Henlius 复宏汉霖

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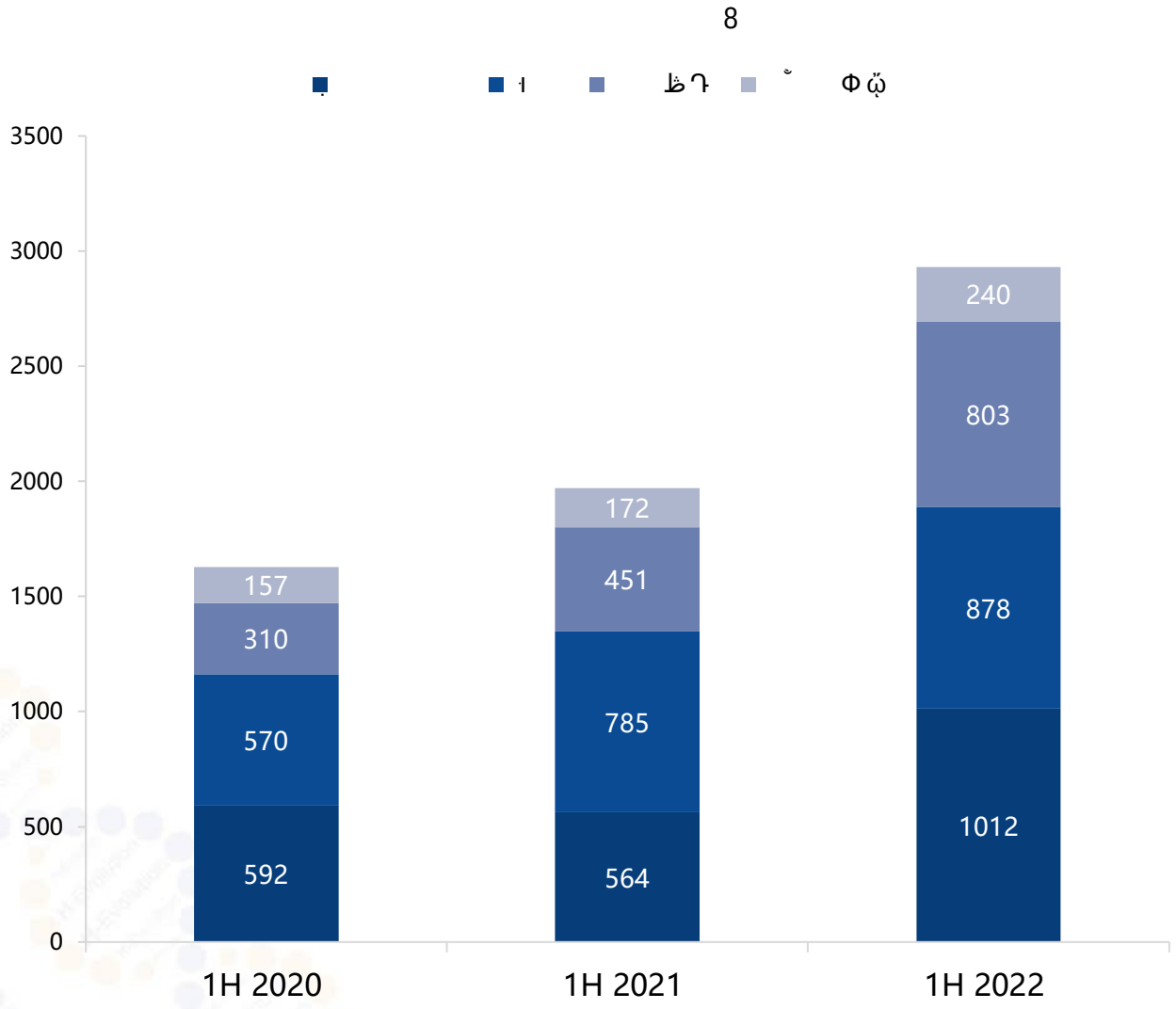


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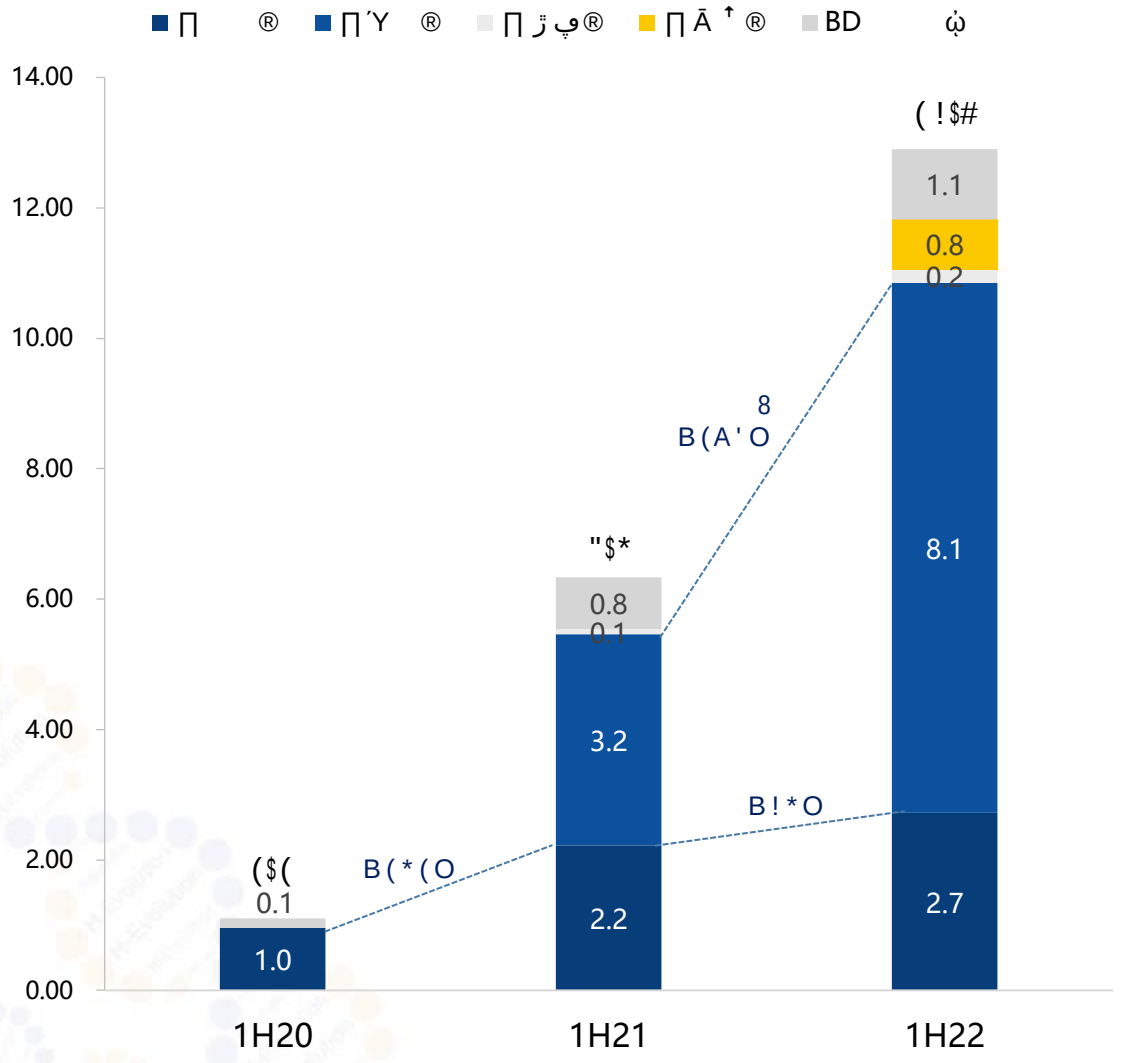


