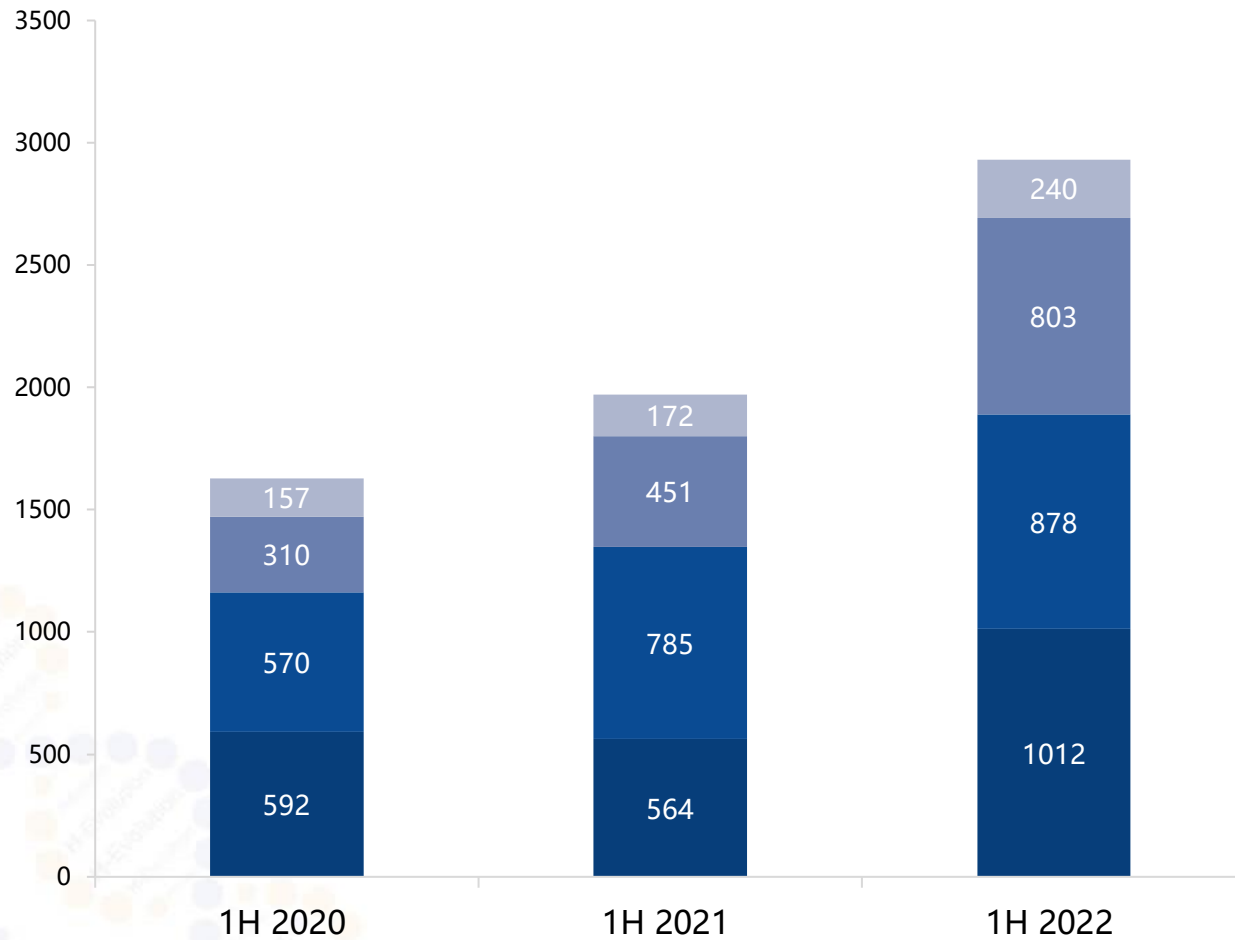


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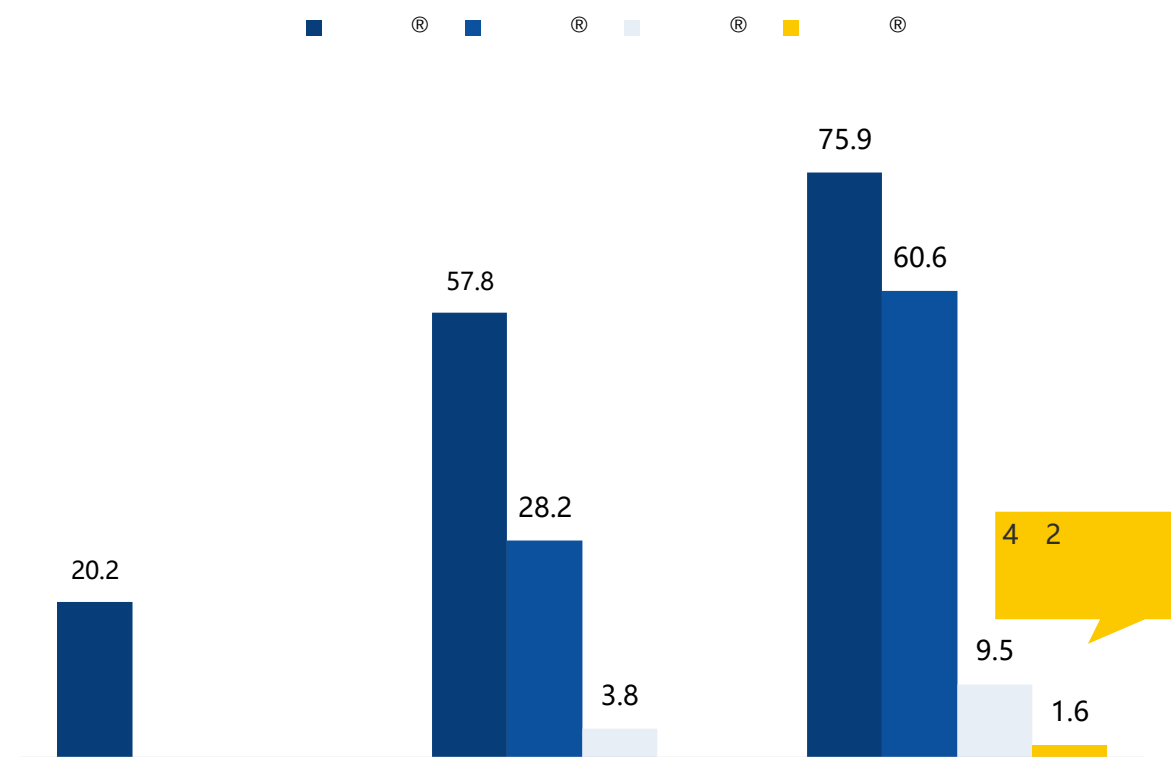
