2026 ASCO年会GFH375及GFS202A临床数据解读会

2026年6月

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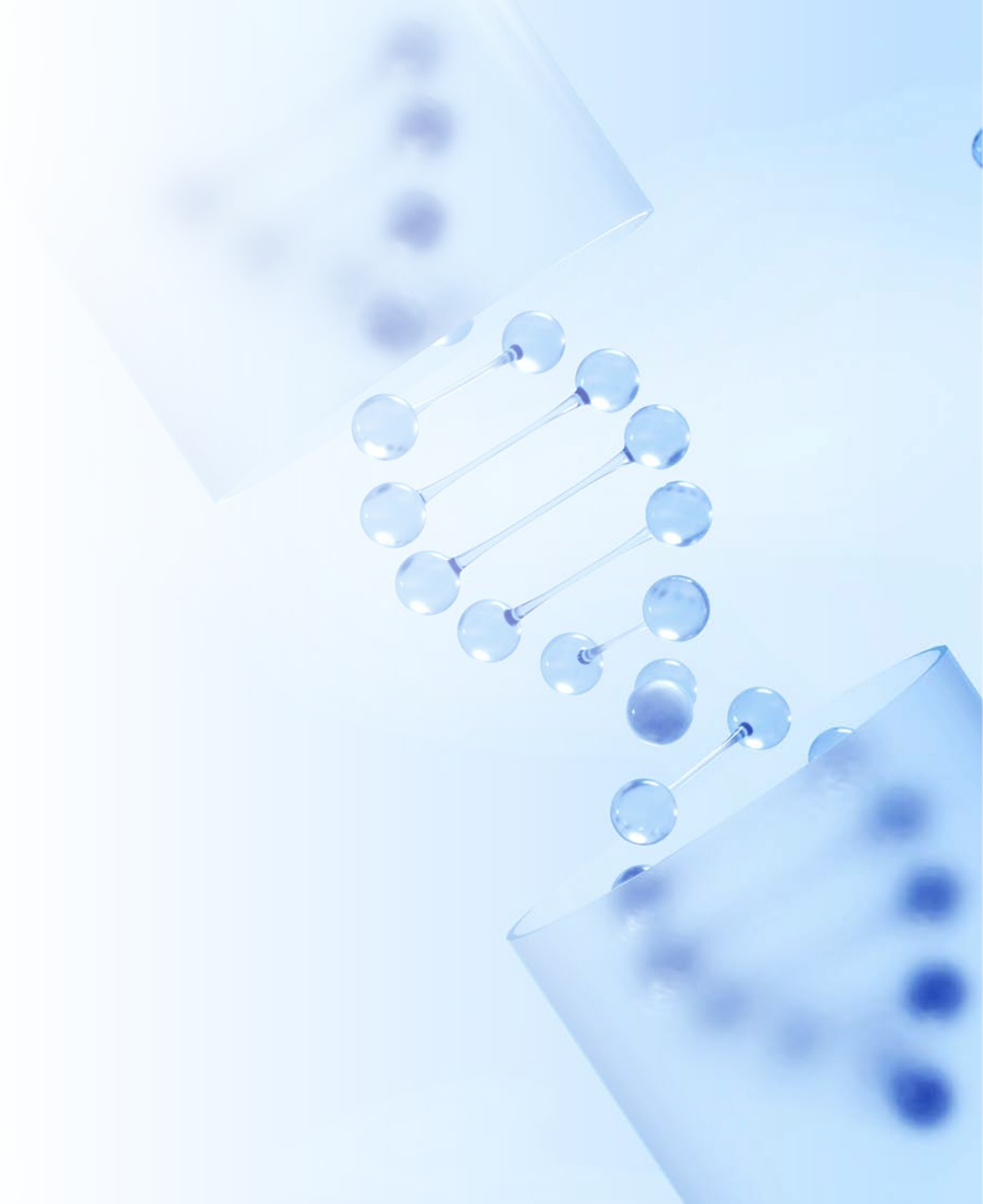
会议议程

- **劲方2026 ASCO展示内容** -- 张巍女士，劲方董事会秘书
- **本次会议两项研究背景** -- 吕强博士，劲方董事长
- **两项研究结果重点及解读** -- 汪裕博士，劲方首席医学官
- **参会者会前及现场问答互动** -- 劲方参会管理层
- **解读会总结及展望** -- 吕强博士，劲方董事长

PART 01

本次会议
两项研究背景



GFH375临床研究数据连续四次入选国际学术会议口头报告

实体瘤数据

2025年ASCO年会

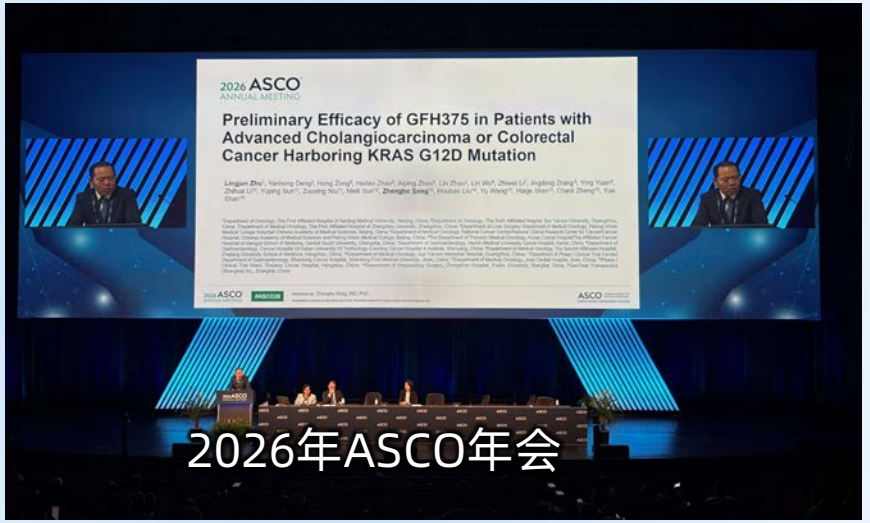
NSCLC数据

2025年WCLC年会

PDAC数据

2025年ESMO年会

CCA & CRC数据



2026年ASCO年会

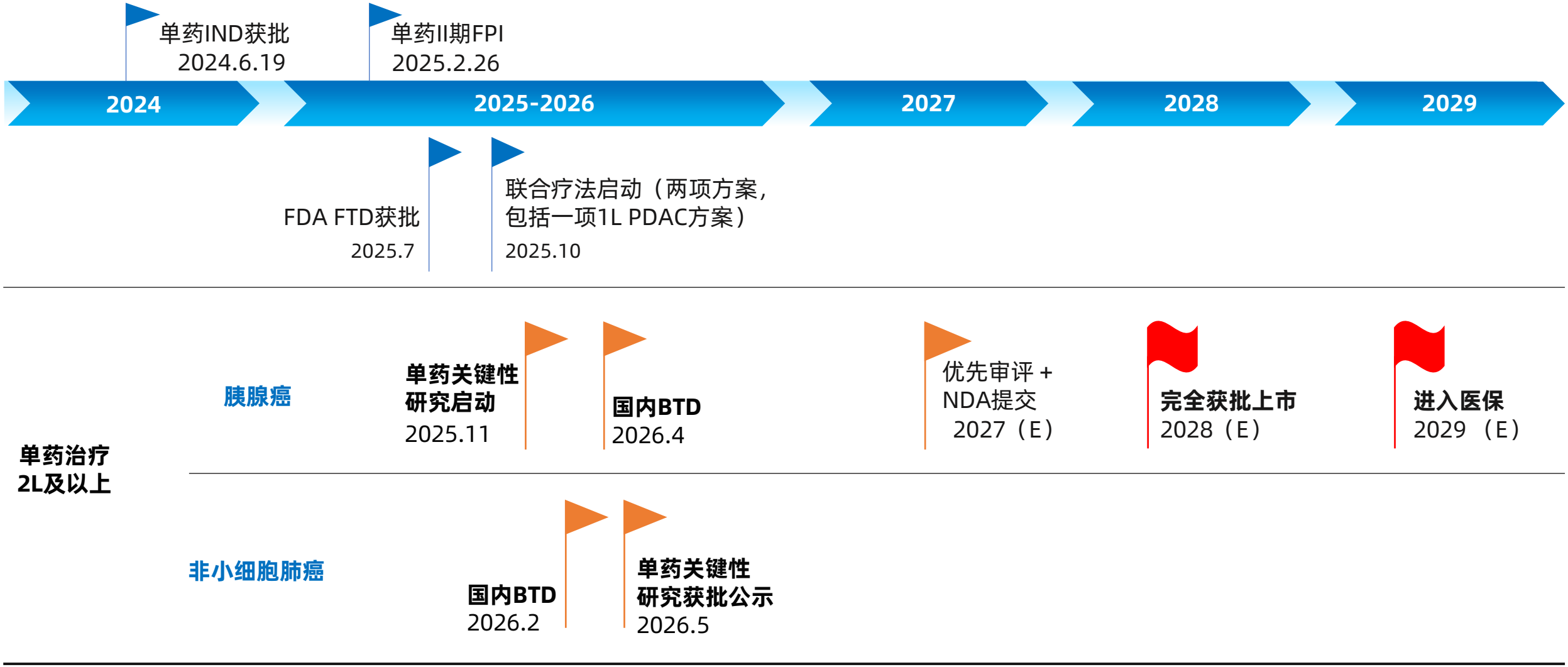
GFH375成药性自去年学术会议报告后进一步确认

GFH375 presented a manageable safety profile in heavily pretreated solid tumor patients harboring KRAS G12D mutations.

	2026 ASCO: CCA 400-600 mg QD (n = 20)	2026 ASCO: CRC 400-750 mg QD (n = 41)	2026 ASCO: Total (n = 61)	2025 WCLC: All cancer types 100-900 mg QD (n=142)
Any TRAE	20 (100)	40 (97.6)	60 (98.4)	139 (97.9)
TRAEs ≥ Grade 3, n(%)	8 (40.0)	11 (26.8)	19 (31.1)	39 (27.5)
Grade 5 TRAE, n(%)	0	1 (2.4)*	1 (1.6)	0
TRAEs leading to discontinuation, n(%)	0	2 (4.9)	2 (3.3)	6 (4.2)
TRAEs leading to dose interruption, n(%)	8 (40.0)	10 (24.4)	18 (29.5)	33 (23.2)
TRAEs leading to dose reduction, n(%)	1 (5.0)	1 (2.4)	2 (3.3)	11 (7.7)
Treatment related SAEs, n(%)	1 (5.0)	4 (9.8)	5 (8.2)	11 (7.7)
Data cut-off date	12 Dec, 2025			17 Jun, 2025

