2026 ASCO: GFH375 and GFS202A Clinical Data Review

June 2026

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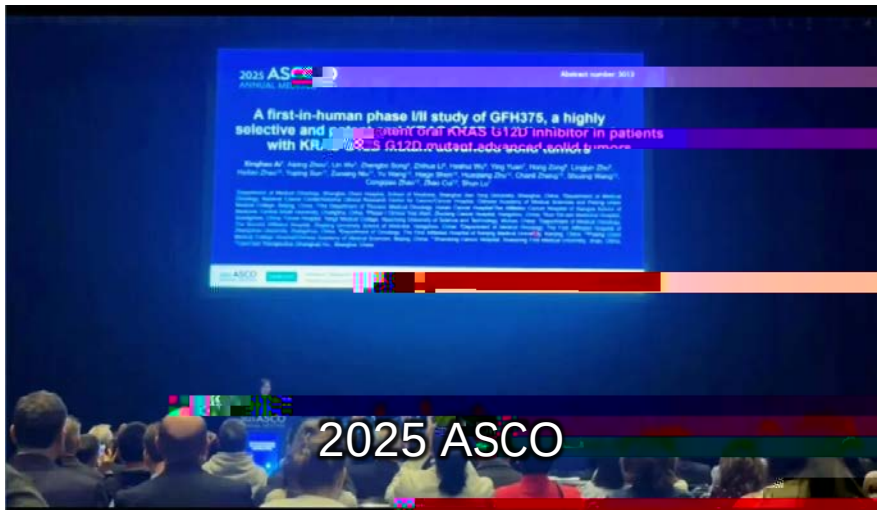
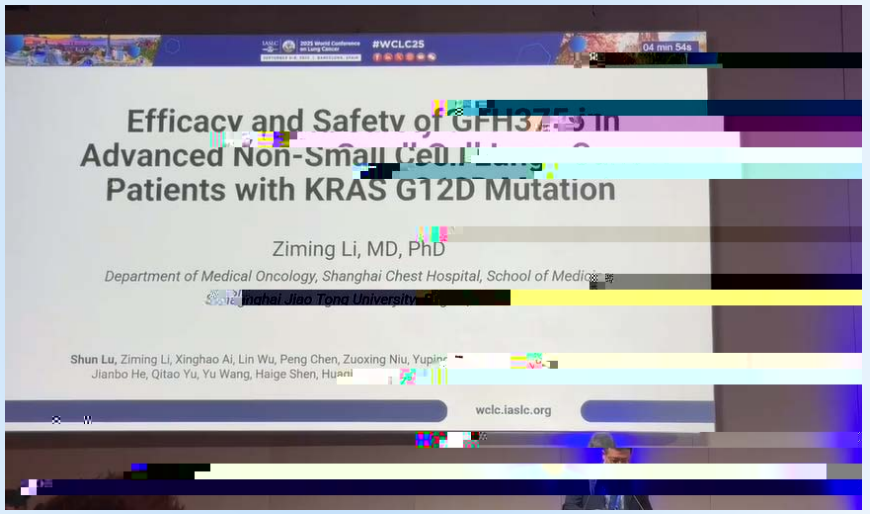
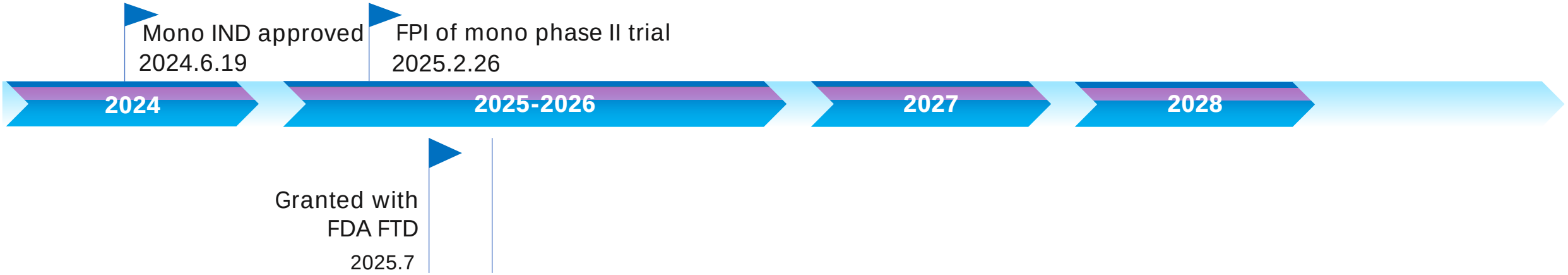
Fourth Consecutive Selection of GFH375's Clinical Data into Oral Presentation at Top-tier Global Academic Meetings





GFH375 Development Features Well-orchestrated Timeline and Powerful Execution; Pancreatic Cancer Trials Enrollment Proceed as Planned