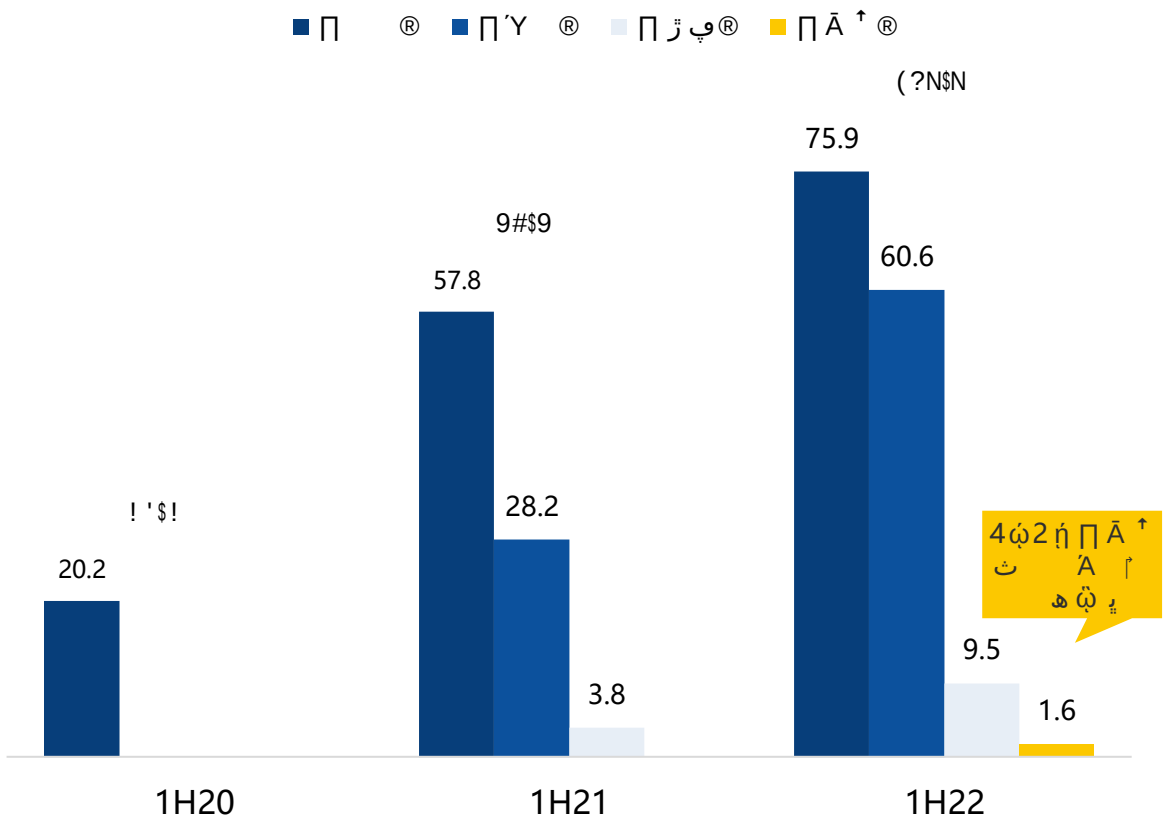


- 2022 H1 12.89 2021 6.55 8.13 7700 3 2.72 4.88 150% 103%
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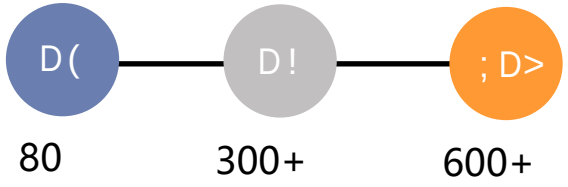


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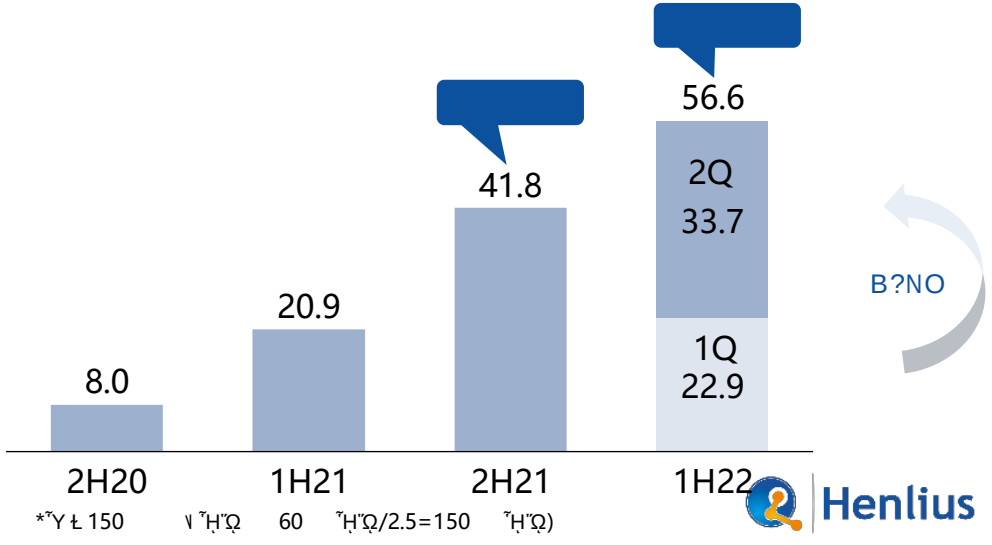