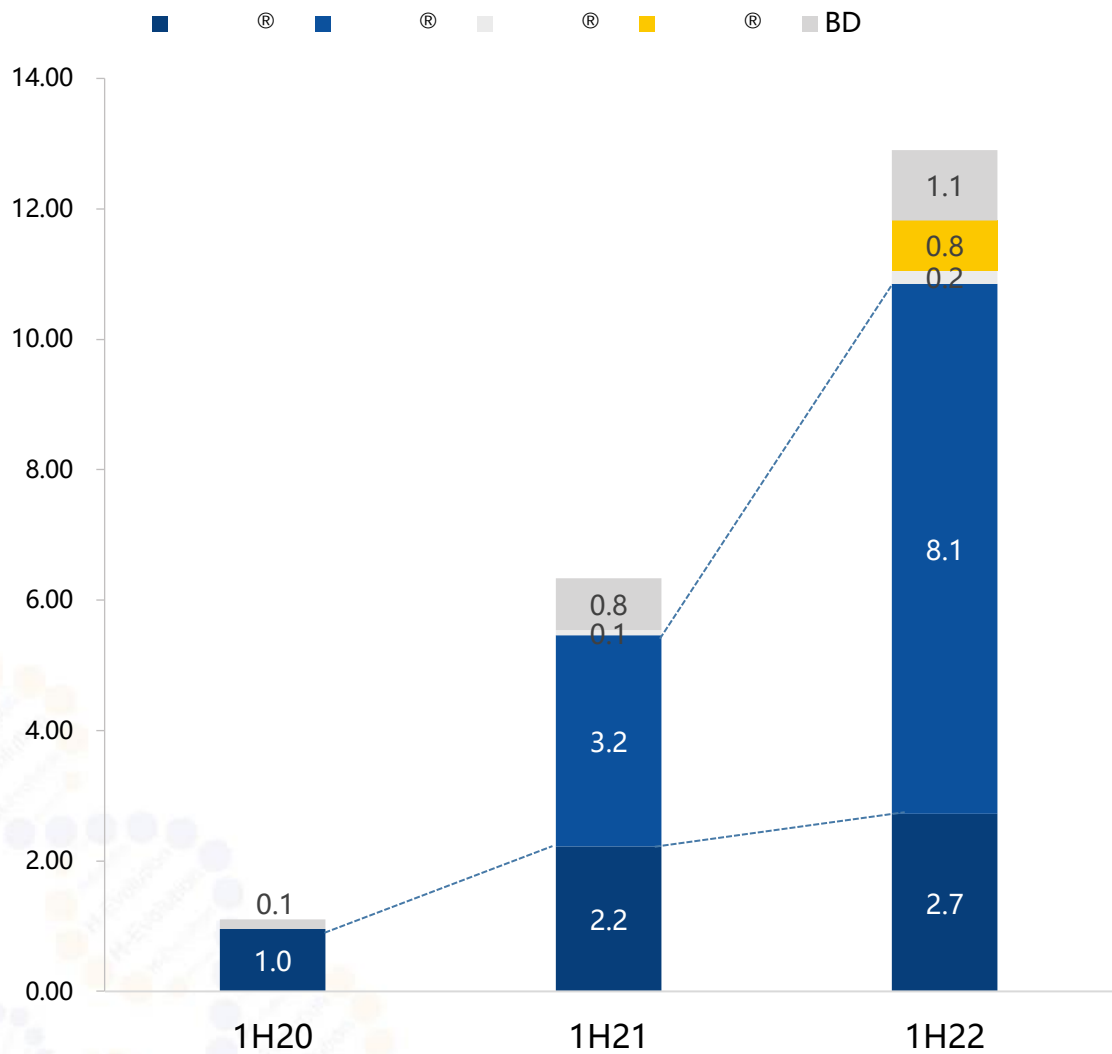
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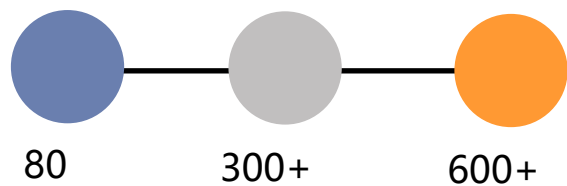
	1012
	878
	803
	240