**该5 级不良事件判定为死因不明确。受试者为 65 岁女性结直肠癌患者，基线期已出现肝转移及淋巴结转移，于家中离世。研究方多方尝试沟通，但患者家属拒绝提供相关信息，因此因资料不足，无法判定事件与研究药物的关联性。*

GFH375两项注册性临床试验精准规划，胰腺癌研究入组进度符合预期

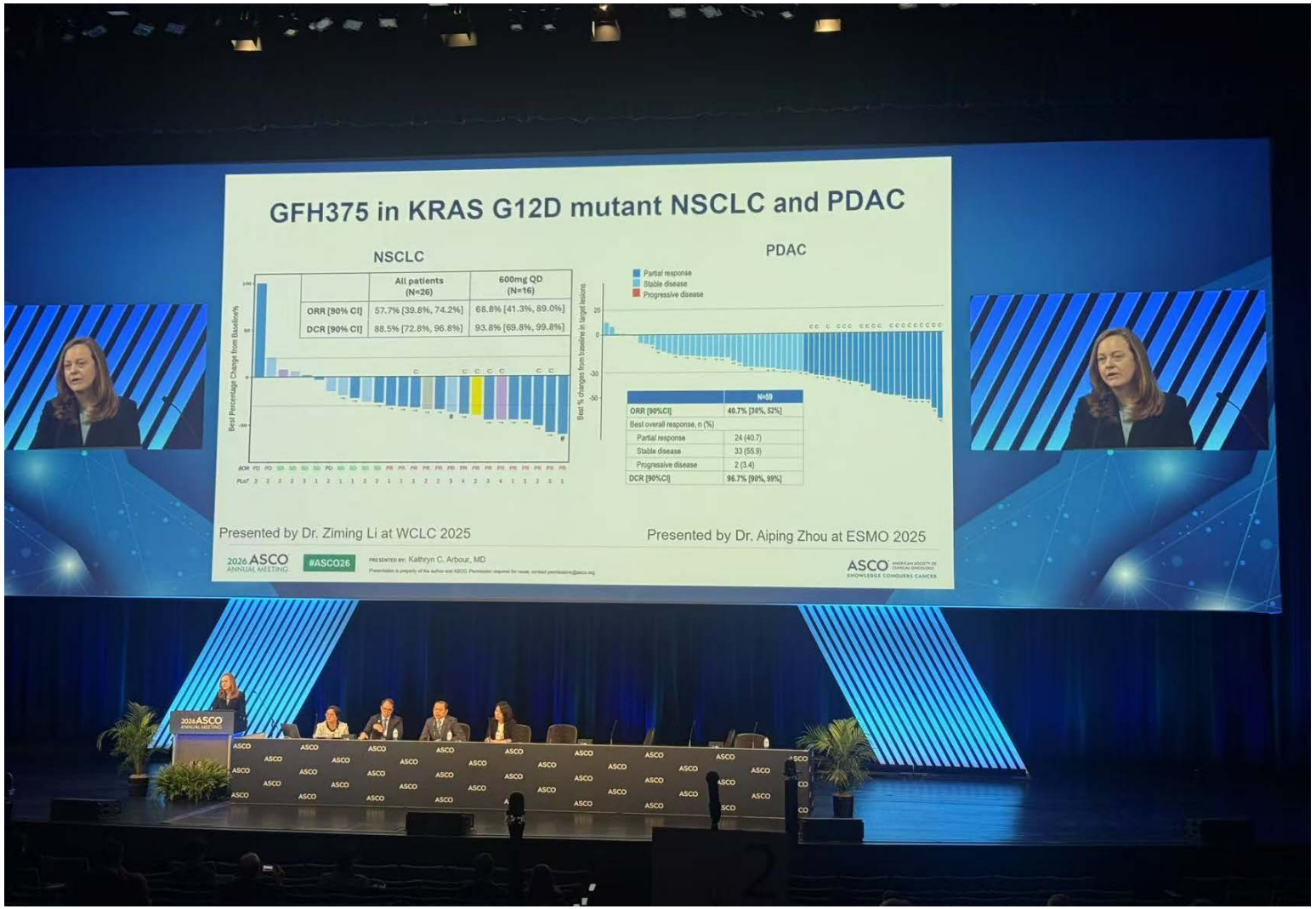


GFH375在确定性基础上的更大商业空间

- KRAS G12D is the most frequent KRAS mutation (29%) driving cancer development, accounting for 5.8–10.8% in CCA and 10.6–19.2% in CRC[1~4]
- KRAS G12D mutation is associated with poor prognosis and confers resistance to conventional chemotherapy[3,5,6]
- Critical unmet medical need remains due to suboptimal efficacy of existing treatment:
  - CCA (in 2L): ORR 5–12.5%, mPFS 4.0–4.2 mo, mOS 6.2–8.6[7]
  - CRC (in 3L): ORR 1–6.1%, mPFS 1.9–5.6 mo, mOS 6.4–10.8 mo[8~11]
- GFH375, a highly selective and potent KRAS G12D inhibitor targeting both the “ON” (GTP-bound) and “OFF” (GDP-bound) states, has shown encouraging clinical activity in PDAC and NSCLC[12,13]
- Herein, we report the efficacy and safety data of GFH375 monotherapy in CCA and CRC

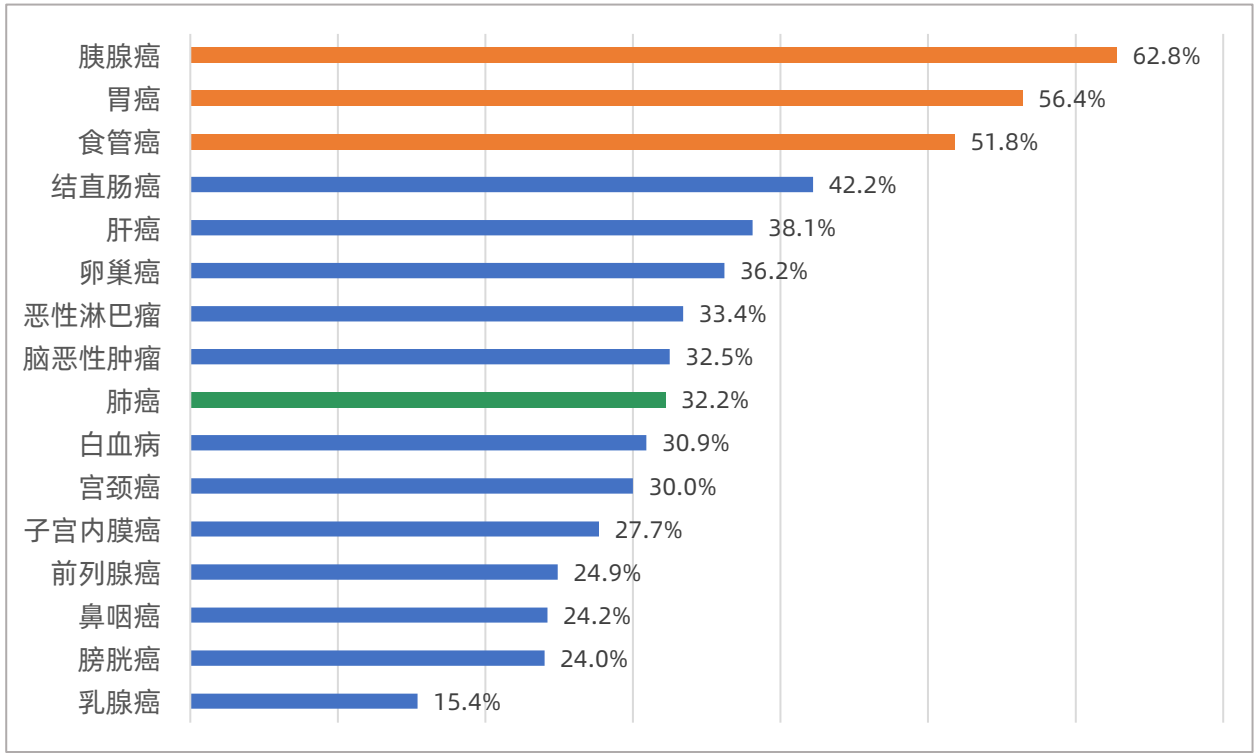
[1]JK Lee et al. npj Precision Oncology (2022) 6:91; 12:924–37. [2]Thongyoo P, et al. Cancer Genomics Proteomics. 2025 Jan-Feb;22(1):112-126. [3]K. Iida, et al. ESMO Open, 2025; 10. [4]Mingjing Meng, et al. Biomedicine & Pharmacotherapy 140 (2021) 111717. [5]Benfeng Xu, et al. Eurasian J Med Oncol. 2025;9(3):122-132. [6]Mitsunobu Takeda, et al. Cancers 2025, 17, 428. [7]Banales, J.M., et al. Nat Rev Gastroenterol Hepatol 23, 65–96 (2026). [8]Grothey, A., et al. Lancet (London, England) 2013, 381(9863), 303–312. [9]Xu, J., et al. Journal of clinical oncology: official journal of the American Society of Clinical Oncology 2018, 36(4), 350–358. [10]Li, J., et al. JAMA 2018, 319(24), 2486–2496. [11]Prager GW, et al; N Engl J Med. 2023 May 4;388(18):1657-1667. [12]Zhou A, et al. Annals of Oncology, 36S1626. [13]Lu S, et al. Journal of Thoracic Oncology, 20, S59-S60.

GFH375在多个癌种的成药性得到会议评论员高度认可

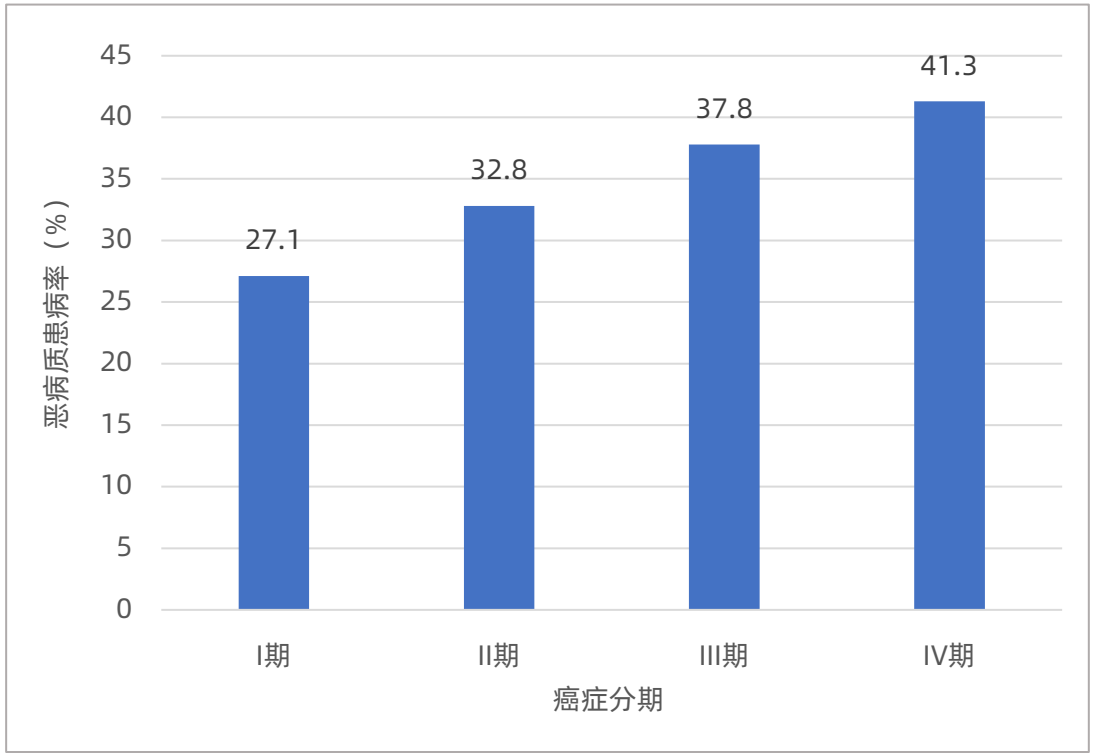


恶病质与肿瘤治疗具有巨大的商业互补性

- 肿瘤恶病质的总患病率达37.0%，肿瘤部位是肿瘤恶病质患病率重要决定因素之一。
- 胰腺癌(62.8%)、胃癌(56.4%)、食管癌(51.8%)是与肿瘤恶病质患病关联最密切的三种肿瘤。
- 肺癌是中国恶性肿瘤中发病率和死亡率均最高的恶性肿瘤，肿瘤恶病质在肺癌患者中占比约32.2%。



中国肿瘤恶病质在不同瘤种中的患病率



不同癌症分期的肿瘤恶病质患病率

1. Li, Xiangrui, et al.. Precision Nutrition 1(1):10.1097/PN9.0000000000000008, June 2022. 2. Han B, et al. 2024;4(1):47-53. 2024 Feb 2.