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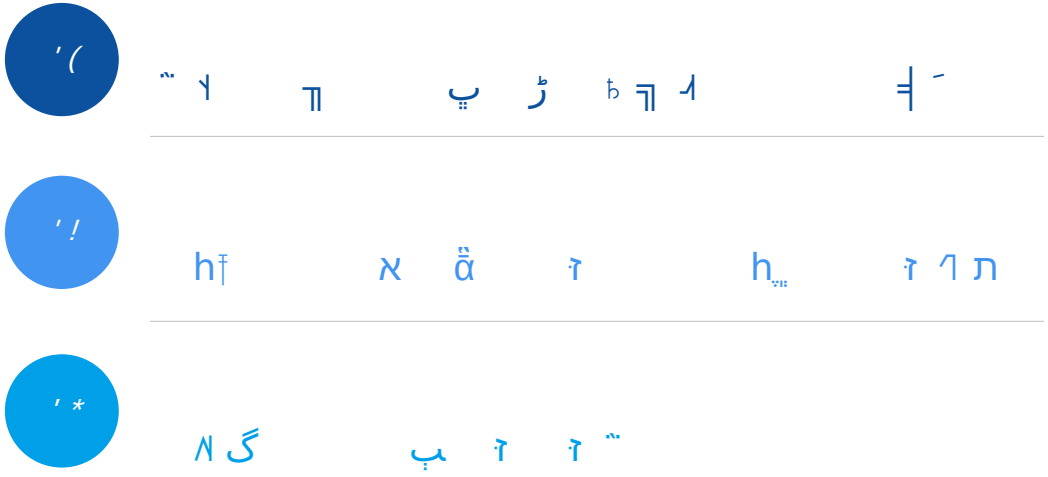




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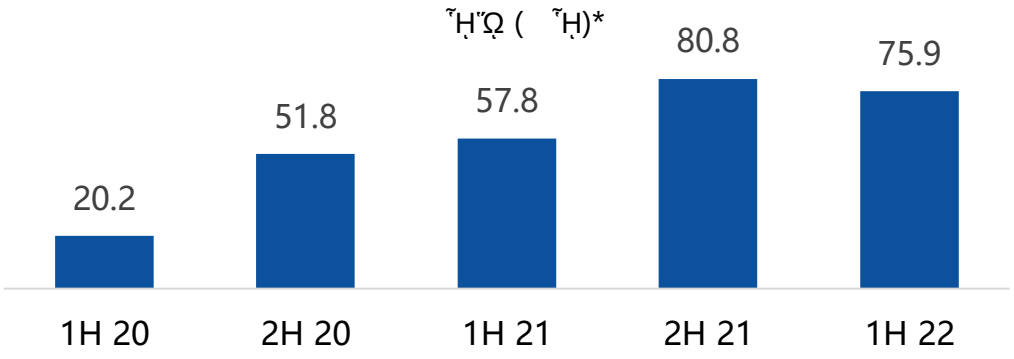


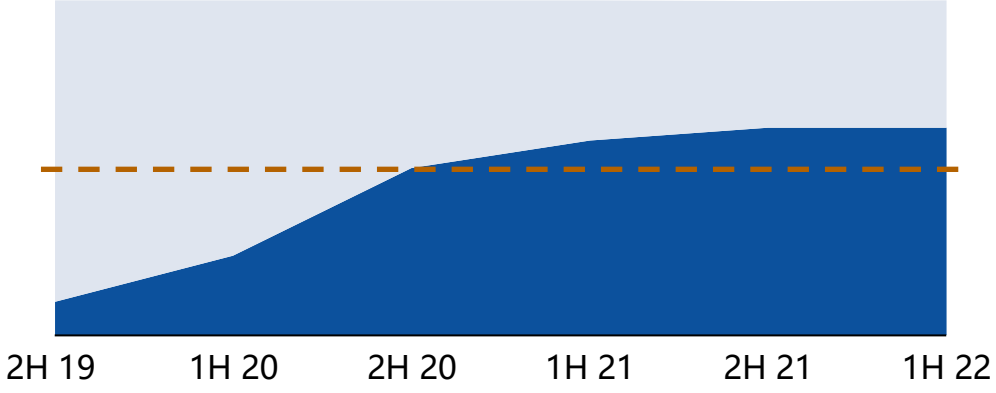


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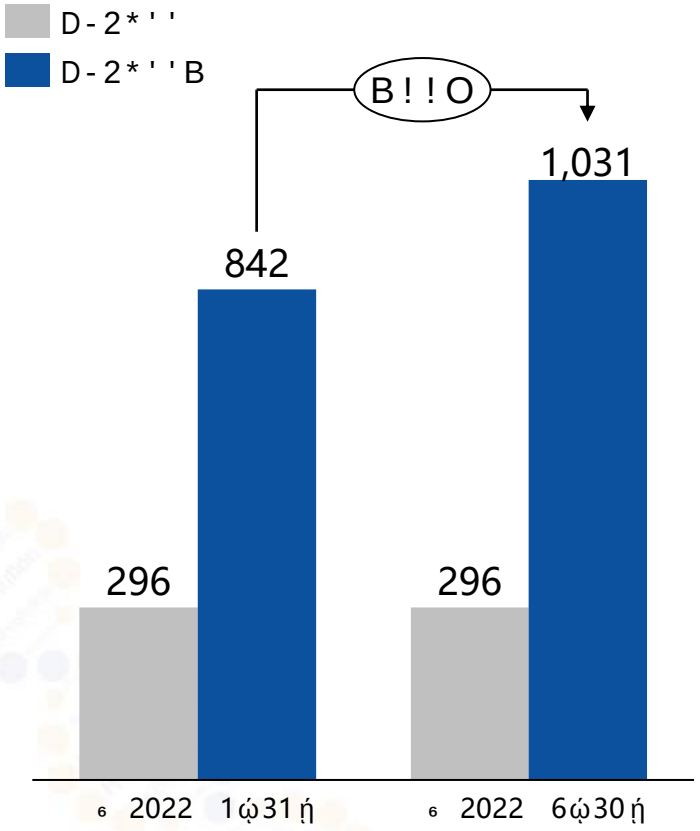


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| HLX10(2) Ā ↓ | + i | PD-1 | ↑ ↓ ↓ | 1L |
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| HLX10(2) | | | | |
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| HLX10 – ب ٦ ↑ ٤ ESCC ٤ ⌂ i | HLX10 – ⌐Ω ٤ ES-SCLC ٤ ⌂ i ℵ` | HLX10 – ↑ ٤ NSCLC ٤ ⌂ i<br>HLX10 – ⌐Ω ٤ ES-SCLC ٤ ⌂ i |

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HLX07 – ' ↑ ٤ CSCC

HLX10 – ↑ ٤



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| (T<br>H + i<br>NMPA NDA ⅞<br>ỉ ɯ ̈Ω ح 2022 9ώ<br>ɹ ̈Ω 537 | | |
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| (T<br>H + i<br>EMA MAA ح ت<br>ỉ ɯ2023 1Qώ | | |