	2022 H1	12.89	2021	6.55
103%	4.88	150%*	2.72	3
	2022	60.6	147.7	2021
1.6	1.6*	115%,	75.9	8.13
				7700

DTP

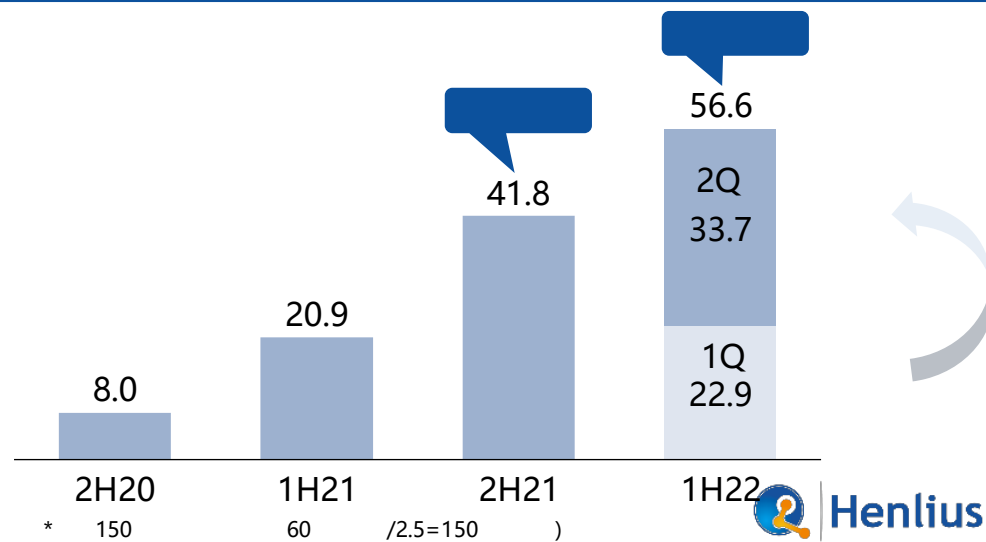


T 1000 (+)714 71%

4 26 6 T 1000
(+)149 64%

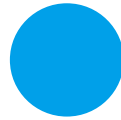
6

HER2+

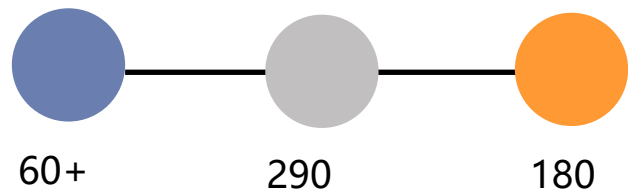




一曲成双
双曲成佳



DTP



18

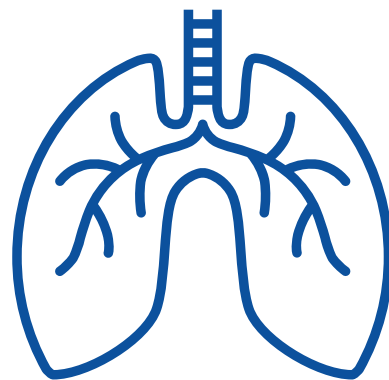
110

21%





17 / PD-1 80 / 12 /



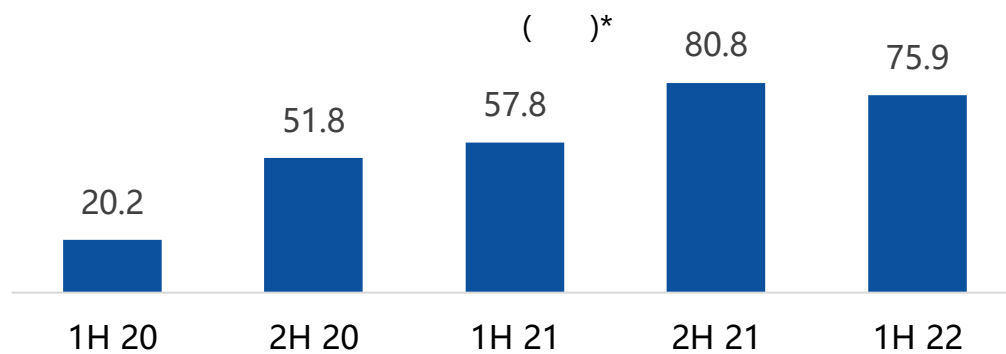
HR



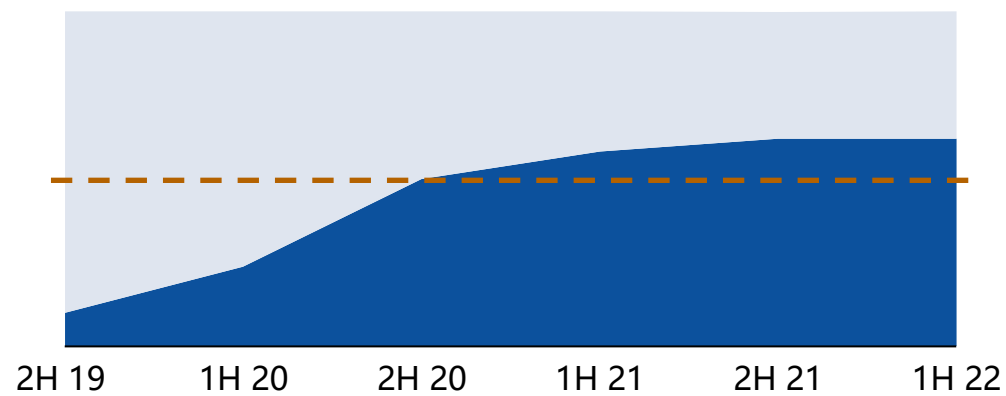
6 中 /

6 , 中 /

6 T 300 /



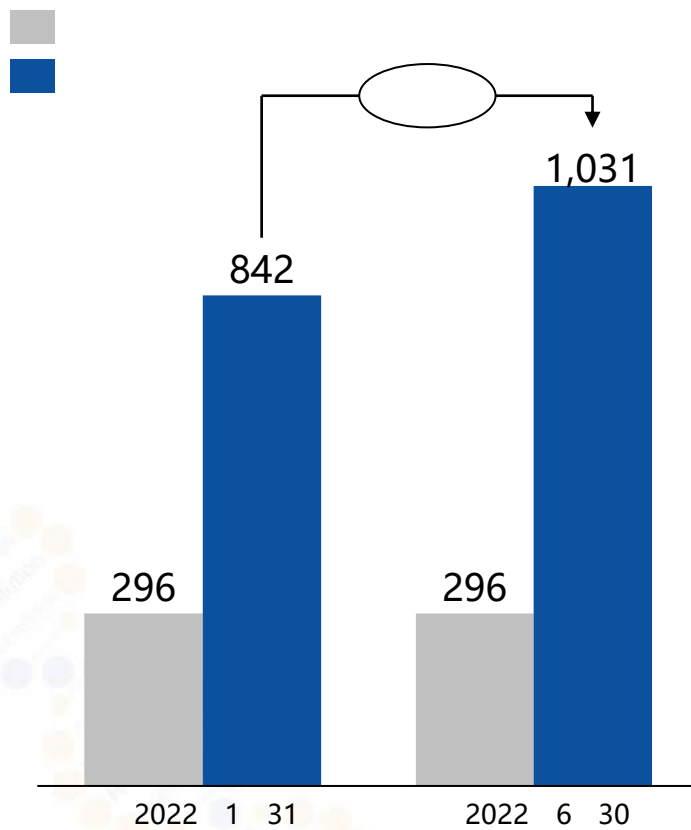
中



*: 100 /

6 T 300+

22%





HLX10 -

ESCC

HLX10 -

ES-SCLC

HLX10 -

NSCLC

HLX10 -

ES-SCLC

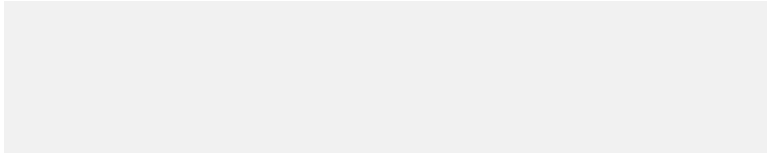
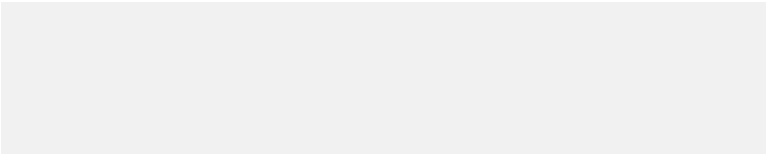
HLX07 -

CSCC

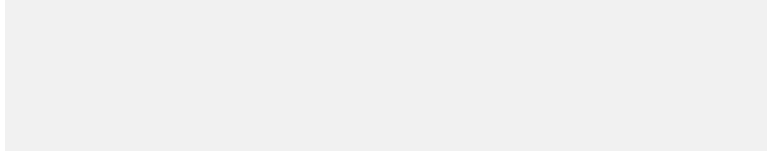
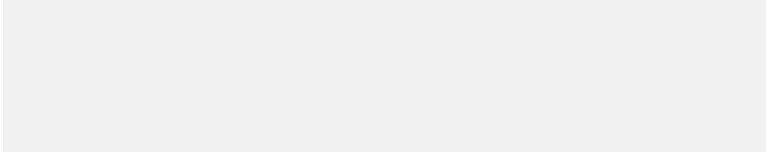
HLX10 -



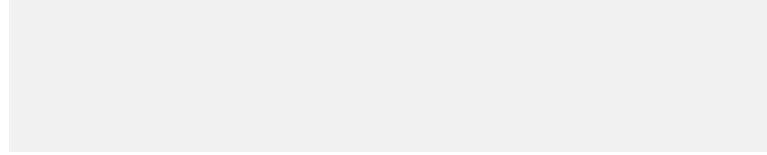
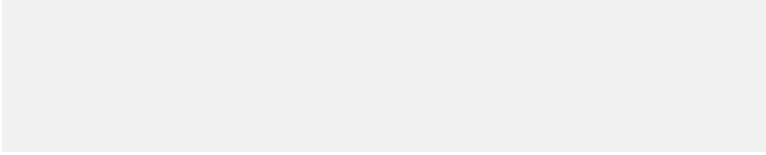
H +
NMPA NDA
2022 9
537