辉瑞GDF15单抗ponsegromab可显著增加肿瘤恶病质期患者体重

II 期，随机，双盲PROACC研究

- 在12周时，与安慰剂组相比，所有剂量水平的活性药物组均观察到体重的增加，且具有剂量依赖性。

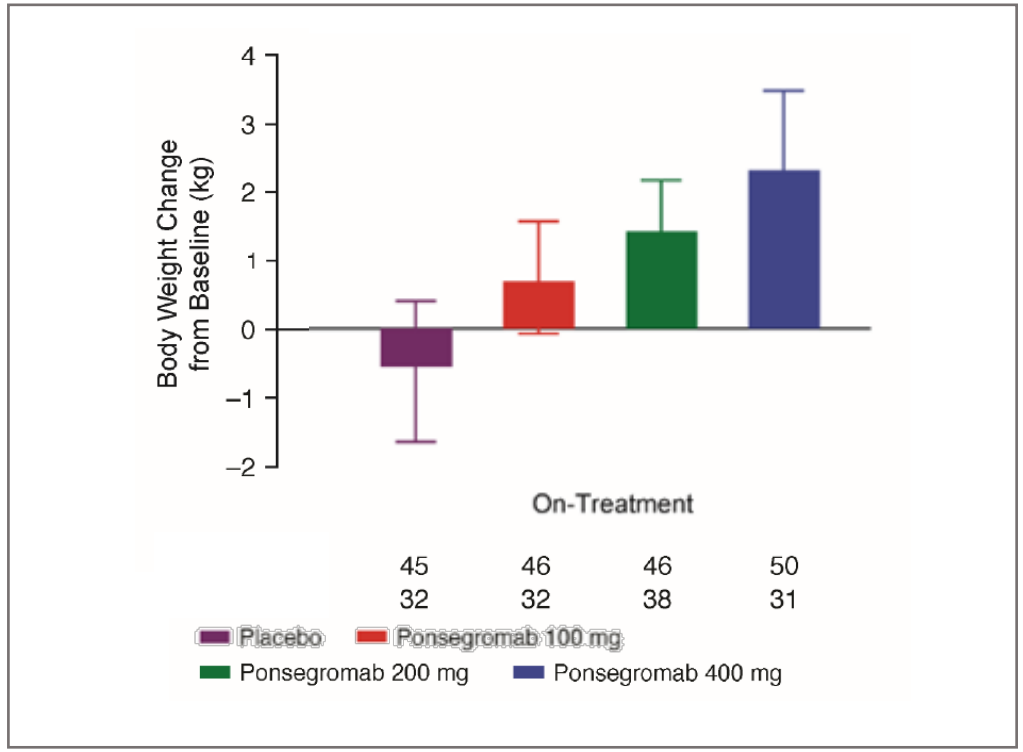
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Ponsegromab for the Treatment of Cancer Cachexia

John D. Groarke, M.B., B.Ch., M.P.H., Jeffrey Crawford, M.D., Susie M. Collins, M.Sc., Shannon Lubaczewski, Pharm.D., Eric J. Roeland, M.D., Tateaki Naito, M.D., Andrew E. Hendifar, M.D., Marie Fallon, M.D., Koichi Takayama, M.D., Timothy Asmis, M.D., Richard F. Dunne, M.D., Isik Karahanoglu, Ph.D., Carrie A. Northcott, Ph.D., Magdalena A. Harrington, Ph.D., Michelle Rossulek, M.A., Ruolun Qiu, Ph.D., and Aditi R. Saxena, M.D.

Groarke, John D et al. The New England journal of medicine vol. 391,24 (2024): 2291-2303.



恶病质期肿瘤患者接受ponsegromab 100mg、200mg、400mg及安慰剂 Q4W 治疗12周后较基线的体重变化

2026 ASCO：劲方两项参会研究成果

GFH375

口头报告

Preliminary Efficacy of GFH375 in Patients with Advanced Cholangiocarcinoma or Colorectal Cancer Harboring KRAS G12D Mutation

Lingjun Zhu, *Yanhong Deng, Hong Zong, Haitao Zhao, Aiping Zhou, Lin Zhao, Lin Wu, Zhiwei Li, Jingdong Zhang, Ying Yuan, Zhihua Li, Yuping Sun, Zuoxing Niu, Meili Sun,* ***Zhengbo Song,*** *Houbao Liu, Yu Wang, Haige Shen, Chanli Zheng, Yue Shan*

GFS202A

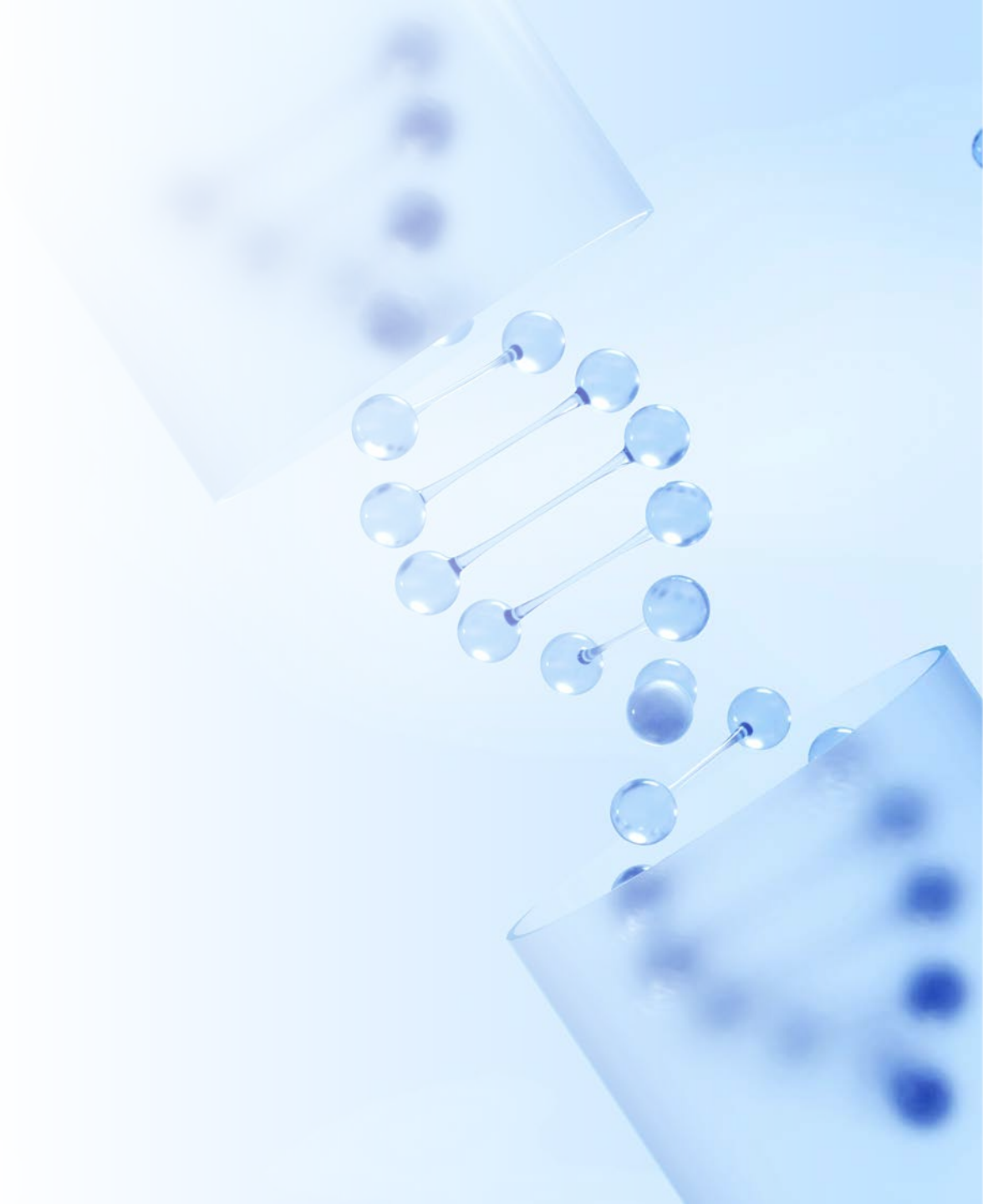
壁报展示

A first-in-human (FiH) phase I study of GFS202A, a GDF15/IL-6 bispecific antibody, in advanced cancer patients with pre-cachexia or cachexia

Hongyun Zhao, *Da Li, Yuxiang Ma, Hong Zong, Yusheng Wang, Xiangcai Wang, Haiyu Yang, Zhen Li, Qian Chu, Yue Shan, Lingyu Tai, Jiani Song, Yue Zhang, Huaqiang Zhu, Haige Shen8, Yu Wang,* ***Li Zhang***

PART 02

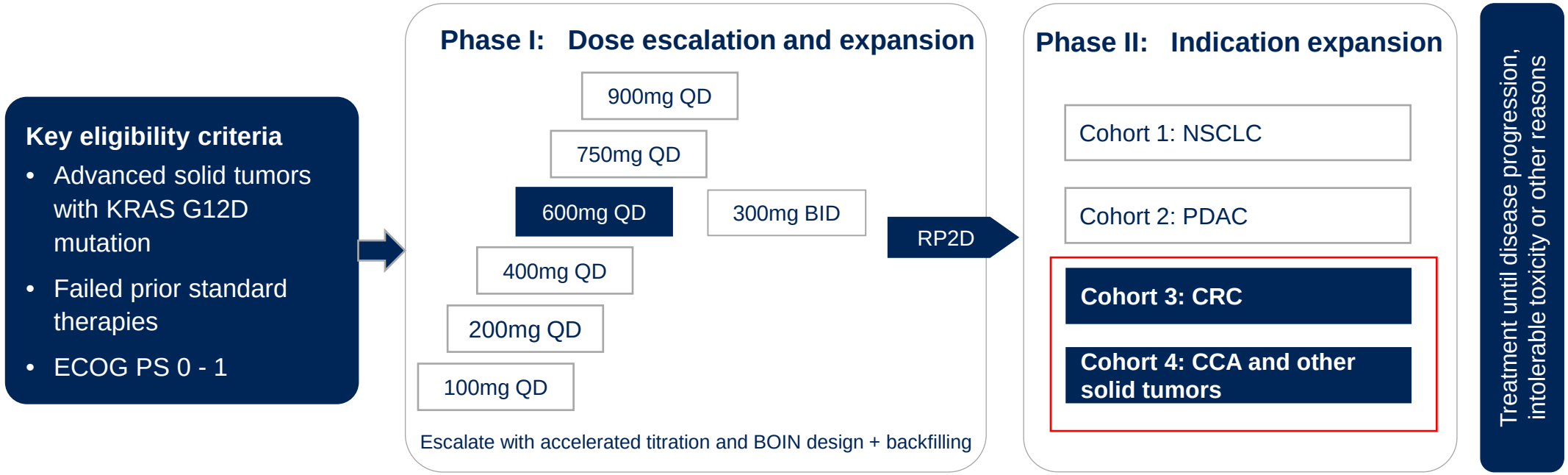
研究结果重点及解读
——GFH375



Key Takeaway Points

- GFH375 monotherapy demonstrated promising clinical activity in heavily pretreated patients with KRAS G12D-mutant CCA and CRC.
  - **CCA** (in 3L+: 75%)**: ORR 40%**, DCR 95%, **mPFS 6.2 mo** and **mOS not reached**
  - **CRC** (in 4L+: 61%)**: ORR 11%,** DCR 77%, **mPFS 4.1 mo** and **mOS 10.3 mo**
- GFH375 exhibits a manageable and consistent safety profile in the previously heavily treated population without new safety signals.
- The preliminary clinical data supports further development of GFH375 monotherapy and in combination regimens for patients with KRAS G12D–mutant CCA and CRC.

Phase I/II Study of GFH375 in Advanced Solid Tumors with KRAS G12D Mutation (NCT06500676)



Phase I endpoints:

- Safety/tolerability and MTD/RP2D: AEs, etc.
- Anti-tumor activity: ORR, DOR, DCR, PFS (per RECIST V1.1) and OS
- Pharmacokinetics
- Biomarkers

Phase II endpoints:

- Efficacy: ORR, DOR, DCR, PFS (per RECIST V1.1) and OS
- Safety: AEs, etc.
- Biomarkers

Abbreviations: AE, adverse event; BID, twice daily; BOIN, Bayesian optimal interval; CCA, cholangiocarcinoma; CRC, colorectal cancer; DCR, disease control rate; DOR, duration of response; ECOG PS, eastern cooperative oncology group performance status; MTD, maximum tolerated dose; NSCLC, non-small cell lung cancer; ORR, overall response; OS, overall survival; PDAC, pancreatic ductal adenocarcinoma; PFS, progression of survival; QD, once daily; RECIST, Response Evaluation Criteria in Solid Tumors; RP2D, recommended phase 2 dose.