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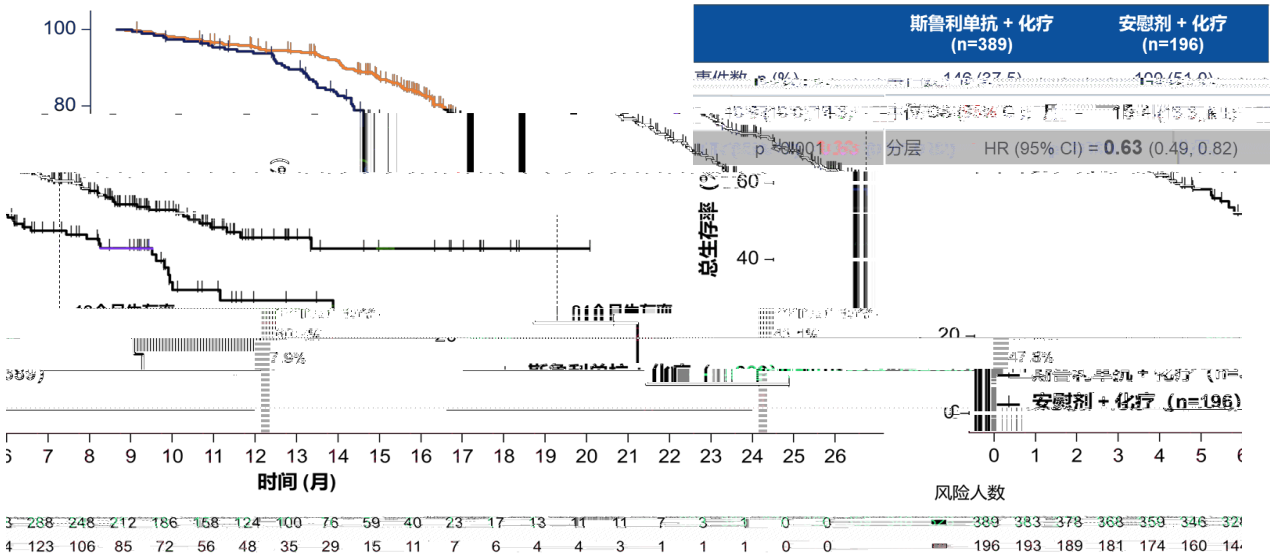

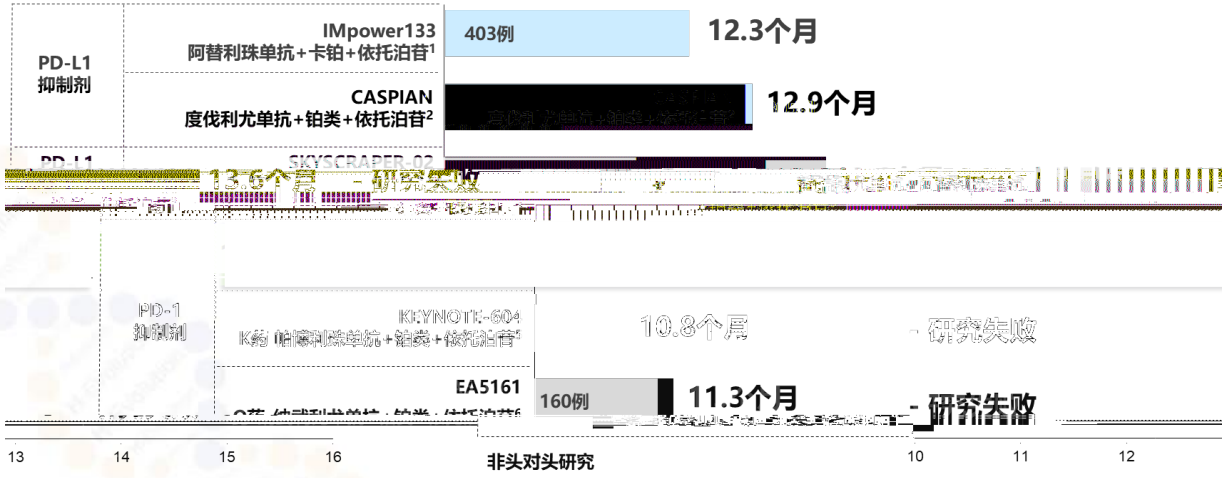


- Ā د ĭ i OS PFS ORR DOR ĭ ~ `H
  ϰ Ā د ⌂ i ⃞ ⃞ Ω n ` :
  - ZY (A$? . 10.9 ώ HR=0.63 <0.001
  - >UY A$N . 4.3 ώ HR=0.48
- Ā د ĭ i ĭ ~ í ⃞ . ϰ ص ϰ ≡ ω ϟ ⃞
- Ā د ϯ ⌂ i SCLC n ´ ب ` ` ϰ ת FDA ά ⃞
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1. H L, e a . N E J Med. 2018 Dec 6;379(23):2220-2229. 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.



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| | ڳ ڽ ط | | | | ط | | د Ā | |
| | ⅄ 2 ´ ⅄ P OS PFS | | ڽ‰ ⅄ 3 ⅄ P OS | | ⅄ 2 ´ ⅄ P OS PFS | | ⅄ 2 ´ ⅄ P OS | |
| | ڳ ڽ ط<br>+ + | | + ⅄ i<br>+ — | | + ⅄ i<br>+ — | | د Ā<br>+ + | |
| | 201 | 202 | 268 | 269 | 228 | 225 | 389 | 196 |
| /0-P '6(aOb | 35/65 | | 36.9/63.1 | | 26/74 | | (9$*69($N | |
| ZY | 12.3 10.3<br>HR =0.76 (0.60–0.95)<br>P=0.0154 | | 12.9 10.5<br>HR=0.75(0.62-0.91)<br>P=0.0032 | | 10.8 9.7<br>HR=0.80(0.64-0.98)<br>P=0.0164 | | (A$?)cG)( '$#<br>%Sd '$" *)a '$?#J '$9!b<br>>R '$' ' ( | |
| | 13.9 | | 14.2 | | 21.6 | | 12.3 | |
| ! ZY | <25% | | 22.9% | | / | | ?*$(O | |
| >UY | 5.2 4.3<br>HR=0.77(0.62 0.96)<br>P=0.017 | | 5.1 5.4<br>HR=0.78 (0.65 0.94) | | 4.5 4.3<br>HR=0.75(0.61 0.91)<br>P=0.0023 | | 5.7 4.3<br>HR=0.48 (0.38-0.59)<br>P 0.001 | |
| ZSS | 60.2% 64.4% | | 67% 58% | | 71% 62% | | 80.2% 70.4% | |
| ; ZS | 4.2 3.9 | | 5.1 5.1 | | 4.2 3.7 | | 5.6 3.2 | |

1.L SV, Rec M, Ma f e d 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.