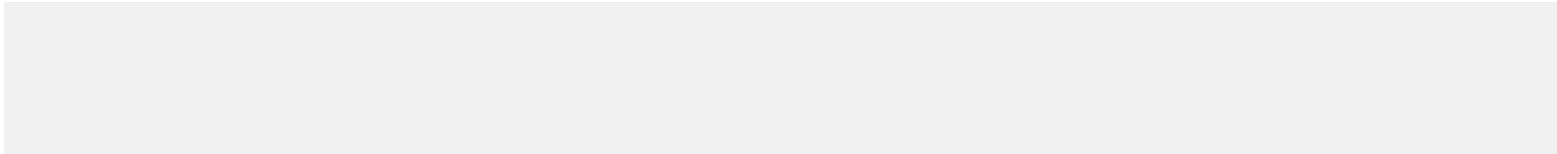
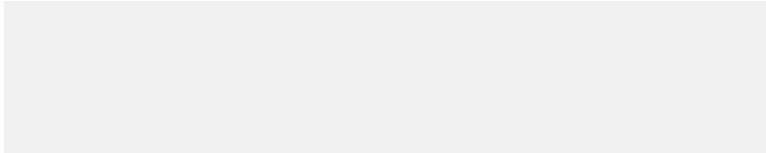
H +
NMPA NDA
585



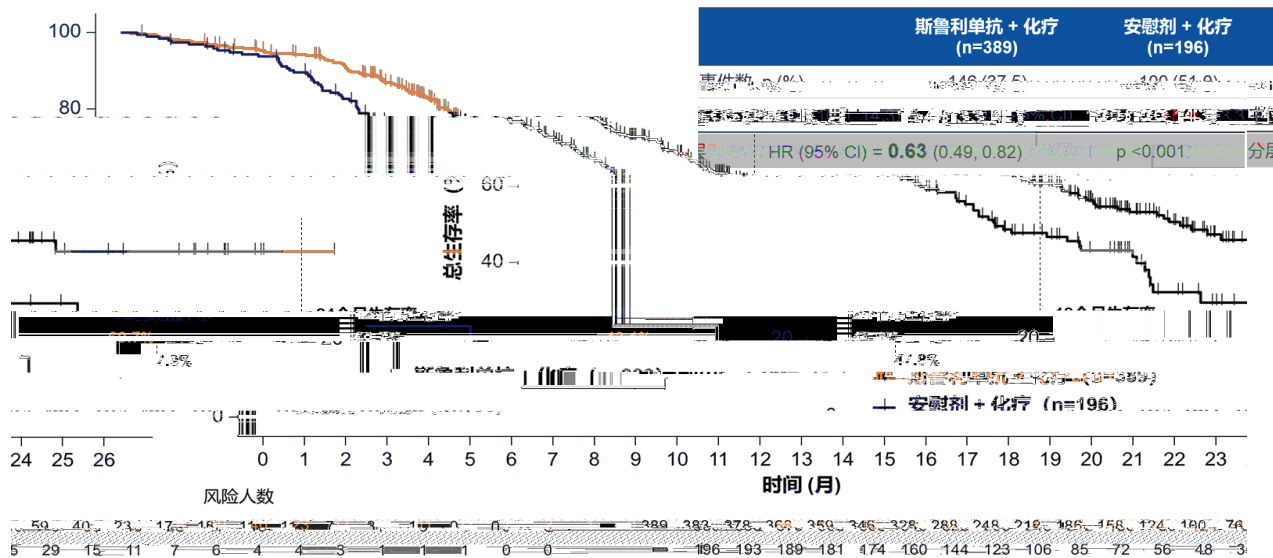
H +
2022 4 FDA
FDA BLA
2023 4Q



H +
EMA MAA
2023 1Q







2022 ASCO

ANNUAL MEETING

ASTRUM-005

免疫联合化疗一线治
双盲、III期临床试验

新型抗PD-1抗体——斯鲁利单抗联合化疗对比安
疗广泛期小细胞肺癌：一项国际多中心、随机、

程颖 教授

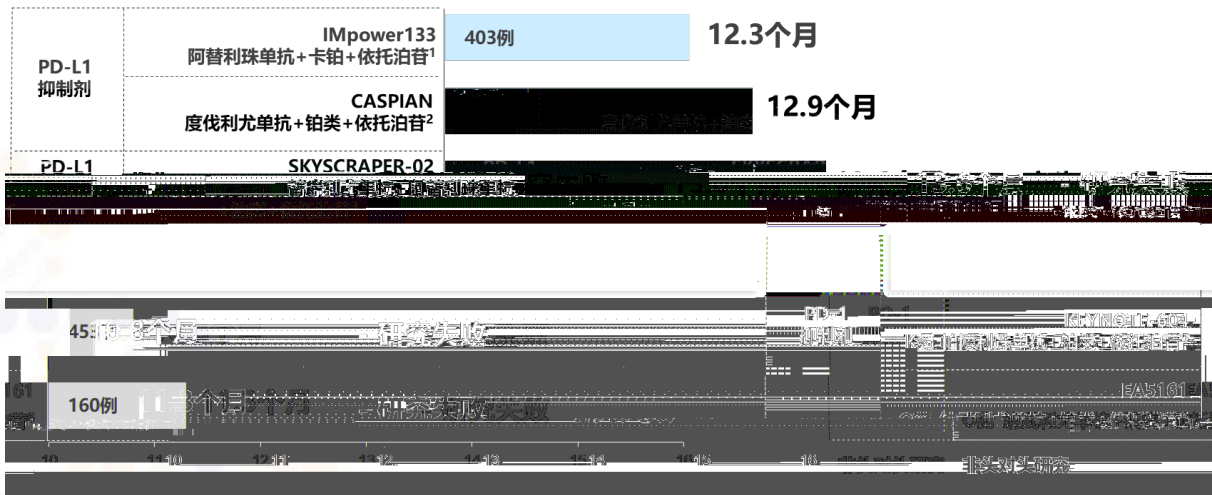
吉林省肿瘤医院 长春

in⁹, 石建华⁹, 潘志杰¹⁰, 石金升¹¹, 王希成¹², 白元松¹³,
朱俊¹⁸, ASTRUM-005 其他研究者

程颖¹, 韩亮², 邹麟³, 陈军⁴, 孙红梅⁵, 温桂兰⁶, 姬颖华⁷, Mikhail Dvork
Tamar Melkadze¹⁴, 潘跃银¹⁵, 闵旭红¹⁶, Maksym Viguro¹⁷, 康文英¹⁸, 王清

⁹佳木斯市肿瘤医院, 佳木斯; ¹⁰南昌大学第一附属医院, 南昌; ¹¹新乡医学院第一
附属医院, 新乡; ¹²Russia; ¹³临沂市肿瘤医院, 临沂; ¹⁴浙江大学医学院附属第一医院, 杭州; ¹⁵沧州市
中心医院, 沧州; ¹⁶Research Institute of Clinical Medicine, Tbilisi, Georgia; ¹⁷安徽省
肿瘤医院, 合肥; ¹⁸安徽医科大学第一附属医院, 合肥

¹吉林省肿瘤医院, 长春; ²徐州市中心医院, 徐州; ³湖南省肿瘤医院, 长沙; ⁴天津医科大学总医院, 天津;
附属第一医院, 新乡; ⁵Budgetary Healthcare Institution of Omsk Region "Clinical Oncology Dispensary", Omsk
人民医院, 沧州; ⁶广东药科大学附属第一医院, 广州; ⁷吉林大学中日联谊医院, 长春; ⁸Acad.Fridon Tod
adze, Tbilisi, Georgia



OS	PFS	ORR	DOR
.10.9		HR=0.63	<0.001
.4.3		HR=0.48	

SCLC

FDA

1. H L, e a. N E J Med. 2018 Dec 6;379(23):2220-2229. 2. Pa -A e L, e a. 2020 ASCO Ab ac 9002. 3. C a e M. R d 2022 ASCO 4. Y C e . 2022 ASCO.
5. R d CM, e a. J C O c . 2020 J 20;38(21):2369-2379. 6. Lea TA, e a. 2020 ASCO Ab ac 9000.