Patient Baseline Characteristics

CCA, 400 mg (n=2), 600 mg (n=18) **:**

- 70% were intrahepatic cholangiocarcinoma and 30% were extrahepatic cholangiocarcinoma at diagnosis
- The majority (75%) received at least 2 prior lines of therapies
- 65% previously received TKIs

CRC, 400 mg (n=5), 600 mg (n=33), 750 mg (n=3) **:**

- 61% received at least 3 prior lines of therapies
- 39% previously received TKIs

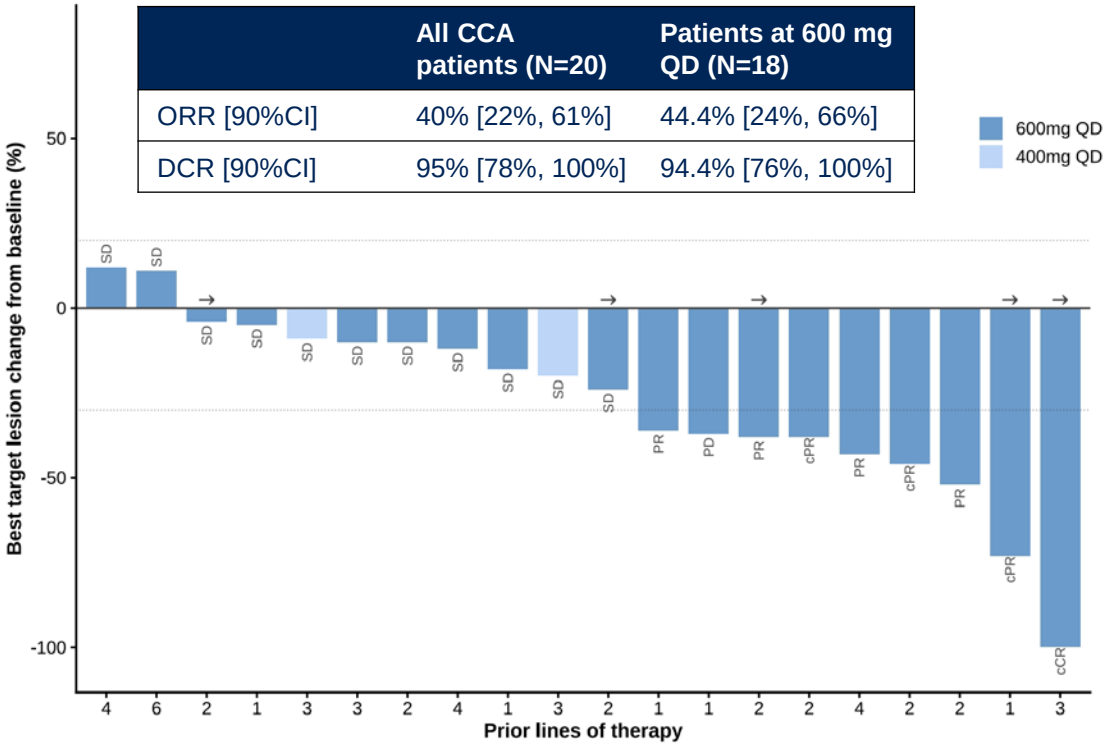
Characteristics	CCA (n=20)	CRC (n=41)
Age, median (range), years	59.5 (41, 74)	56 (29, 71)
Male, n(%)	16 (80.0)	25 (61.0)
ECOG PS, n(%)		
0/1	2 (10.0)/18 (90.0)	5 (12.2)/36 (87.8)
Metastasis at baseline [stage IV], n(%)	17 (85.0)	41 (100)
Liver	14 (70.0)	23 (56.1)
Lung	8 (40.0)	34 (82.9)
Peritoneum	4 (20.0)	12 (29.3)
Bone	4 (20.0)	7 (17.1)
Number of prior anti-cancer therapies, n(%)		
1	5 (25.0)	2 (4.9)
2	7 (35.0)	14 (34.1)
≥ 3	8 (40.0)	25 (61.0)
Median (range)	2 (1, 6)	3 (1, 6)
Prior therapies, n(%)		
Fluoropyrimidine/capecitabine	13 (65.0)	41 (100)
Oxaliplatin or other platinum	18 (90.0)	41 (100)
Irinotecan	4 (20.0)	40 (97.6)
Gemcitabine	18 (90.0)	0
Anti-PD1/PD-L1	17 (85.0)	15 (36.6)
Anti-angiogenic biologic	1 (5.0)	41 (100) *
Tyrosine kinase inhibitors	13 (65.0%) #	16 (39.0%)&

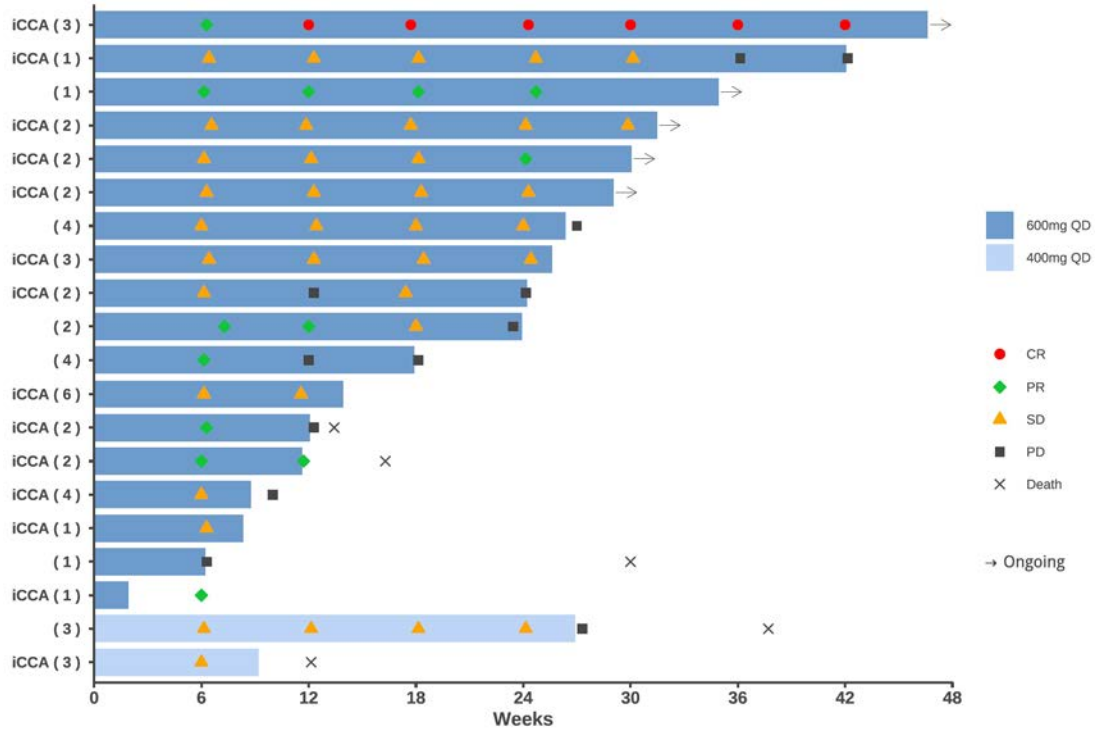
Enrollment cut-off date: 31-Oct-2025.
* Included Bevacizumab (n=41), Ivonescimab (n=1), LM299 (n=1). # Included Lenvatinib (n=9), Anlotinib (n=4), Surufatinib, Afatinib, Entrectinib and Donafenib (n=1 each). & Included Fruquintinib (n=15), Regorafenib (n=7).

Efficacy in CCA

- All CCA patients had at least one post-treatment tumor evaluation. The minimum follow-up time was 5.7 months.
- The ORR was 40% (8/20); confirmed ORR was 20% (4/20); 1 was ongoing for confirmation.

	All CCA patients (N=20)	Patients at 600 mg QD (N=18)
ORR [90%CI]	40% [22%, 61%]	44.4% [24%, 66%]
DCR [90%CI]	95% [78%, 100%]	94.4% [76%, 100%]



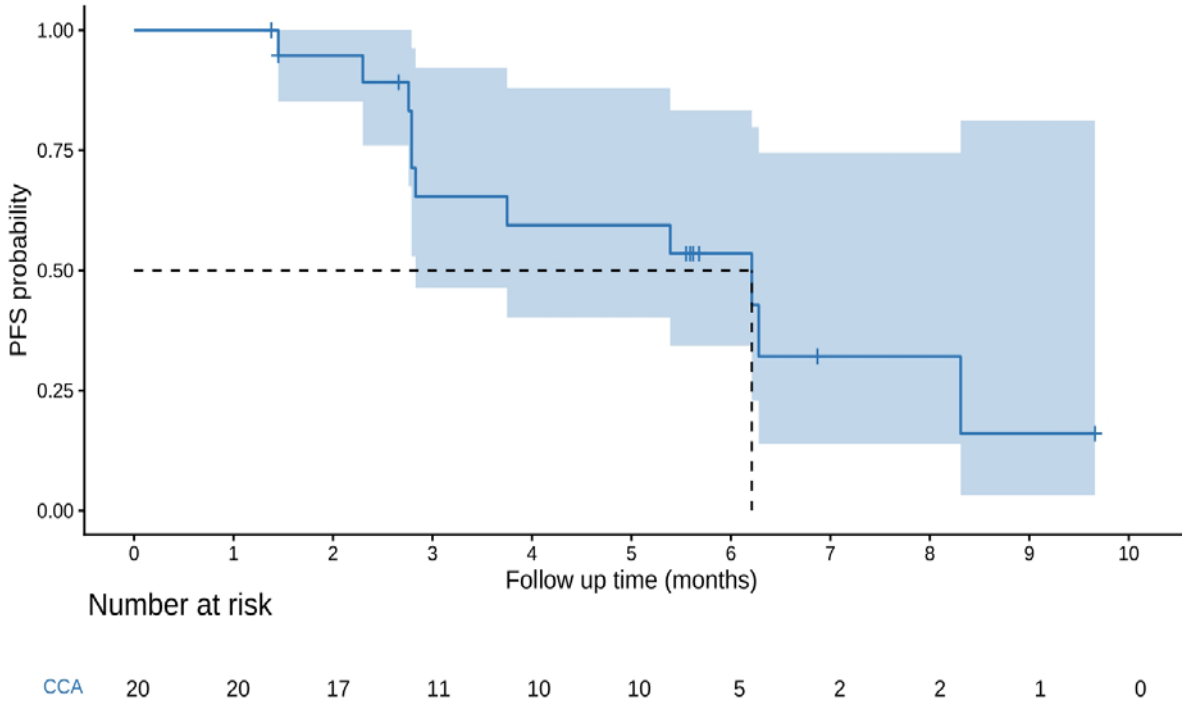


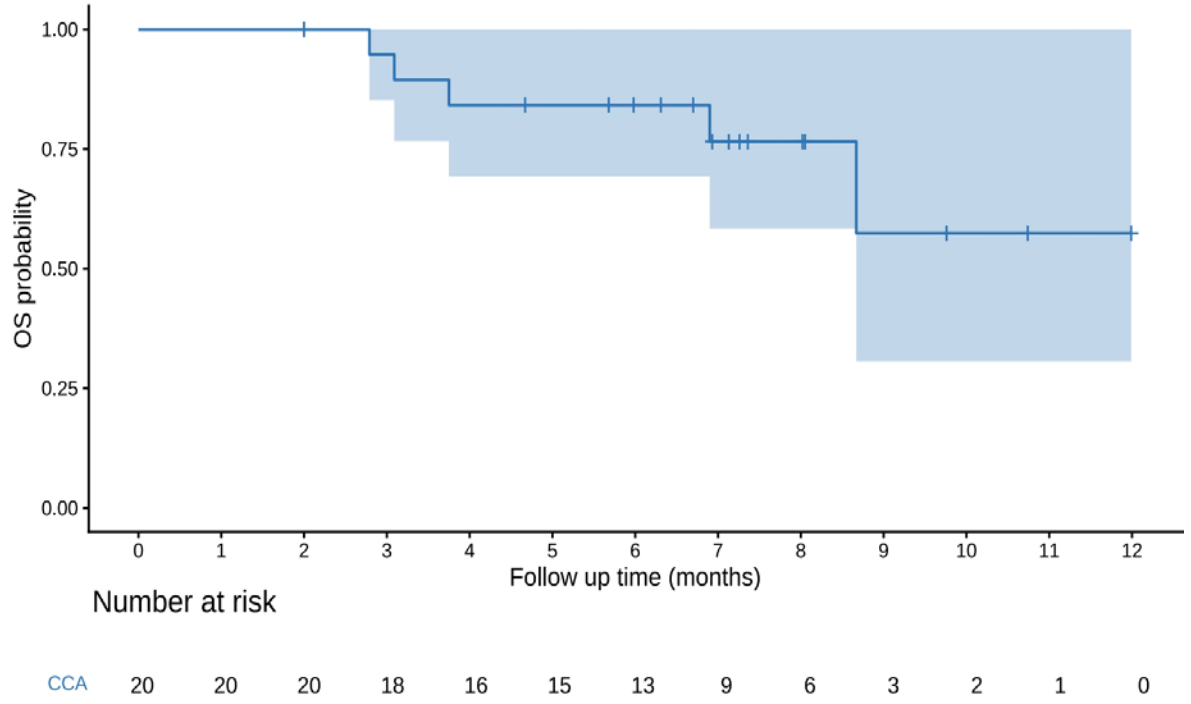
Data cut-off date: 20-Apr-2026.
The number in parentheses on the left side of y-axis in the swimming plot refers to the number of prior lines of therapies.
Abbreviations: cCR, confirmed complete response; cPR, confirmed partial response; DCR, disease control rate; iCCA, intrahepatic cholangiocarcinoma; ORR, overall response; PD, progressive disease; PR, partial response; QD, once daily; SD, stable disease.