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# 776777

**%Te ' N (EGFR)**

- HLX07 ھ ￼h ⅝ ۔ ۔ ۔
- IIΩ ؛ ۔ ۔ ۔ ۔ ¶ IRRC INV ۔ n￼ORR 38.5% ۔ ۔ 23% ل

**%Te ! ' 9 (BRAF V600E)**

- HLX208 ￼ ۔ ۔ ۔ ۔ ۔ ￼ ۔ ۔ ۔ ۔ ۔ n LCH ۔ ￼
- HLX208 IIΩ ۔ ۔ ۔ ￼BRAF

**%Te ! ! (HER2)**

- HLX22 He 2 ￼[ - 5 3, I)7 f ´ PD ۔ ۔ ۔ ۔ ۔ He 2 d a IV￼´Y ل ￼ ۔ ۔ ⅝´Y ل ۔ ل ۔ ۔ ۔ ۔ ۔

# %Te!!　77

## %XS!

1. ° ⊿ i ษ ˜ Ω/ج ⊿ ä ´ Ω ⊿ ⊿ HLX22 ǐ ´Y ⊃ ǐ i XELOX ⅝ ´ i ǖ ˜Ω˜Ω ǐ ˜ HLX22 õ ˚ ⊿ i ǖ ☺ ä´ HLX22 ⊿ ǐ ɯ ز 85% ษ ⊿ ⊿ ' ǐ Ω ؛ جـ Ω ف ⊿ ⊿ ή ⊿ ⊿ ⊿

# %Te'N XLUS)

| | | |
|---|---|---|
| | • IΩ ķ 19 ؛ ā ORR 5.3% PFS | |
| • ِ HNSCC ĭ Ā د 1L 2L | • 13 ؛ ā IRRC-ORR 38.5% INV-ORR 38.5% INV- PFS 5.45 INV-6- PFS a e 34.6% | P II |
| • ↑ ُ NSCLC ĭ Ā د i 1L | • 14 ؛ ā ŋ DLT | P II |
| • ' ↑ CSCC) 1L 2L 3L | • ŏ ŏ ھ n ũ Ω ث ⌂ i CSCC EGFR | P II |
| | | P II |
| • ب ESCC ĭ Ā د i 1L 3L<br>• SCLC ĭ Ā د i 1L<br>• ج CRC ĭ Ā د i 1L 3L<br>• HCC ĭ Ā د HLX04 VEGF 1L ĭ i 2L 3L | • ´ h ⌂ i ' ◗ ' ∂ ŋ ĭ ⌂ i<br>• EGFR PD-1 ₩ ´ א<br>ق ℓ EGFR ز ´ ق Φ i ŋ IIIΩ . ☺<br>گ | |



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# %Te!'9 +S<U)f"''X

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| • ST - Ä | • IΩ ķ ℓ i ۿ<br>• 26 ۳ 20 SD DCR 77% 13 50% ۱ | P I |
| • ۶ ۱ NSCLC | • “ ھ ” ° ´<br>• HLX208 ۵ Ω ۷ BRAF | P II |
| • ۵ ۱ ۱ ۱ ۱ ۱ ۱ ۷ LCH E d e - C e e ۵ ECD | • “ ھ ” ° ´<br>• HLX208 ۵ Ω ۵ Ω n BRAF LCH&ECD<br>• ؛ ۵ ۵ ف Φ i ۿ ۳ CMR PMR ۷ ۵ PERCIST) | P II |
| • ج ۷ ۱ ´ CRC ۱ | • گ ۷ —— ۱ ۲ i ۿ ھش ۱ Ω ؛ جـ<br>• HLX208 أ گ ۷ ھ ۷ ۵ ع | P II |
| • ' ↑ ATC | • HLX208 ۵ Ω ۵ Ω n BRAF ATC | P Ib/II |
| • ۵ ۷ Me<br>• ۵ BT<br>• | • ☺ گ ۷ | P II |



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## %Te ! *
## (CD73)

- CD73
- CD73 CD73

## %TeA*
## (TIGIT)

- HLX53 H ab A e ab

## %Te ! "
## (LAG-3)

- PD-1 CRC NSCLC

## %Te " '
## (GARP)

- U,4G.J,I JVK3GG
- 7 : ;

## %Te*A
## (EGFR 4-1BB)

- U,4G.J,I JVK3GG
- EGFR NK EGFR

## %Te*' (
## (PD-L1 TIGIT)

- HLX301
- T a ab A e ab



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- HLX01/02/03/04[1] ㆍ ㆍ ㆍ ㆍ
- HLX10 (PD-1) ㆍ ㆍ ㆍ ㆍ ㆍ ㆍ ㆍ ㆍ ㆍ ㆍ

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

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- / ق Ä (AXC: A b d X- ec e C a e)
- 7 ; ; ])4-5₲ADC AXC 2 ☺ F - -c a ADC ا ш 2023 6ش ن IND
- ADC



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## %TeA( ( Ab)

- ☼ ╗
- PD1/PDL1
- PD1/PDL1

## %Te ; " ' (9 ( Ab)

- ☺ U,4G.J,IJOK3GG
- ₩

## %Te ; ?! (ADC)

- ☺ U,4G.J,IJOK3GG)< ; V
- a ad
- EGFR
- ⌂ i ┐

## %Te ; N! ( P )

- U,4G.J,IJO-IO/2.
- ₩

## %Te ; ?* (ADC)

- ☺ U,4G.J,IJOK3GG)< ; V
- a ad
- PD1/PDL1
- ⌂ i ┐

## %Te ; * 'N ( P )

- U,4G.J,IJO-IO/2.
- ₩



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| ∏´Y ´Y ل (3) | HER2 | ج ا | | | | | | | | accord The Evolution of Generics Cipla |
| ∏ ڤ ژ ژ ً ڭ (4) | TNF-α | ا ا ▶ ` ً آ ₁P ط ق | | | | | | | | |
| ∏ف ف ل (5) | VEGF | ا ج ا ً ل ا ٌ ج ا Ω ¨ | | | | | | | | |
| ∏ف ف ل | VEGF | ا ⅔ و أ | | | | | | | | |
| HLX11 ( ل ) (6) | HER2 | ذ A | | | | | | | | |
| HLX14 ( ً ) (7) | RANKL | ح و ш — ا | | | | | | | | |
| HLX05 ( h ) (8) | EGFR | ج ا ً ل إ ظh ↑ ا | | | | | | | | |
| HLX12 ( ` ب ) | VEGFR2 | ج ا ً ل ج ا ٌ ا | | | | | | | | |
| HLX13 ( ً ) | CTLA-4 | ج ا ً ل ا ا ًس | | | | | | | | |
| HLX15 ( ب ژ ) | CD38 | ح | | | | | | | | |