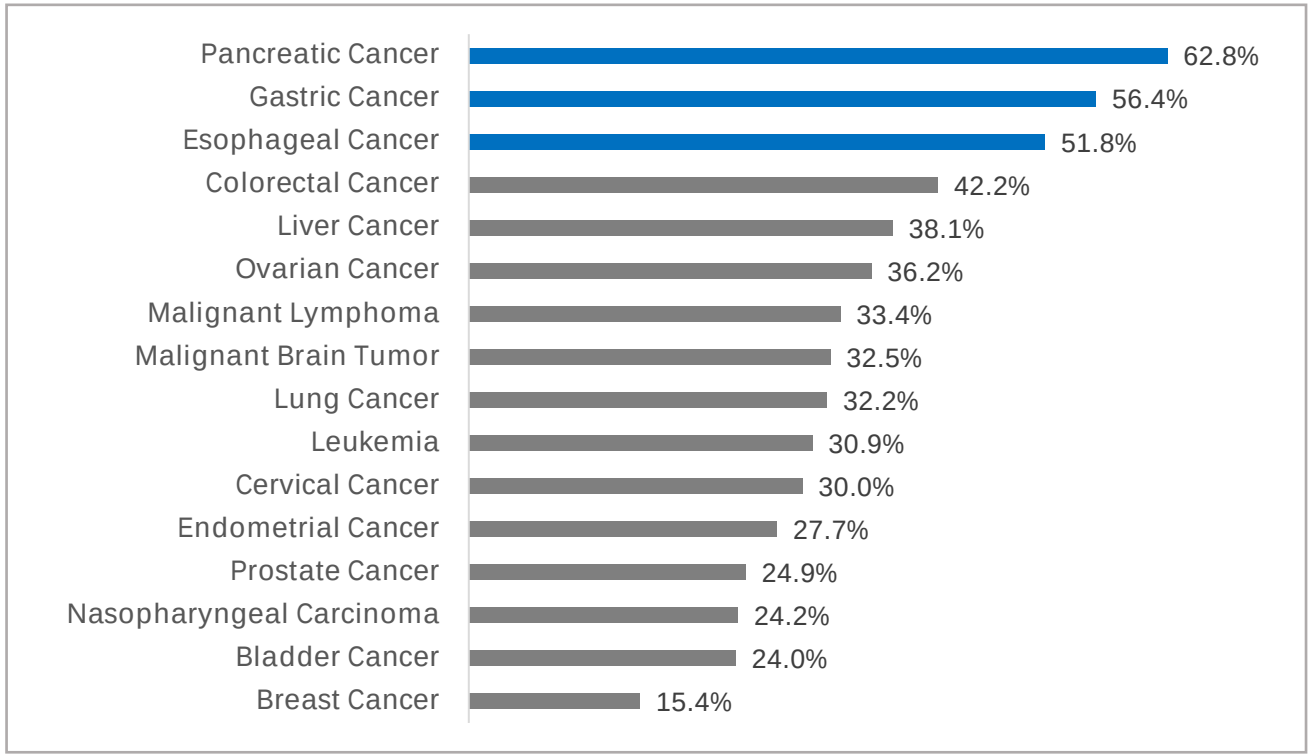
Broad Market Potential upon GFH375's Encouraging Clinical Efficacy