PFS and OS in CCA

In heavily pretreated CCA patients (75% in 3L+ setting):

- **Median PFS** was **6.2 months** with median follow-up time of 5.7 months.
- **Median OS not reached** with median follow-up time of 7.3 months.





Data cut-off date: 20-Apr-2026.

Case Report: Patient with KRAS G12D Mutant CCA

Baseline Characteristics

- 69-year-old male
- Initially diagnosed with KRAS G12D intrahepatic cholangiocarcinoma on 07-Oct-2024
- Stage IV (T1N1M1) at baseline, liver, lung and peritoneum metastasis
- Concurrent TP53, APC and MSH6 mutations

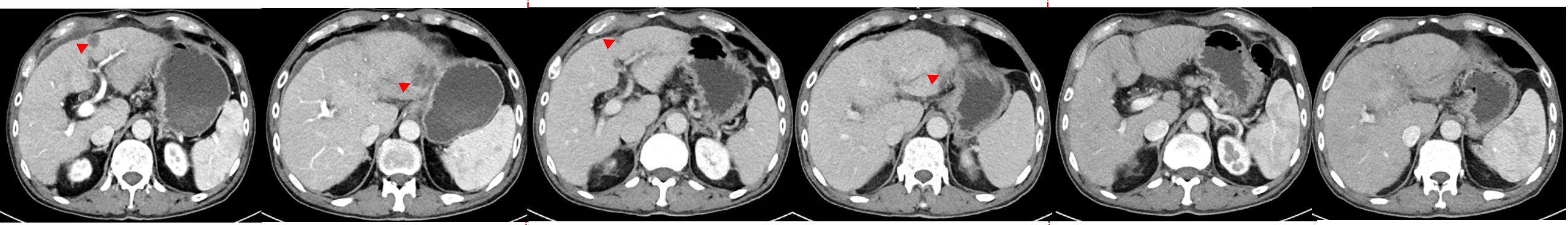
Treatment History

- 1st line: GEMOX, 6 cycles, 2024.10- 2025.1
- 2nd line: FOLFIRI, 3 cycles, 2025.2- 2025.3
- 3rd line: Lenvatinib + Cadonilimab, 2025.4- 2025.4
- Disease progressed 2025.5

GFH375 Treatment Courses

- C1D1: 29-May-2025, GFH375 600 mg QD treatment ongoing as of the data cutoff date
- TRAE: G3 neutrophil count decreased, G3 white blood cell count decreased, G1 platelet count decreased and G1 asthenia

Baseline (May 23, 2025) | **Week 7: PR (July 11, 2025)** | **Week 12: CR (August 20, 2025)**

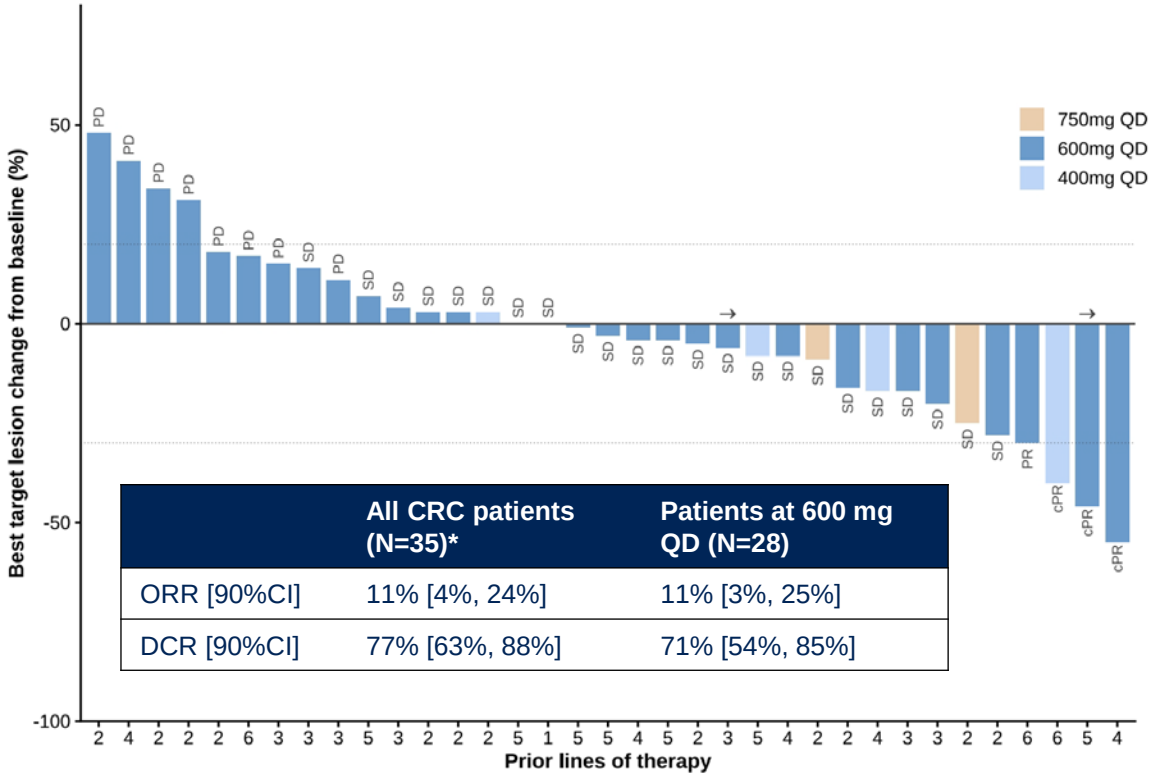


Target lesions with SoD of 66 mm | Target lesions with SoD of 25 mm | Target lesions with SoD of 0 mm

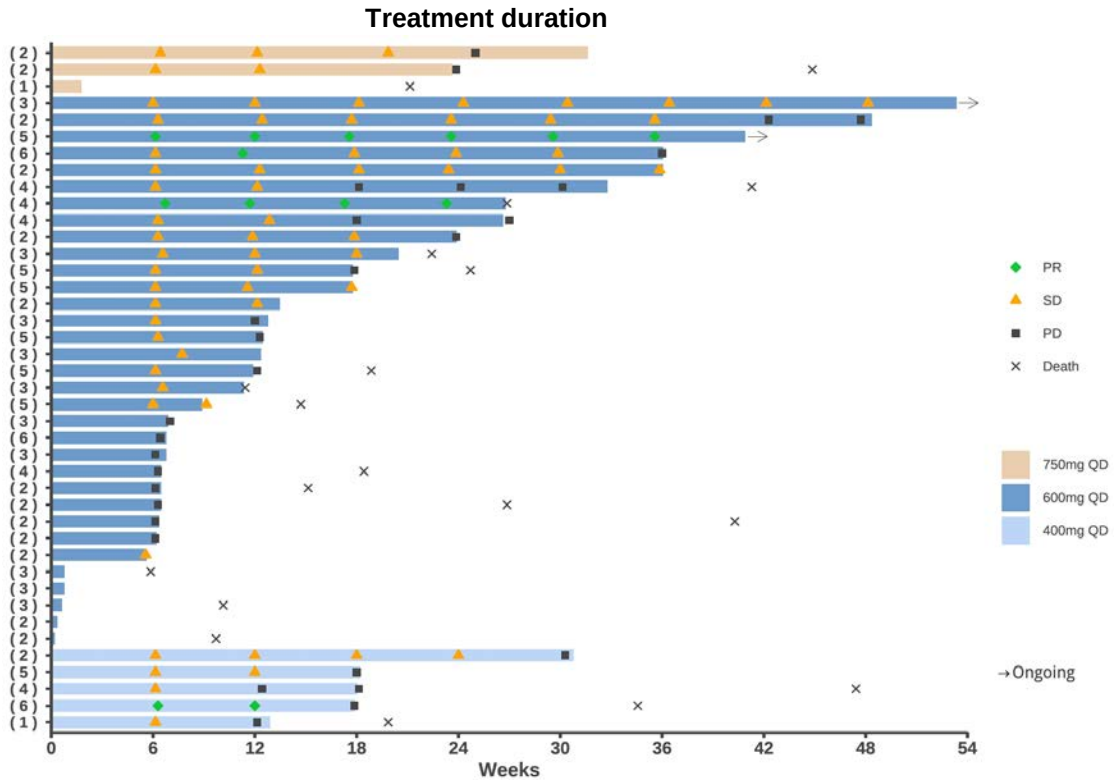
Abbreviations: CR, complete response; FOLFIRI, Irinotecan + Fluoropyrimidine + Leucovorin; GEMOX, Gemcitabine + Oxaliplatin; PR, partial response; QD, once daily; SoD, sum of diameters; TRAE, treatment related adverse event.

Efficacy in CRC

- 35 CRC patients had at least one post-treatment tumor evaluation. The minimum follow-up time was 8.4 months.
- The ORR was 11% (4/35), confirmed ORR was 9% (3/35).



	All CRC patients (N=35)*	Patients at 600 mg QD (N=28)
ORR [90%CI]	11% [4%, 24%]	11% [3%, 25%]
DCR [90%CI]	77% [63%, 88%]	71% [54%, 85%]