(1)2019 2ώ n NMPA ث ا ـ ا
(2) n أ گ ا [OBJ]
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T a c ®
(4)2020 12ώ n NMPA

5) 2021 11ώ n NMPA
(6) ά a ▪ ● [OBJ] ا
(7) ά a ▪ ● [OBJ] ا ● n ! ج
(8) ά ⊥ ˆ ╤ [OBJ]


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Organon 5.41

HLX11 HLX14

300 HLX13

¡ Ø

Abbott 440 300

®



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(N SE: OGN)

2021 6ώ3ή

HLX11 ϟ

HLX14 ϡ



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- 2022 — ( ) Δ ژ أ : 48,000L
- GMP ۱ : 450 + 2019
- ۱ ' : ≥98%
- ۱ و ۲ : 878
- ۱ ؤگ

## 2022 5

- ۲ ۱ ۲ : 24,000L
- n ۱ ∏´Y ® ´Y ط
- ۲ ۱ ق Φ : جـ HLX04-O HLX11 HLX14 ۱

- n ۲ ` GMPn - ۱ ۱ ۰ ق ۵ گ
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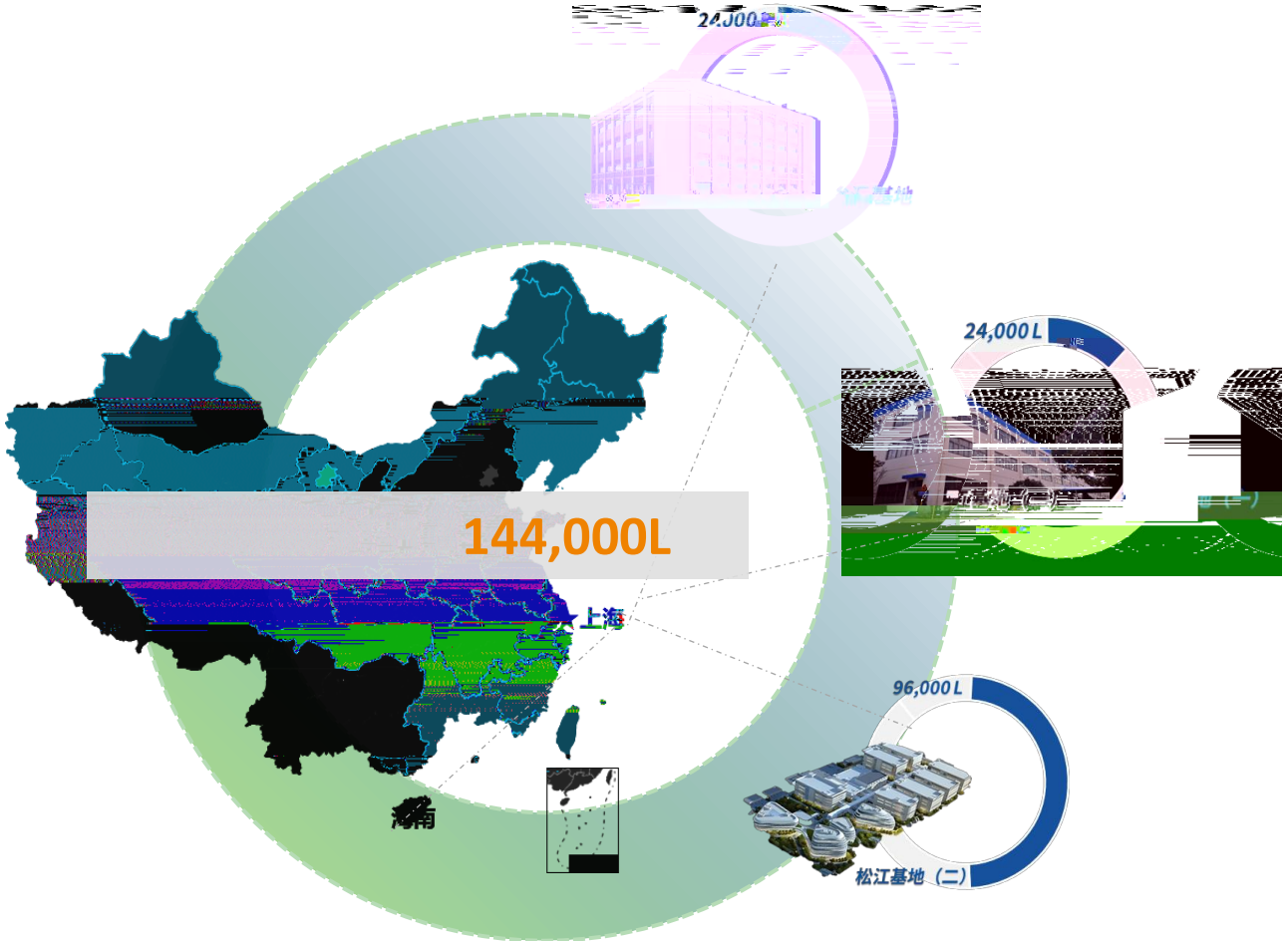


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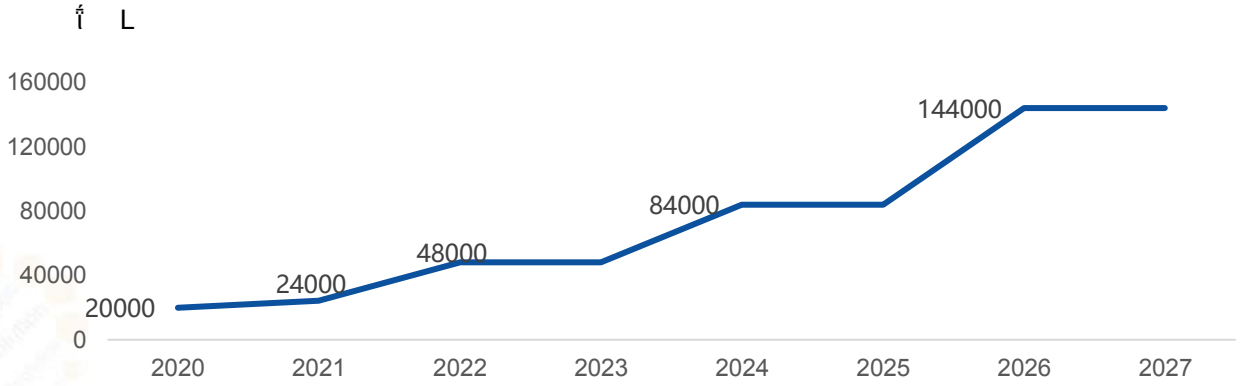