	2		3		2		2	
	OS	PFS	OS	OS	OS	PFS	OS	OS
	+	+	+	+	+	+	+	+
	+	+	+	+	+	+	+	+
	201	202	268	269	228	225	389	196
	35/65		36.9/63.1		26/74			
	12.3	10.3	12.9	10.5	10.8	9.7		
	HR =0.76 (0.60-0.95)		HR=0.75(0.62-0.91)		HR=0.80(0.64-0.98)			
	P=0.0154		P=0.0032		P=0.0164			
	13.9		14.2		21.6		12.3	
	<25%		22.9%		/			
	5.2	4.3	5.1	5.4	4.5	4.3	5.7	4.3
	HR=0.77(0.62 0.96)		HR=0.78 (0.65 0.94)		HR=0.75(0.61 0.91)		HR=0.48 (0.38-0.59)	
	P=0.017				P=0.0023		P 0.001	
	60.2%	64.4%	67%	58%	71%	62%	80.2%	70.4%
	4.2	3.9	5.1	5.1	4.2	3.7	5.6	3.2

1.L SV, Rec M, Ma fed AS, e a. J C O c . 2021 Feb 20;39(6):619-630. 2.G d a JW, D M, C e Y, e a. La ce O c . 2021 Ja ;22(1):51-65.

3.C a e M. R d , e a. J C O c . 2020 J 20 38(21) 2369-2379. 4.Y C e . 2022 ASCO.

(EGFR)

HLX07

II

IRRC INV

ORR 38.5%

23%

(BRAF
V600E)

HLX208

LCH

HLX208

II
BRAF

(HER2)

HLX22

He 2

PD

He 2 d a IV

II

1

ORR 85% 10

(VEGF)

I/II

BCVA

III

LUCENTIS

1. HLX22 / HLX22 HLX22 XELOX
 PD-1 H 85%
2. 2023 HLX22 HER2
3. E e 125 E e .62 / FDA ()HER2 DESTINY-Ga c01
 ORR 51% .14%

HLX22-GC-201 II	+XELOX +XELOX +XELOX	54+128	PFS/ORR	:
KN811 III	+CF/XELOX +CF/XELOX	732 1:1 264	PFS/OS	N=133 131 =0.00006
NCT04276439 II	+C e	33	ORR	
T GA III	+CF/CX CF/CX	584 1:1	OS	47.3% 34.5% =0.0017



I 19 ORR 5.3% PFS

HNSCC 1L 2L

13 IRRC-ORR 38.5% INV-ORR 38.5% INV- PFS
5.45 INV-6- PFS a e 34.6%

P II

1L NSCLC

14 DLT

P II

CSCC) 1L 2L 3L

CSCC EGFR

P II

P II

ESCC 1L 3L
SCLC 1L
CRC 1L
3L
HCC 1L 2L 3L
HLX04 VEGF

EGFR PD-1
EGFR III

ST -	I 26 20 SD DCR 77% 13 50%	P I
NSCLC	" " HLX208 BRAF	P II
C e e ECD LCH E d e -	" " HLX208 BRAF LCH&ECD CMR PMR PERCIST)	P II
CRC	HLX208 ---	P II
ATC	HLX208 BRAF ATC	P Ib/II
BT Me		P II



(CD73)

“ ”
CD73

CD73
CD73

(TIGIT)

HLX53
T a ab A e ab

(LAG-3)

PD-1
NSCLC

CRC

(GARP)

(EGFR 4-1BB)

NK
EGFR
EGFR

T

(PD-L1 TIGIT)

HLX301
T a ab A e ab





- HLX01/02/03/04¹
- HLX10 (PD-1)