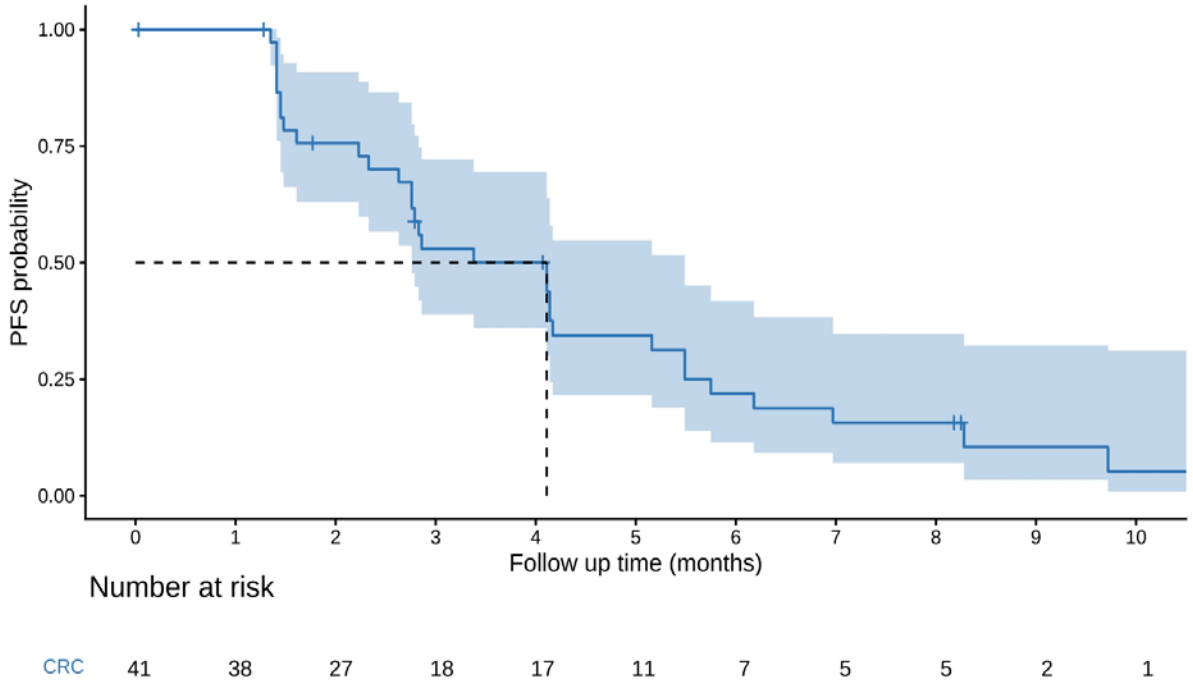


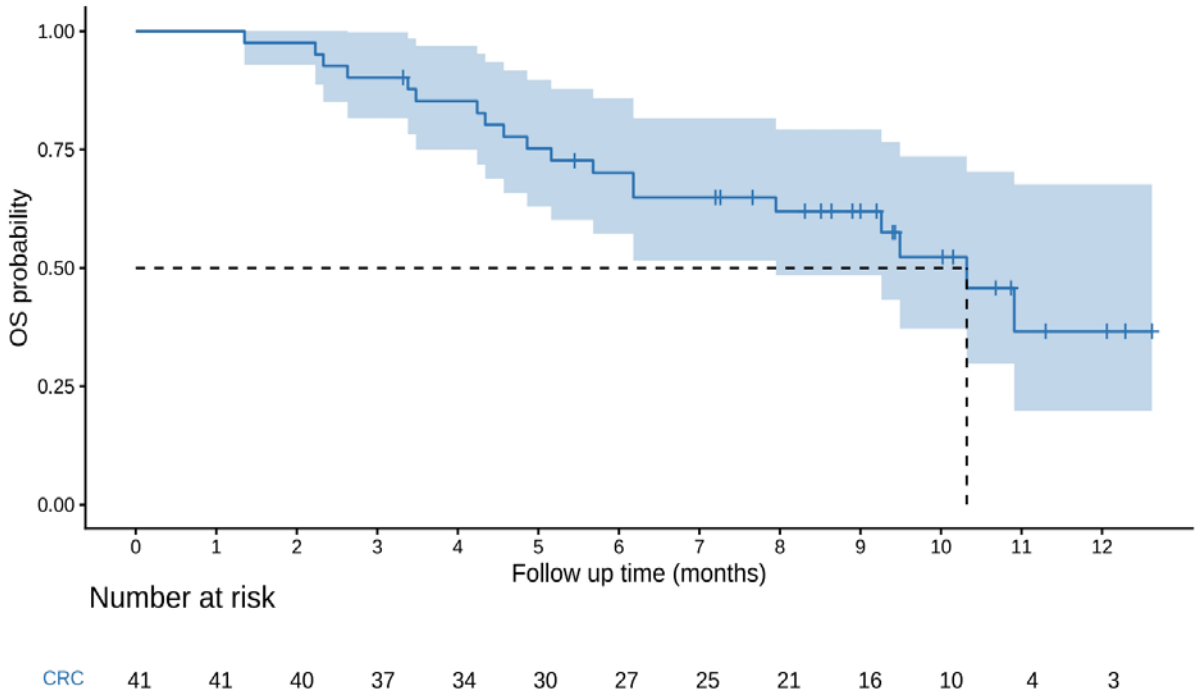
Data cut-off date: 20-Apr-2026.
The number in parentheses on the left side of y-axis in the plot of treatment duration is the number of prior lines of therapies.
* Six patients dropped out early without post-baseline tumor assessments, four due to patient's decision and 2 due to death.

PFS and OS in CRC

In heavily pretreated CRC patients (61% in 4L+ setting):

- **Median PFS was 4.1 months** with median follow-up time of 8.3 months.
- **Median OS was 10.3 months** with median follow-up time of 9.4 months.





Data cut-off date: 20-Apr-2026.

Treatment Related Adverse Events (TRAEs)

- GFH375 presented a manageable safety profile in heavily pretreated CCA and CRC patients.

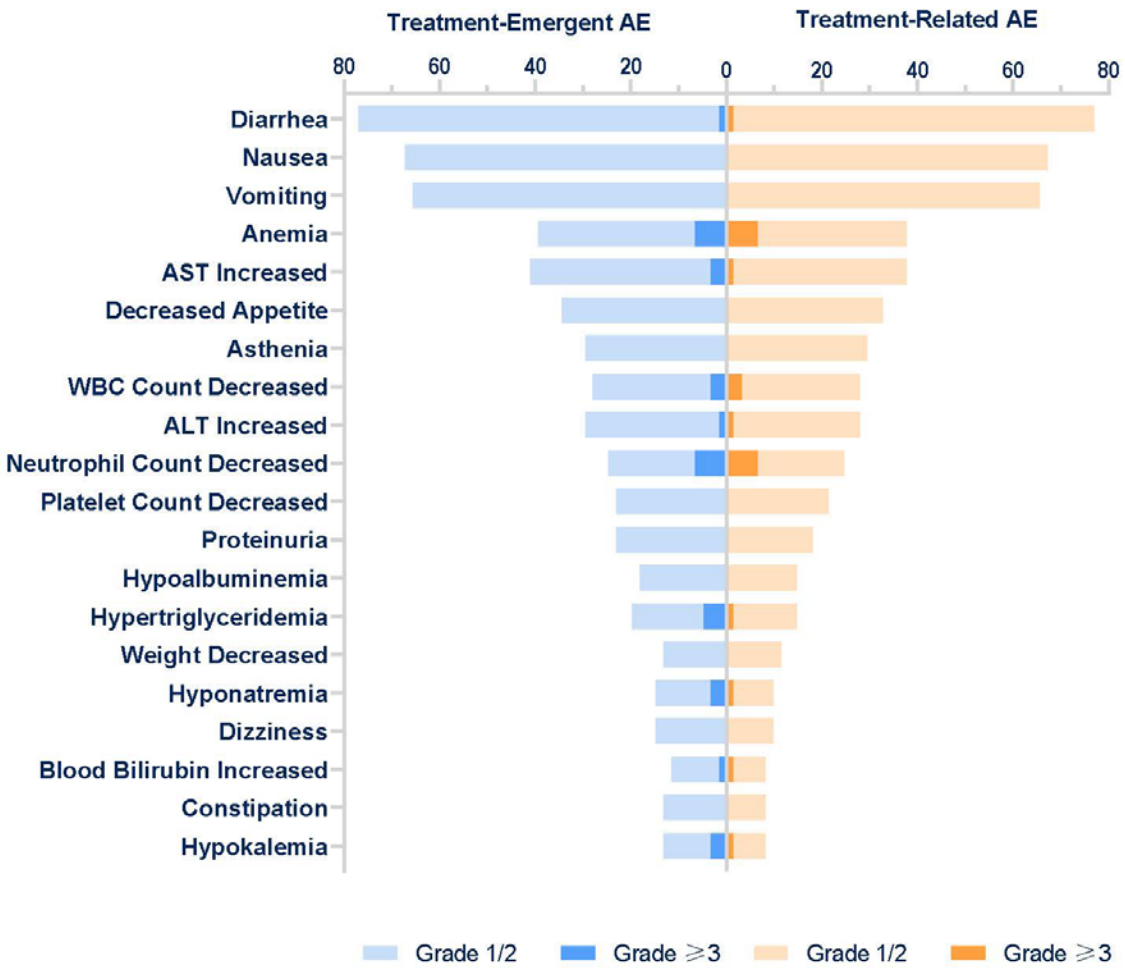
	CCA (n = 20)	CRC (n = 41)	Total (n = 61)
Any TRAE	20 (100)	40 (97.6)	60 (98.4)
TRAEs ≥ Grade 3, n(%)	8 (40.0)	11 (26.8)	19 (31.1)
Grade 5 TRAE, n(%)	0	1 (2.4)*	1 (1.6)
TRAEs leading to treatment discontinuation, n(%)	0	2 (4.9)	2 (3.3)
TRAEs leading to dose reduction, n(%)	1 (5.0)	1 (2.4)	2 (3.3)
TRAEs leading to dose interruption, n(%)	8 (40.0)	10 (24.4)	18 (29.5)
Treatment related SAEs, n(%)	1 (5.0)	4 (9.8)	5 (8.2)

Data cut-off date: 12-Dec-2025.
The median exposure time was 2.7 (range: 0.5-7.6) months among CCA patients and 3.0 (range: 0.1-8.0) months among CRC patients, 2.9 (range: 0.1-8.0) months among all patients. The mean relative dose intensity was 98.5%.
* This grade 5 event was coded as “undetermined death”. It occurred in a 65-year-old female CRC patient with liver and lymph nodes metastasis at baseline. The patient passed away at home. Despite all attempts, no relevant information could be obtained as the family declined to provide. Therefore, the causality could not be concluded due to insufficient information available.
Abbreviations: CCA, cholangiocarcinoma; CRC, colorectal cancer; SAE, serious adverse event; TRAE, treatment related adverse event.

Adverse Events in ≥10% of Patients

- The safety profile in CCA and CRC was consistent with prior reports[1,2,3], without new safety signals observation.
- Common TRAEs were gastrointestinal, hematological AEs and transaminitis; most were grade 1 or 2 and recovered with supportive treatment.

Most frequent TEAE/TRAEs (≥10% of all CCA and CRC patients)



Data cut-off date: 12-Dec-2025.

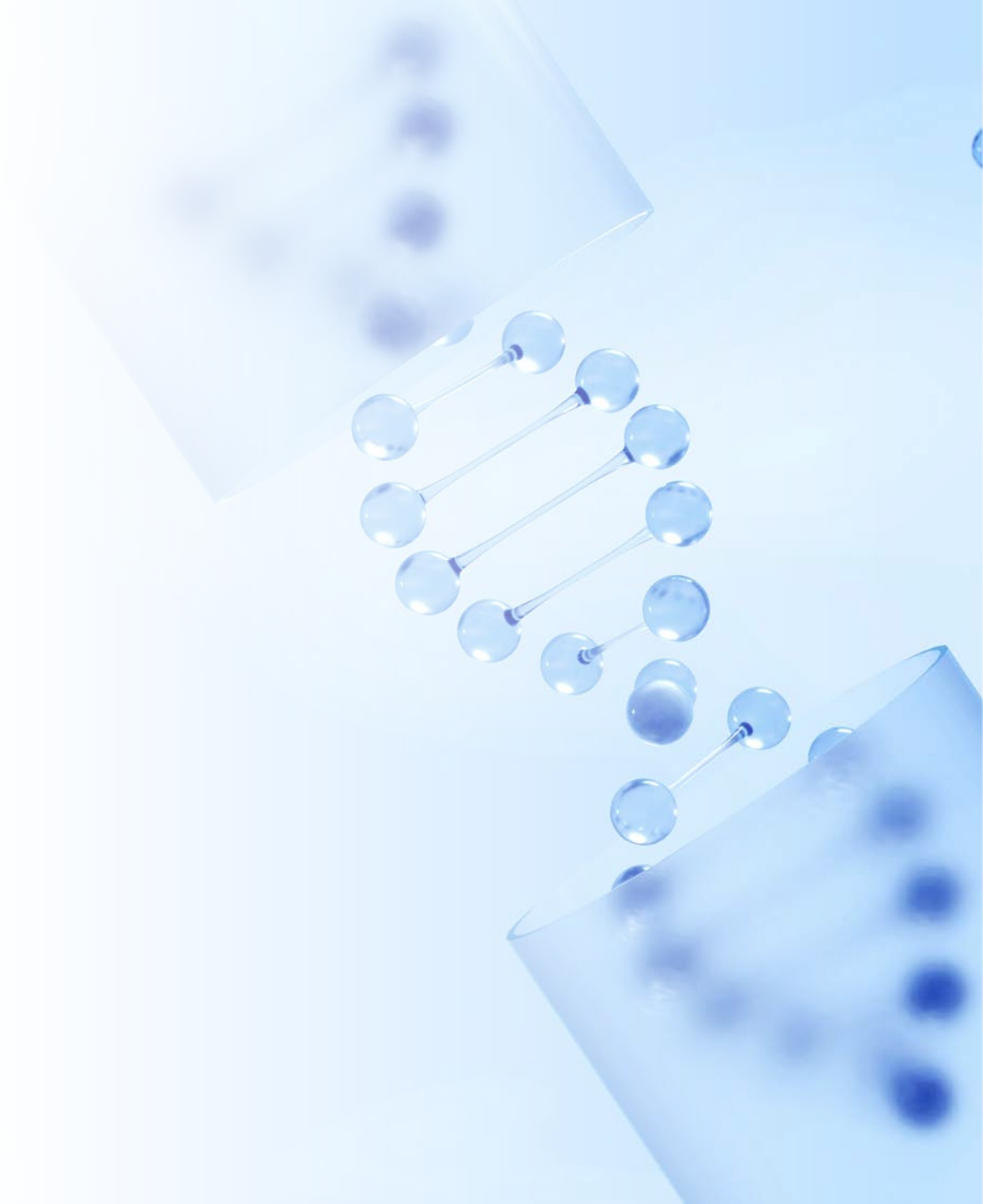
[1] Ai X, et al. J Clin Oncol 43, 3013-3013(2025). [2] Lu S, et al. Journal of Thoracic Oncology, 20, S59-S60. [3] Zhou A, et al. Annals of Oncology, 36S1626.