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|---|---|---|---|
| ϒ ώ | 1,289.4 | 633.6 | 103.5% |
| ɔ | 983.8 | 412.2 | 138.7% |
| ɔ ' | 76.3% | 65.1% | 11.2% |
| ϒ ϕ * | 1,073.7 | 767.4 | 39.9% |
| ⅔ | (252.1) | (393.8) | 36.0% |
| ° ϔ | 472.7 | 189.8 | 149.1% |

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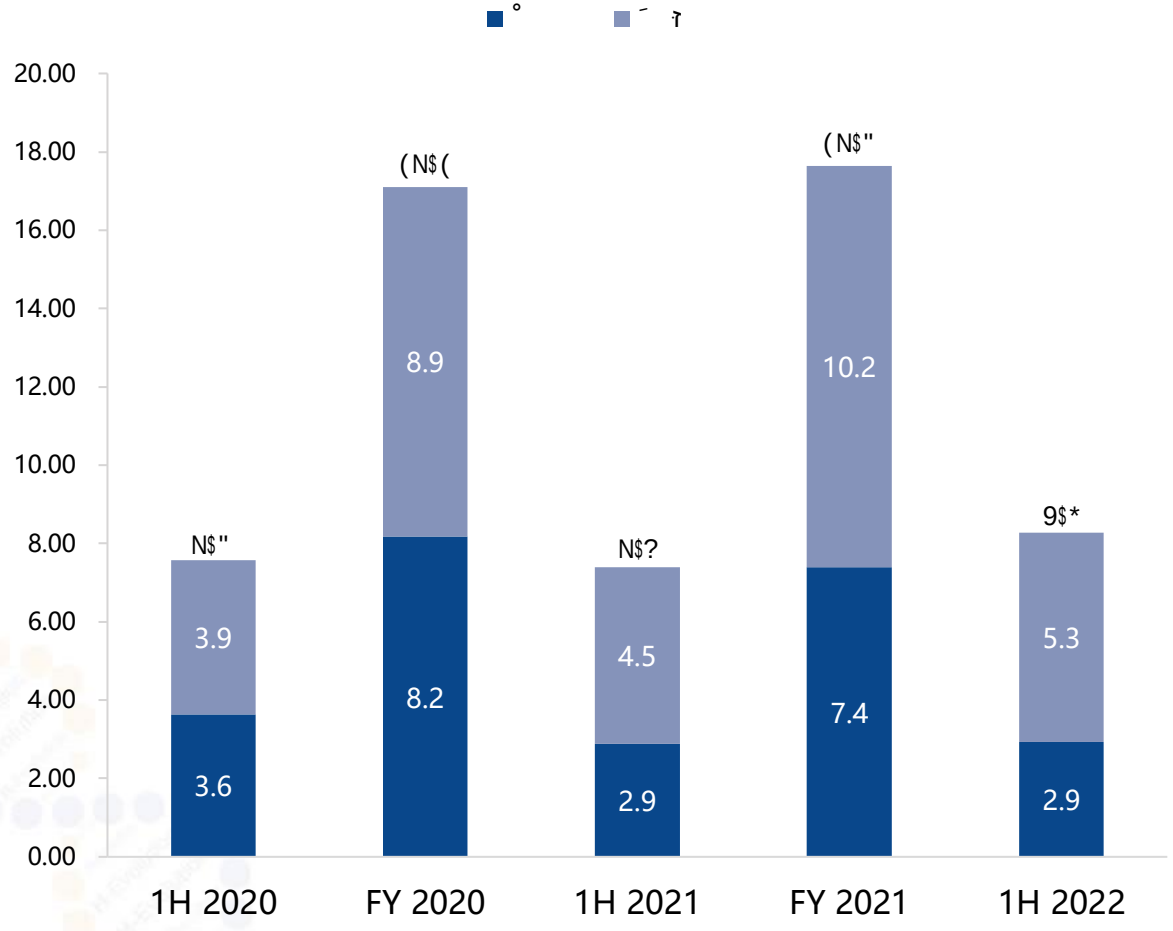