- (PD-1, HER2)
- AXC
- PS

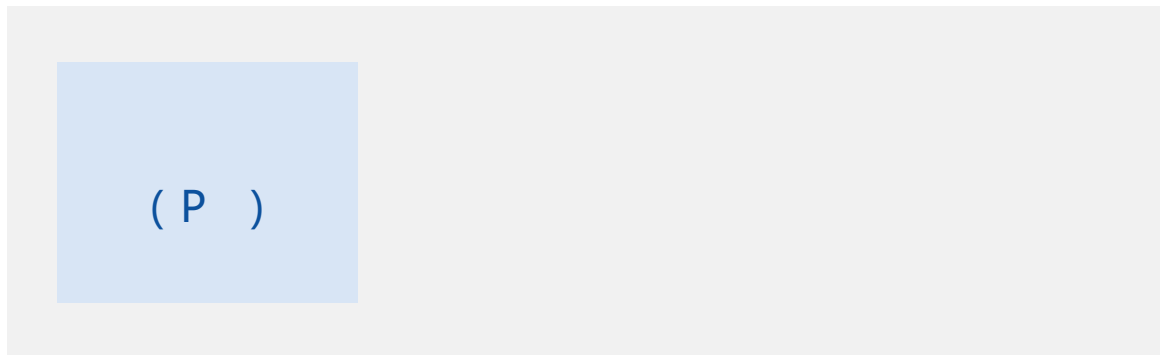
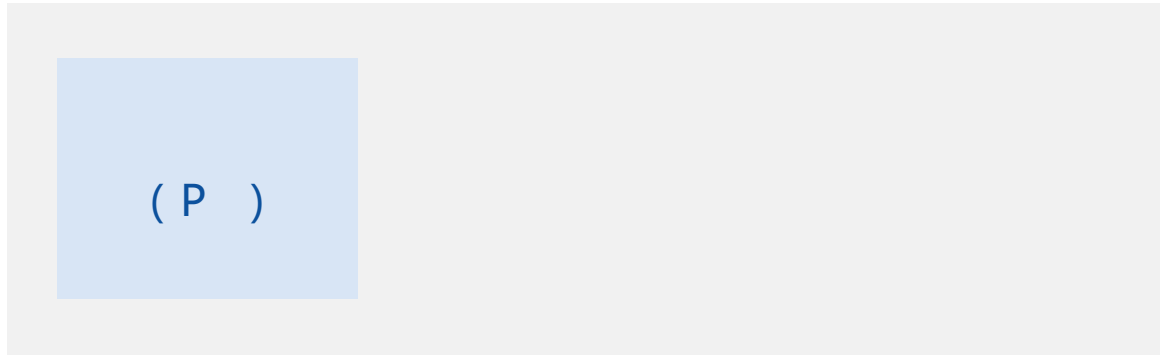
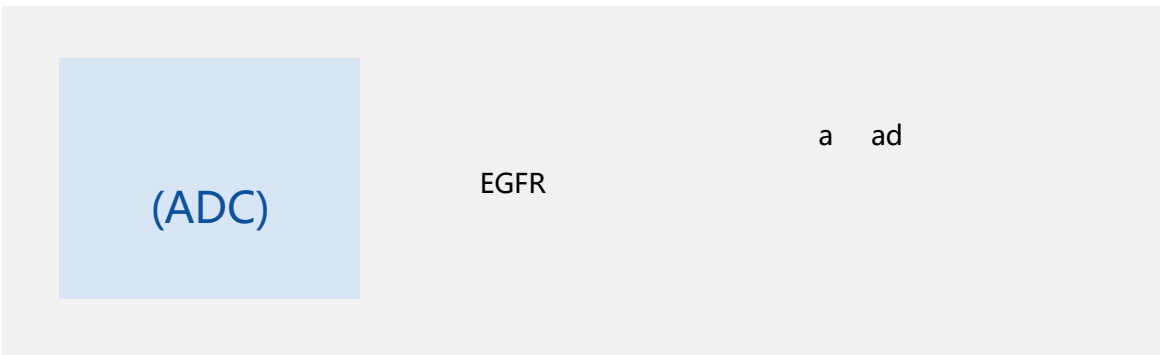
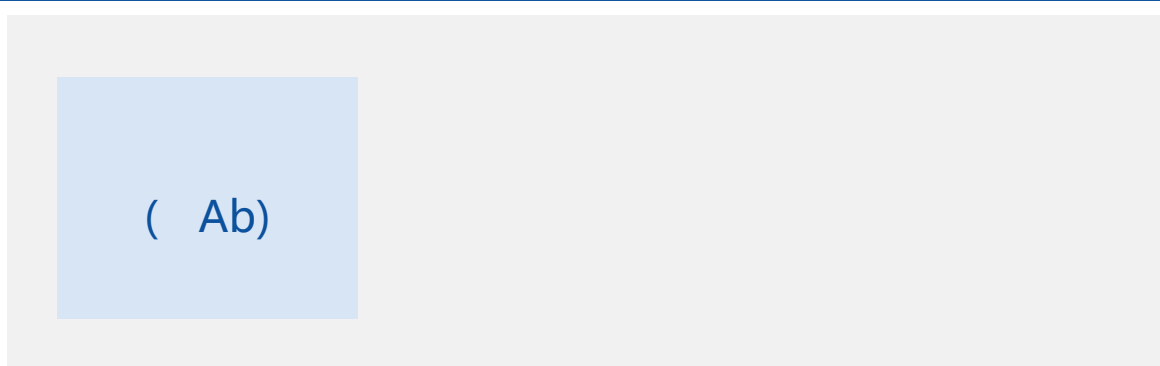
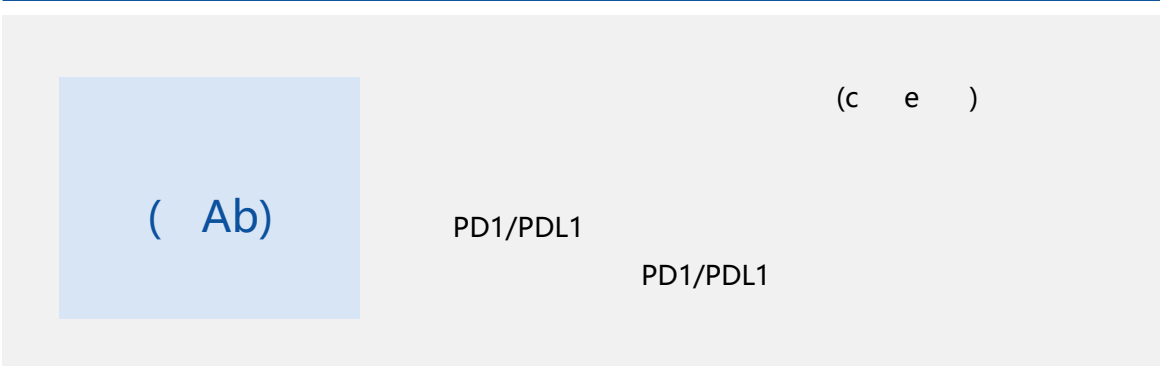


- d ca + Be - - d ca F - -
- +
-


XXC



C a e) (AXC: A b d X- ec e
ADC 4-5 ADC AXC 2 F - -c a
2023 6 IND
ADC





(1)	CD20	(2)								
(3)	HER2									
(4)	TNF-									
(5)	VEGF									
	VEGF									
HLX11 () ⁽⁶⁾	HER2									
HLX14 () ⁽⁷⁾	RANKL									
HLX05 () ⁽⁸⁾	EGFR									
HLX12 ()	VEGFR2									
HLX13 ()	CTLA-4									
HLX15 ()	CD38									

(1) 2019 2 NMPA
(2)
(3)
T a c ®
(4) 2020 12 NMPA

5) 2021 11 NMPA
(6) a
(7) a
(8)