Conclusions

- GFH375 single agent showed promising clinical activities in previously heavily treated CCA and CRC.
  - CCA (75% in 3L+ setting) : **ORR 40%,** DCR 95%, **median PFS 6.2 months** and **median OS not reached**
  - CRC (61% in 4L+ setting): **ORR 11%,** DCR 77%, **median PFS 4.1 months** and **median OS 10.3 months**
- The safety profile was tolerable and manageable without new safety signals.
- The preliminary clinical data supports further development of GFH375 monotherapy and in combination regimens for KRAS G12D–mutant CCA and CRC.
- GFH375 plus cetuximab or chemotherapy are currently being studied in solid tumors including CRC (NCT07259590).

PART 03

研究结果重点及解读
——GFS202A



Study Plan for GFS202A：World's First Bispecific Antibody for Cachexia

GFS202A, 600 mg, IV, Q3W
N = 3 - 6

GFS202A, 400 mg, IV, Q3W
N = 3 - 6

GFS202A, 200 mg, IV, Q3W
N = 3 - 6

GFS202A, 100 mg, IV, Q3W
N = 3 - 6

GFS202A, 25 mg, IV, Q3W
N = 3 - 6

GFS202A, 5 mg, IV, Q3W
N = 1

Primary Endpoints

- Incidence and severity of AEs and SAEs
- Incidence of DLT

Secondary Endpoints

- Pharmacokinetics
- GDF15 and CRP
- Body weight and L3SMI
- Appetites

Pre-cachexia and Cachexia Patients: Baseline Characteristics and Demographics

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➢ As of March 11, 2026, a total of 19 patients received GFS202A (5-400 Q3W)

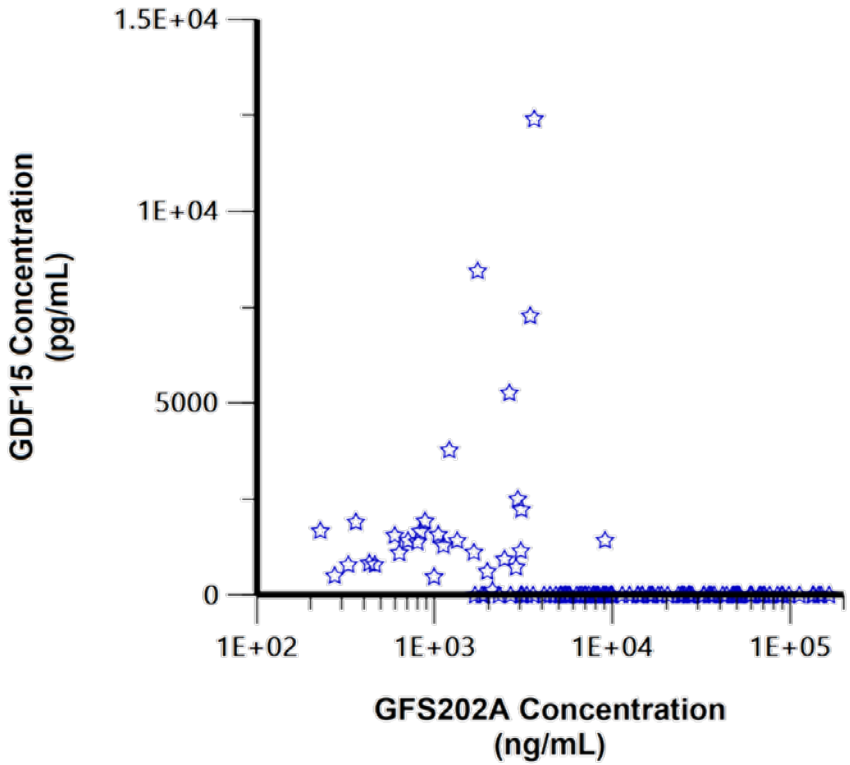
- 5 mg [N = 1];
- 25 mg [N = 4];
- 100 mg [N = 4];
- 200 mg [N = 4];
- 400 mg [N = 6]

➢ Baseline characters:

- Median weight: 52.9 kg.
- Baseline ECOG PS ≥ 1: 16 (84.2%) patients.
- Median GDF15 level: 968.58 pg/mL.
- 18 (94.7%) patients had stage IV disease at study entry. 15 (78.9%) had received ≥ 2 prior lines of therapy.
- During the study, 13 (68.4%) patients received antitumor therapy, including 5 (26.3%) with platinum-based regimens.

	Total (N=19)
Age (years), median (range)	62 (43, 76)
Male, n (%)	14 (73.7)
Weight (kg), median (range)	52.9 (37, 71)
% weight loss during 6 months before screening[a] (%)	
Median (range)	11.4 (2.5, 19)
BMI (kg/m²), median (range)	18.5 (13.9, 27.2)
< 21, n (%)	13 (68.4)
ECOG PS, 0/1/2	3 (15.8)/14 (73.7)/2 (10.5)
GDF15 (pg/mL), median (range)[b]	968.58 (99.63, 1898.57)
Modified Glasgow performance score (mGPS)[c]	
0/1/2	8 (42.1)/8 (42.1)/3 (15.8)
Cancer type, n (%)	
NSCLC	7 (36.8)
PC	2 (10.5)
CRC	4 (21.1)
GC/GEJC	3 (15.8)
Others[d]	3 (15.8)
Stage IV at study entry, n (%)	18 (94.7)
Prior lines of antitumor therapy, median (range)	2 (0, 7)
1, n (%)	3 (15.8)
≥ 2, n (%)	15 (78.9)
Receipt of antitumor therapy during the study, n (%)	
Any	13 (68.4)
Platinum-based	5 (26.3)

PK/PD: Dose-dependent Suppression of GDF15



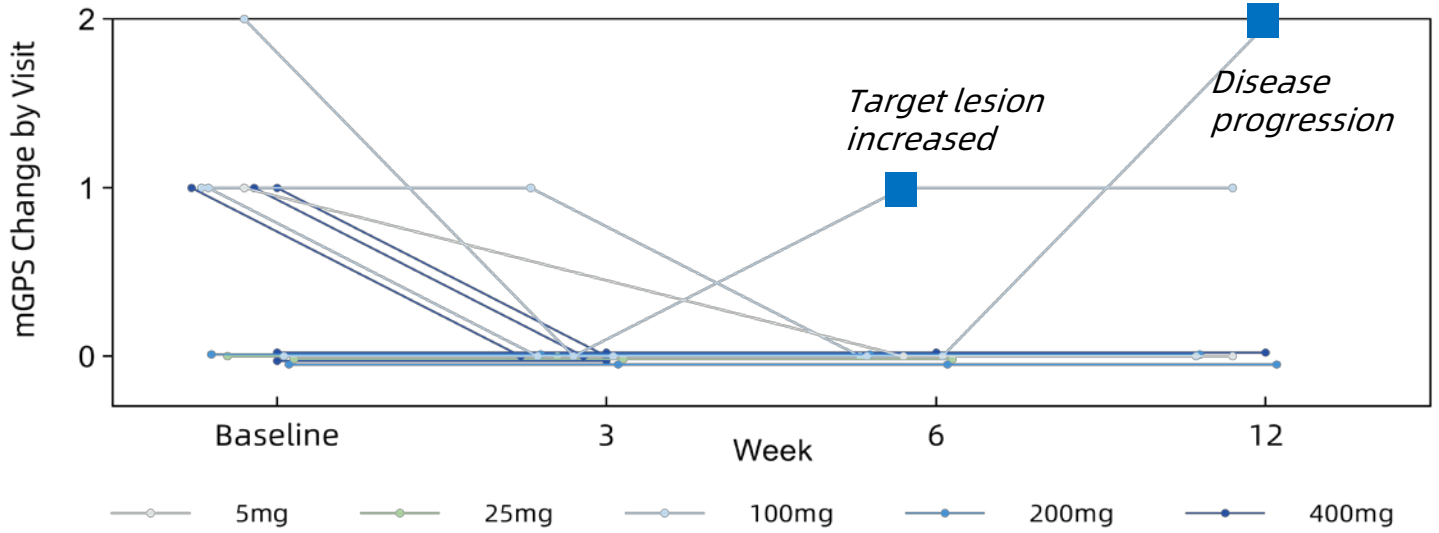
- PK exposure increased with escalating dose levels with a 3.2-7.5 days $T_{1/2}$.
- No obvious accumulation.
- About 30% positive ADA tested without compromising PK exposure and safety.
- Complete and constant inhibition of GDF15 achieved at 200 mg Q3W dose level and above.

mGPS Improvements Observed for Majority of Patients: Notable Decrease in CRP, and Increase in Albumin

➢ mGPS: modified Glasgow Prognostic Score

Crucial inflammation-based prognostic index that predicts survival and clinical outcome

➢ Baseline to week 12 mGPS change by visit: most patients had improved mGPS after treatment with GFS202A

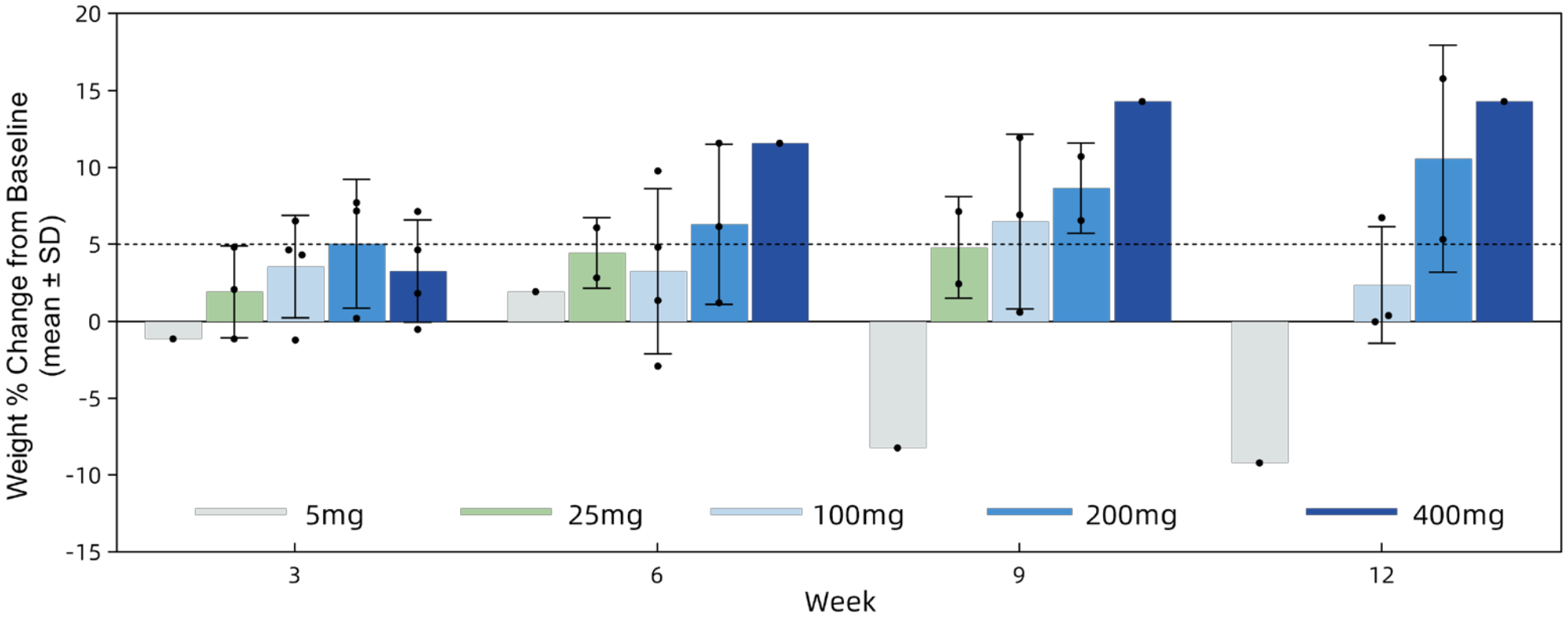


	Week 6	Week 12
Mean decrease of C-reactive protein	39.81 mg/L	49.42 mg/L
Mean increase of albumin	3.4 g/L	2.8 g/L