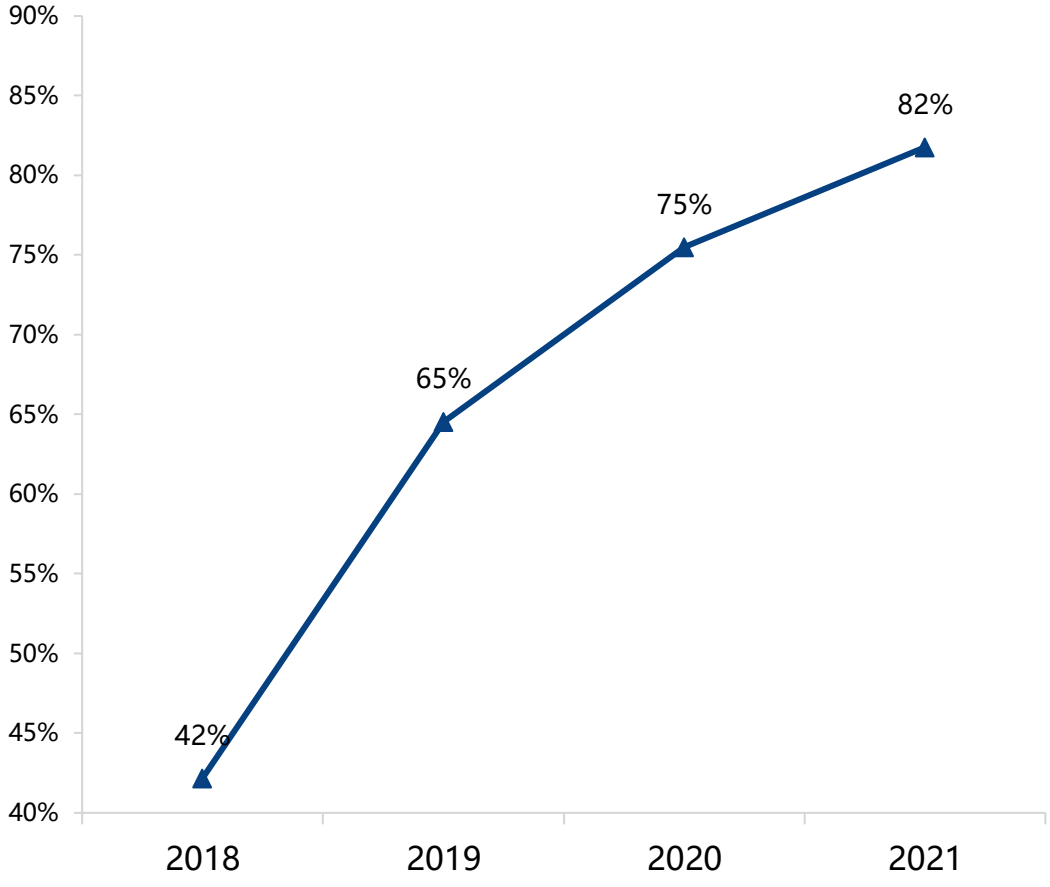




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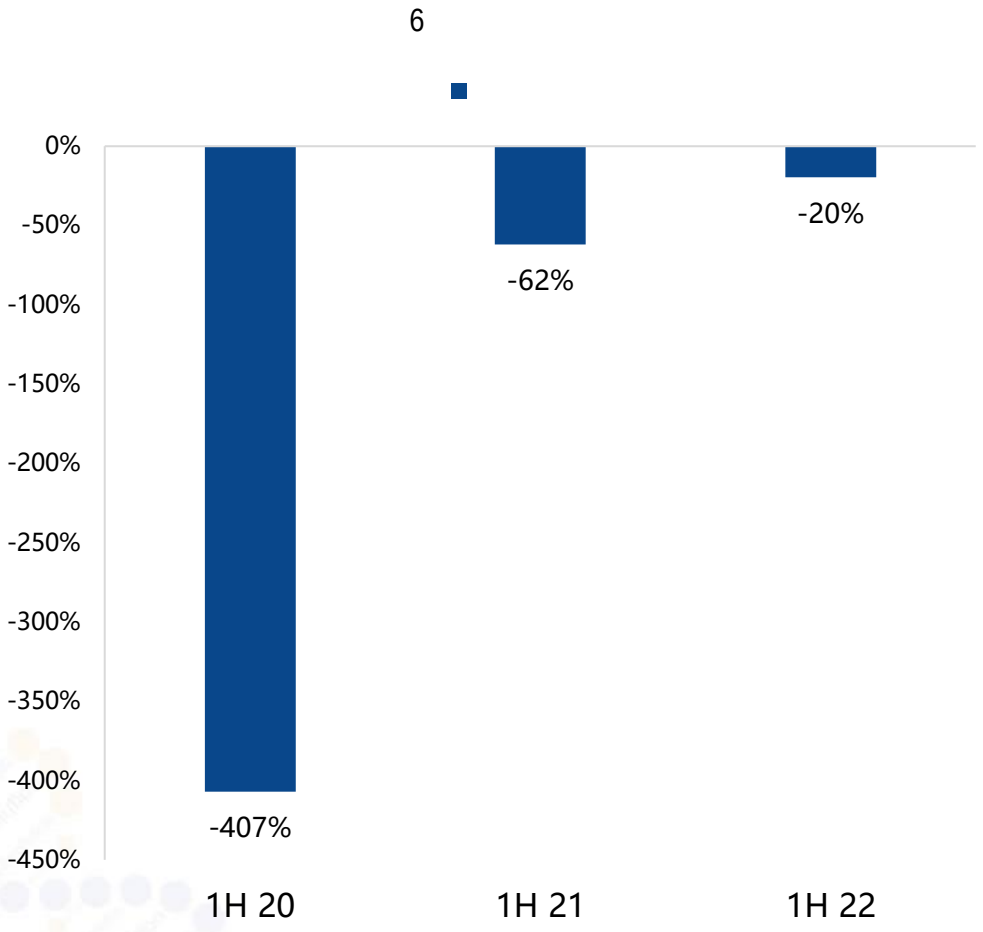


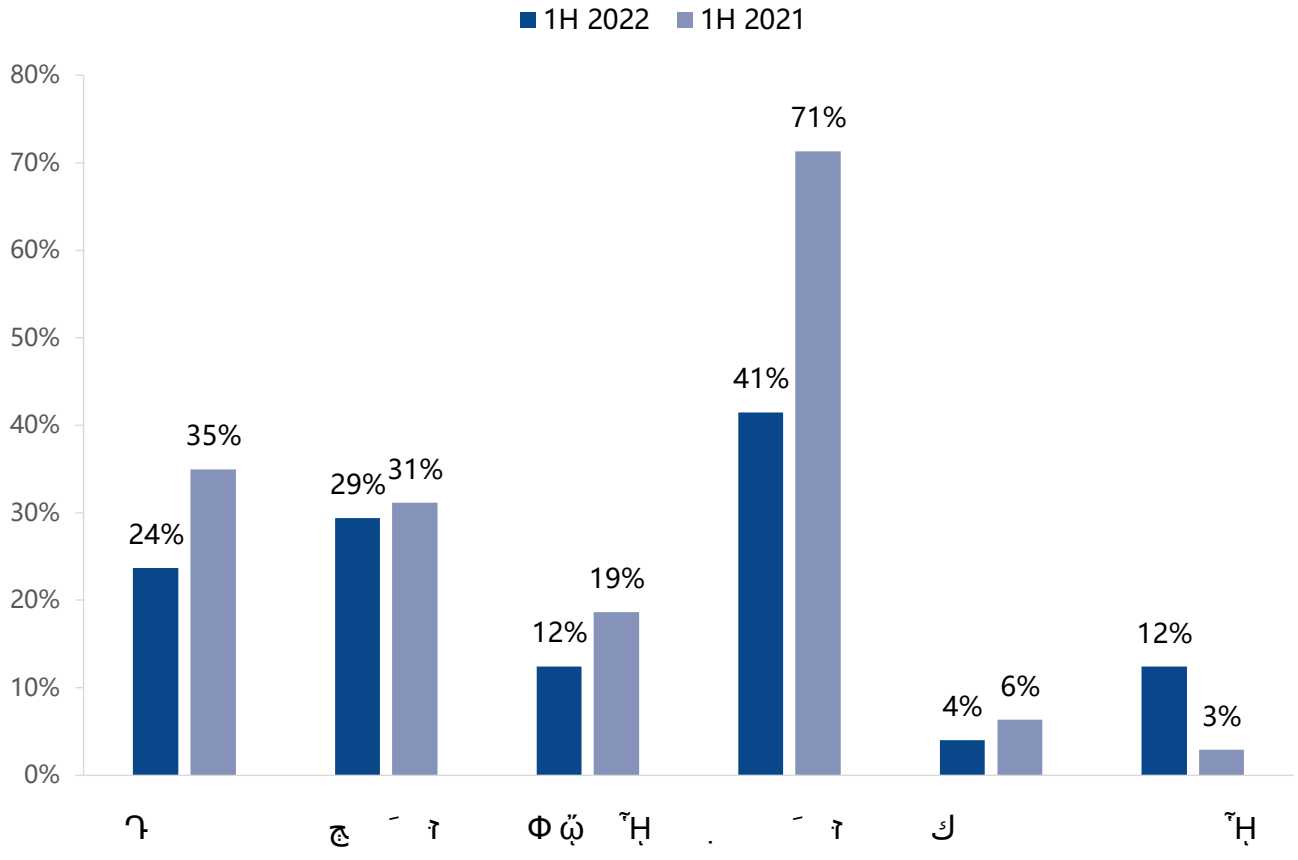


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Affordable Innovation