100

Organon 5.41

7300

HLX11

HLX14

300

HLX13

Abbott 440

300

®

(N SE: OGN)
2021 6 3



HLX11

III

HLX14

III



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50%

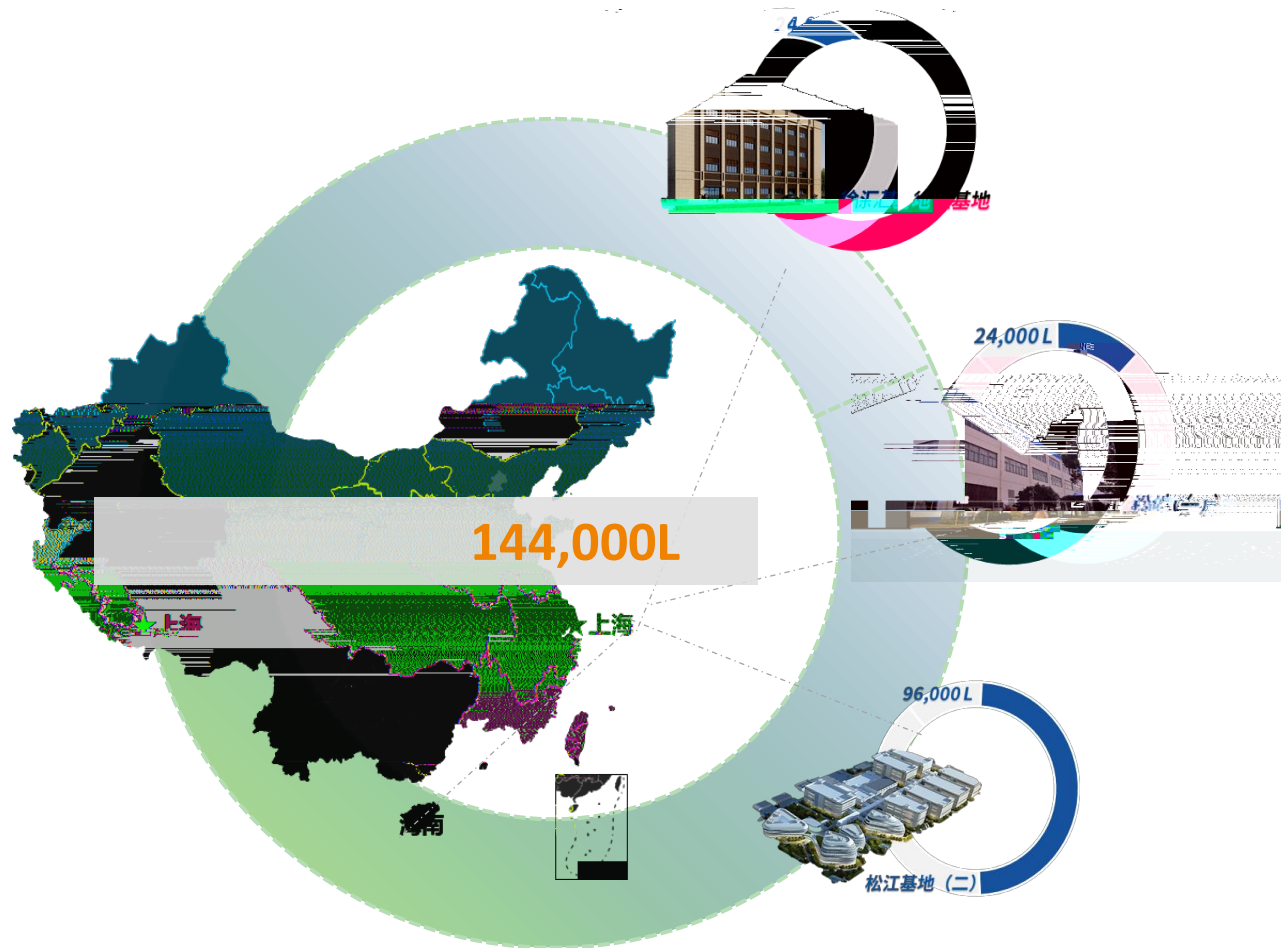




2022 () : 48,000L
 GMP : 450 + 2019
 : 98%
 : 878

2022 5
 : 24,000L
 ®
 HLX04-O HLX11 HLX14

GMP
 FDA EMA





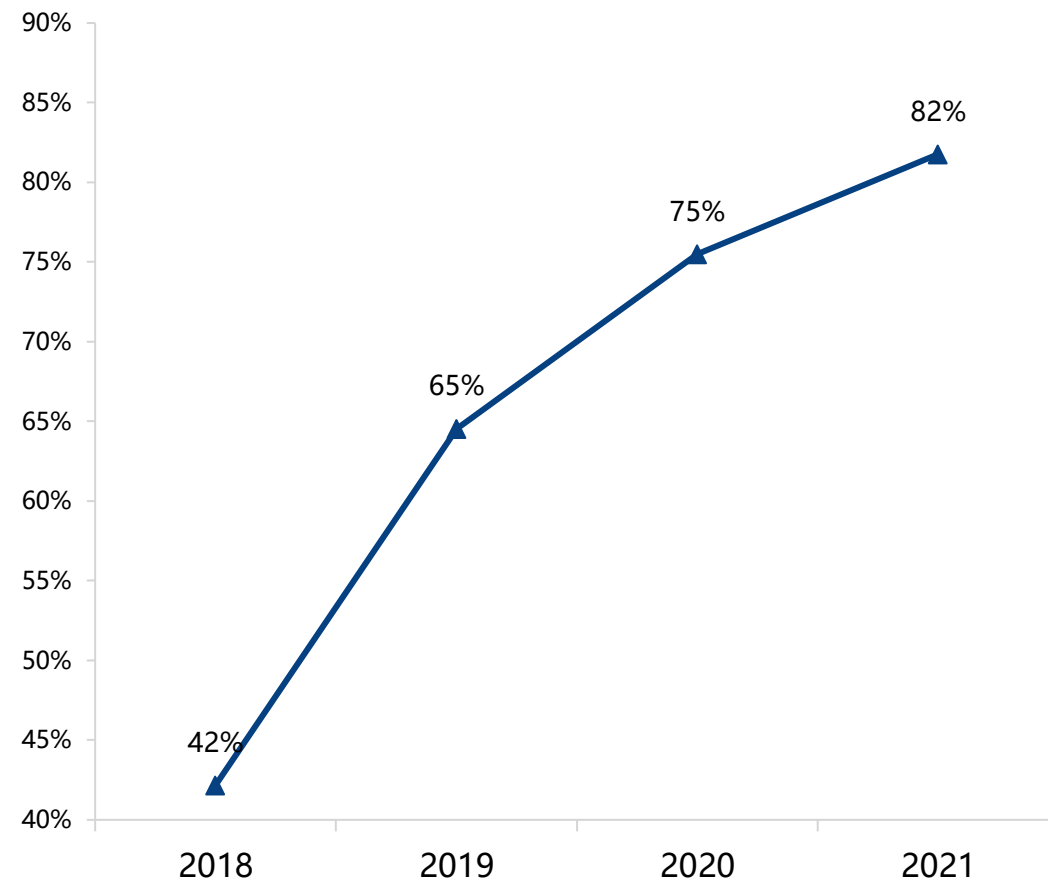
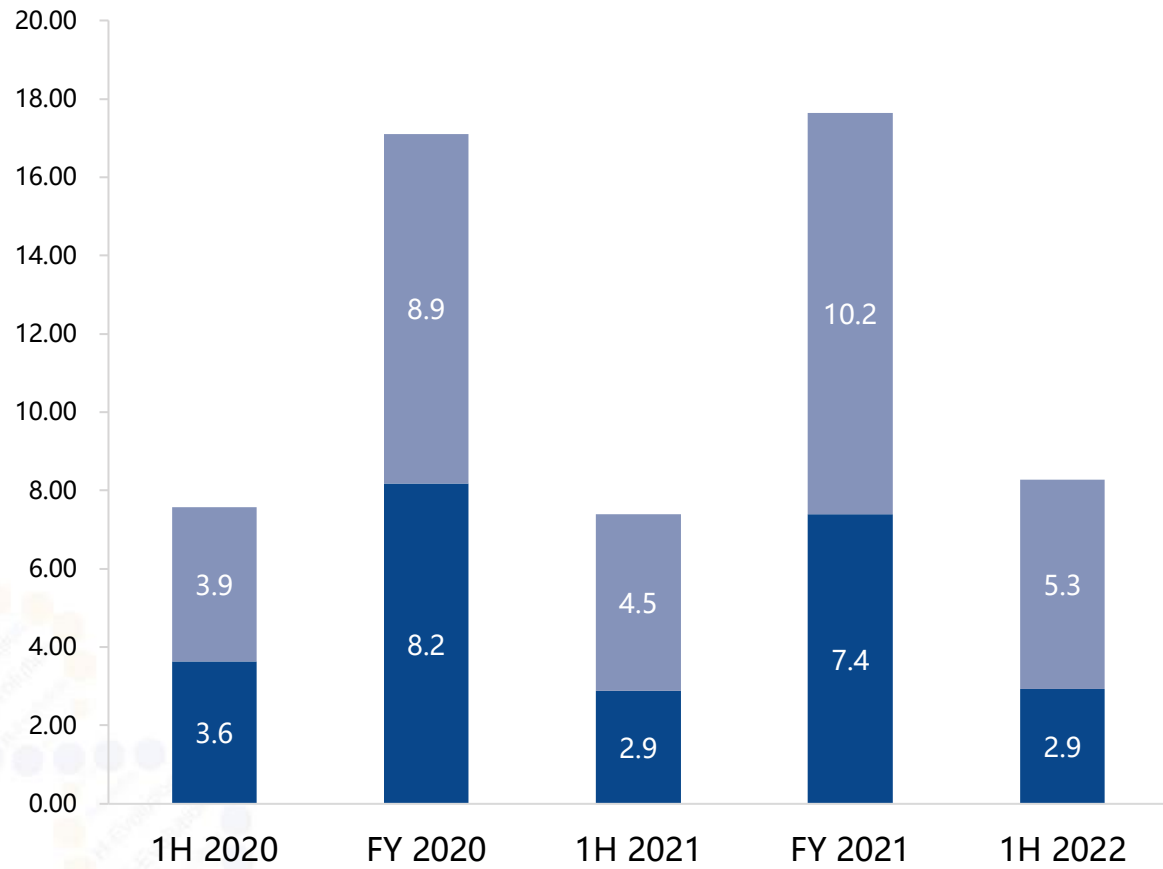
CDMO