➢ mGPS rating (calculated based on CRP and albumin)

- mGPS= 2: CRP≥10mg/L & ALB<35g/L
- mGPS= 1: CRP≥10mg/L & ALB≥35g/L,
- mGPS= 0: CRP<10mg/L & any ALB

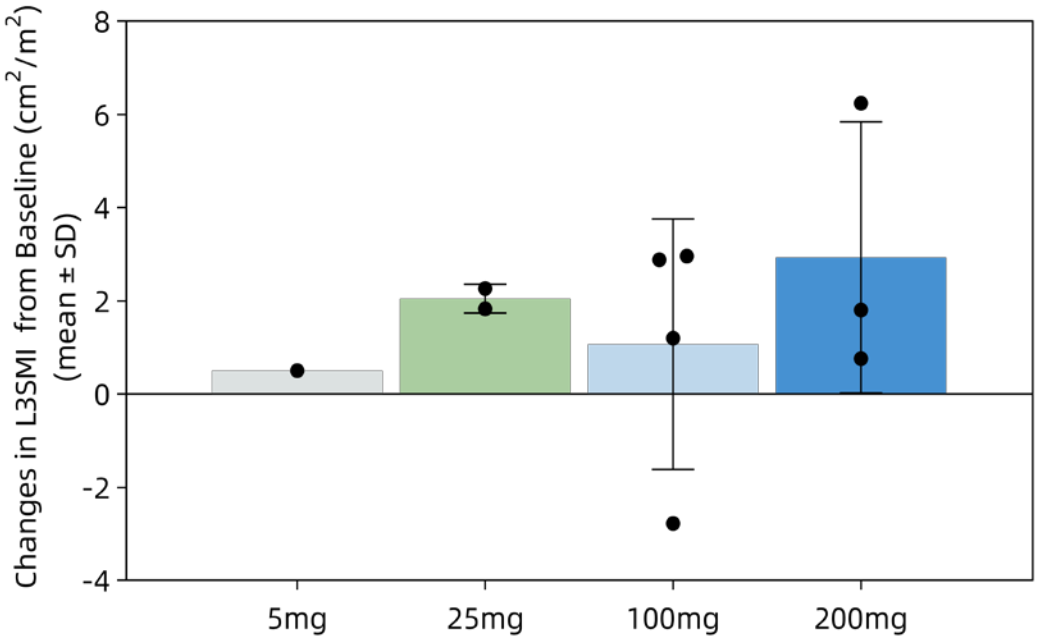
Dose-dependent Increase Observed in Body Weight



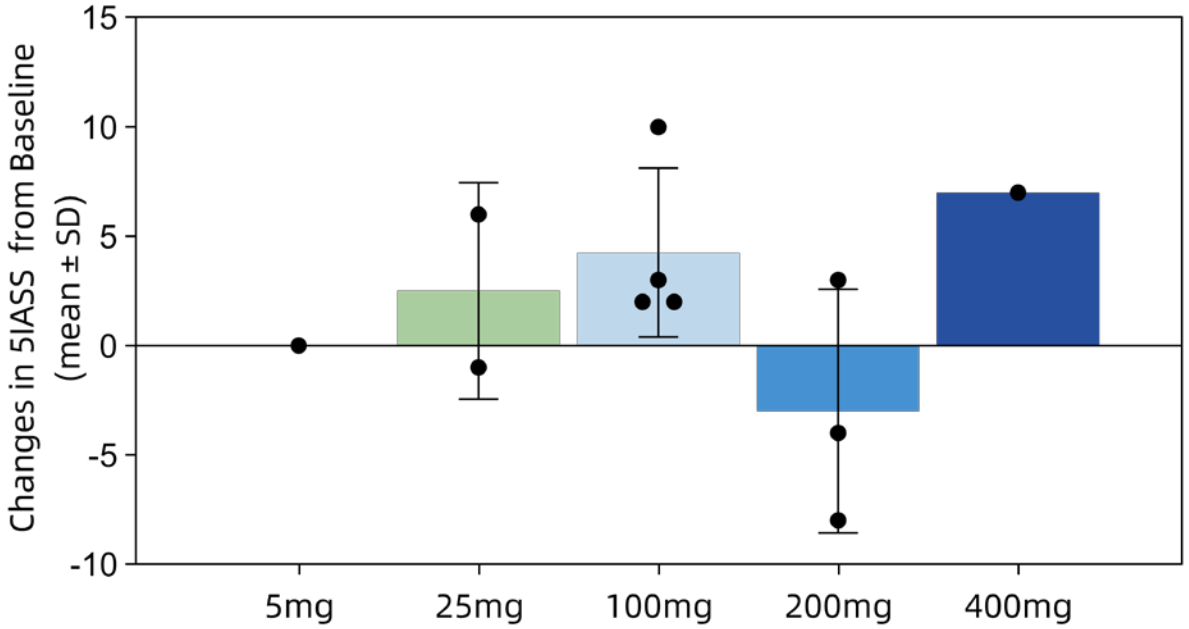
- *Data points indicate values of individual patients; bars indicate mean values.*
- *All patients in the 25 mg group prematurely discontinued from the study before 12-week treatment period completion, thus no available data included in the above plot.*

Improvements in Skeletal Muscle Mass and Appetite

L3SMI by IRC at Week 6



Appetite changes (FAACT-5IASS) at Week 6

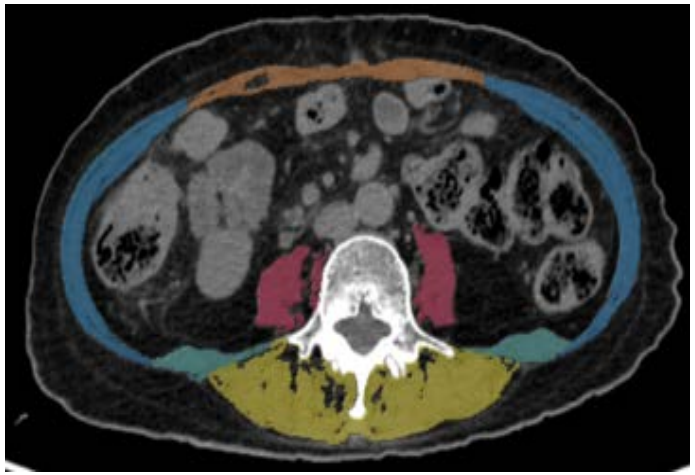


- *Data points indicate values of individual patients; bars indicate mean values.*
- *L3SMI was calculated centrally using Independent Review Committee (IRC). FAACT-5IASS was collected using paper form. Abbreviations: TL, target lesion.*

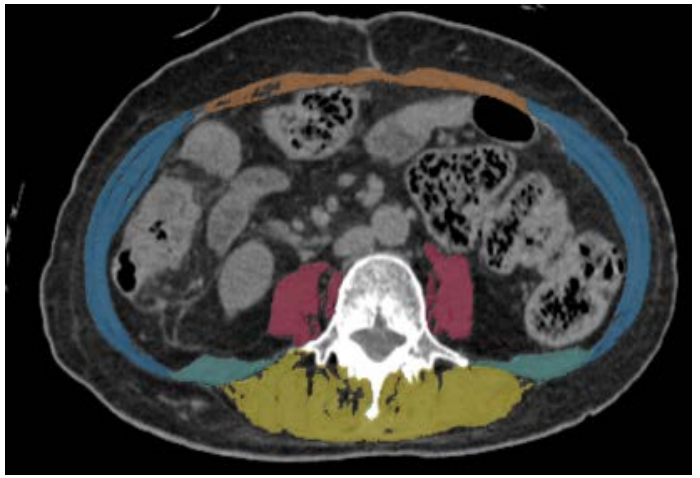
Case Study (GFS202A 100mg Q3W)

Case Study

Baseline



Week 6



- Female, 71 yrs old, gallbladder cancer
- Prior antitumor therapy: GEMOX
- On-treatment antitumor therapy: gemcitabine + pembrolizumab/CAPOX + pembrolizumab
- Baseline GDF15: 957.15 pg/mL; mGPS: 0

Efficacy at Week 6

- Weight: + 9.78% ; L3SMI: + 2.96 cm^2/m^2
- Appetite: + 2 points
- Overall response per RECIST v1.1: PD

Favorable Overall Safety and Tolerability

	Total (N=19), n (%)
At least one TRAE	**8 (42.1)**
Asthenia	1 (5.3)
Anemia	1 (5.3)
Hyperlipidemia	1 (5.3)
Abdominal pain	1 (5.3)
Electrocardiogram QT prolonged	1 (5.3)
Blood pressure increased	1 (5.3)
Protein urine present	1 (5.3)
Hypertension[1]	1 (5.3)
Diarrhea	1 (5.3)
Atrial fibrillation	1 (5.3)
Rash	1 (5.3)
Neutrophil counted ddecreased	1 (5.3)
Complement factor C3 decreased	1 (5.3)
Complement factor C4 decreased	1 (5.3)
Decreased appetite	1 (5.3)
Hypokalaemia	1 (5.3)
Hpyercholesterolaemia	1 (5.3)
Low density lipoprotein increased	1 (5.3)
Glucose urine present	1 (5.3)
Blood triglycerides increased	1 (5.3)
Hyperglycaemia	1 (5.3)

- No DLTs were observed, and the MTD was not reached.
- No patients discontinued or interrupted due to treatment-related AEs (TRAEs).
- Neither infusion-related reaction nor AEs of special interest (defined as infection) occurred.
- Eight patients experienced TRAEs; all were grade 1 or 2 except one grade 3.

The G3 patient had received anlotinib plus capecitabine until 3 days prior to the first dose of GFS202A. Following the first dose of GFS202A, the patient developed asymptomatic G3 hypertension on day 63, which resolved after adequate treatment.

Conclusions

- GFS202A showed a favorable safety profile and promising efficacy, accompanied by reduced systemic inflammation, weight gain, and improved muscle maintenance.

- The data support that dual-targeting GDF15 and IL-6 is a feasible way to mitigate cancer cachexia clinically. Future studies are warranted.

总结与展望

已开展，入组进展符合预期

单药治疗胰腺癌
III期注册性研究

联合化疗治疗胰腺癌
Ib/II期，一线治疗

联合西妥昔单抗治疗实体瘤
Ib/II期，一线及各线治疗

GFH375
KRAS G12D (ON/OFF)
抑制剂

近期CDE公示多项试验或IND申请
（单药、联合疗法）

GFH375+GFS202A
联合方案II期IND申请获得受理

唯一拥有RAS矩阵+恶病质疗法企业

创新组合方案：RAS靶向疗法+恶病质双抗

疗效有望超越

GDF15单抗+化疗
NCT06989437

RAS+RAS
RAS+SOC（PD-1或化疗）
NCT07491445, NCT06128551,
NCT06040541, etc.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