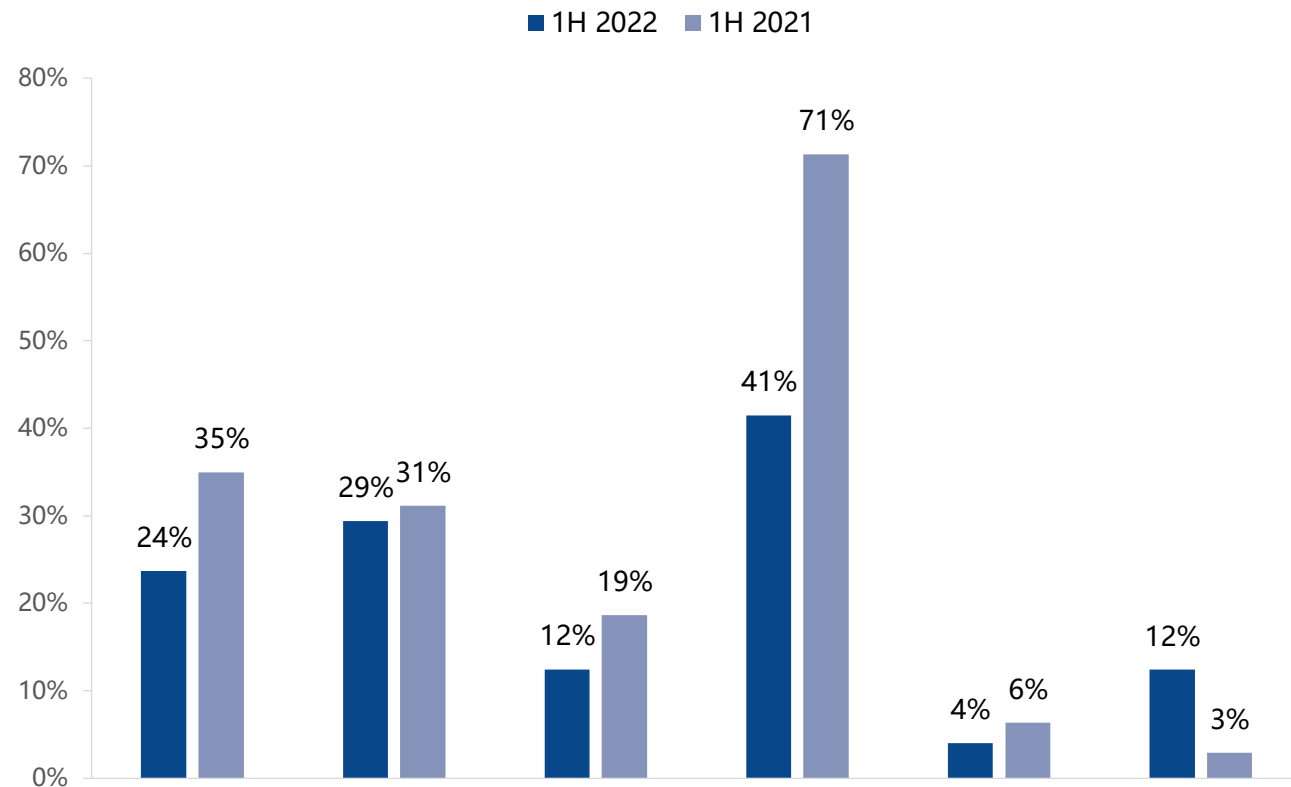
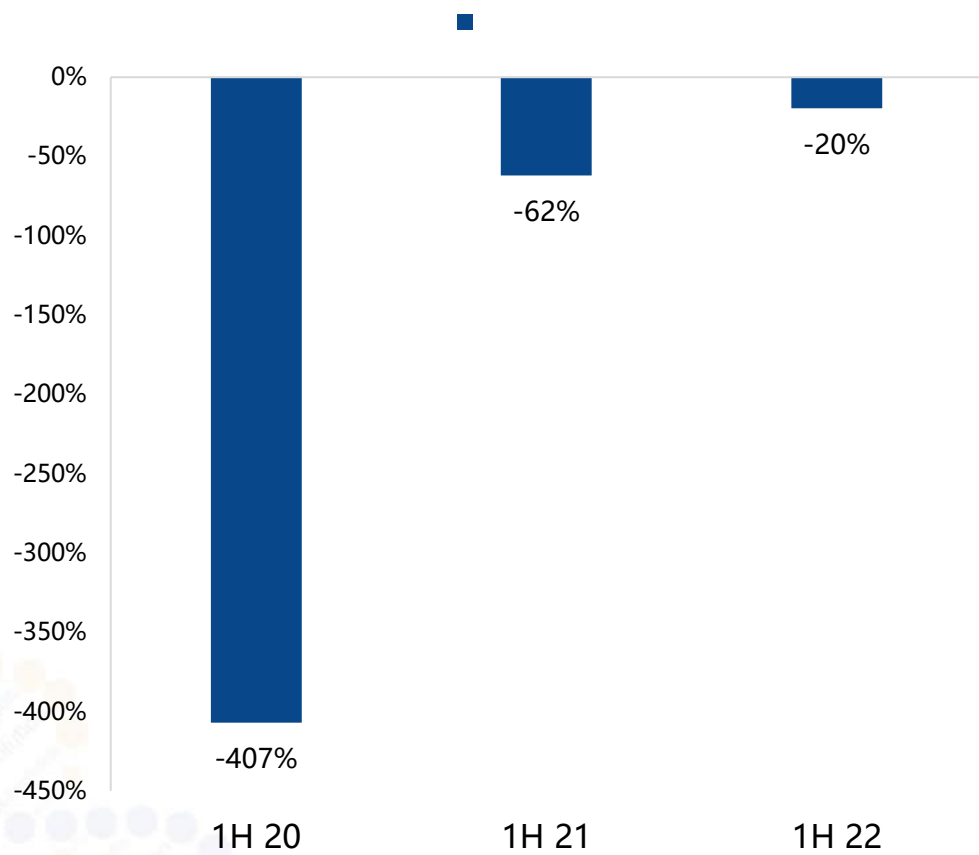




	1,289.4	633.6	103.5%
	983.8	412.2	138.7%
	76.3%	65.1%	11.2%
*	1,073.7	767.4	39.9%
	(252.1)	(393.8)	36.0%
	472.7	189.8	149.1%

Lice e-





2022	2.52	2021	1.42	2022	20%
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- 2024
-
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- He 2
- 150/60
- 2023 IO
- 2023 SCLC







“ He ” “ ” “ ” LOGO

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Henlius 复宏汉霖

可负担的创新 值得信赖的品质

Reliable Quality
Affordable Innovation