- 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

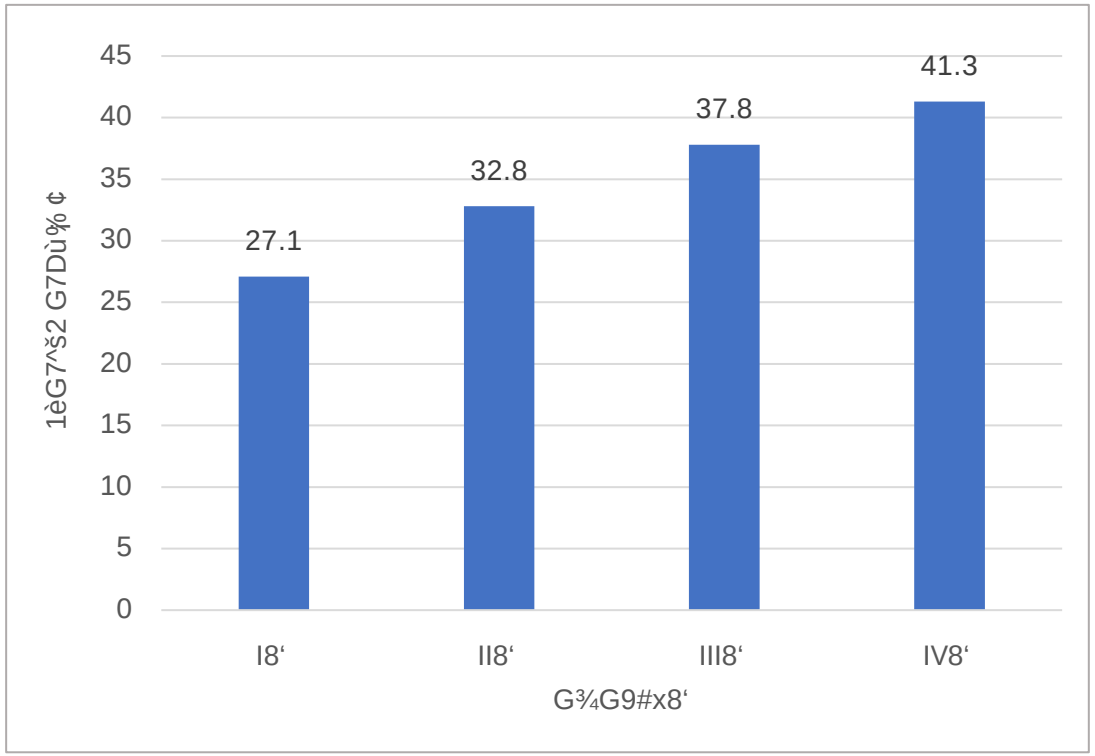
[1]JK Lee et al. npj

Cachexia and Oncology Treatments Exhibit Strong Potential of Commercial Synergy

Overall prevalence of cancer cachexia stands at 37.0%, with primary tumor site serving as a key determinant of cachexia occurrence. Pancreatic (62.8%), gastric (56.4%) and esophageal cancers (51.8%) demonstrate the strongest correlation with cancer cachexia. Lung cancer ranks first in both incidence and mortality among all malignancies in China, with approximately 32.2% of lung cancer patients developing cancer cachexia.



Cachexia incidence across different cancer types



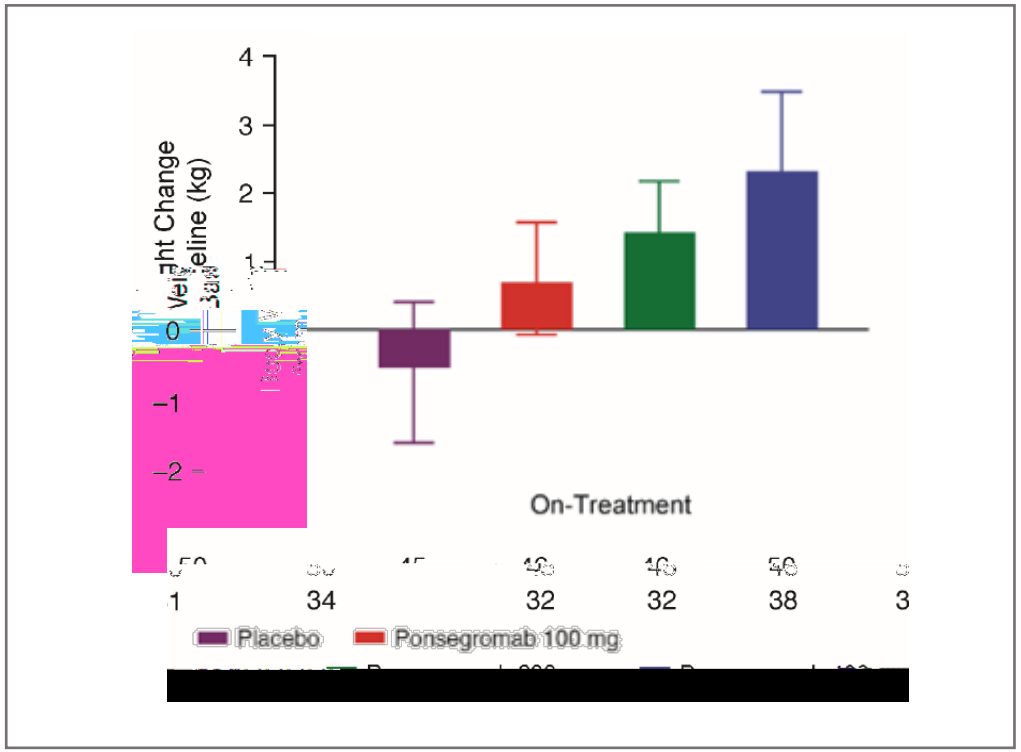
Cachexia incidence across cancer disease stages

i, 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.

Ponsegromab (Pfizer's anti-GDF15 mAb) Delivers Meaningful Weight Gain in Patients with Cancer Cachexia

At Week 12, all active-dose cohorts demonstrated dose-dependent body weight gains versus placebo.

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



Body weight change from baseline

PROACC study, phase II

GenFleet’s Presentations at 2026 ASCOA

GFS202A

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.

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

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 aden.5 (opt)-9.5 (iC)1.6 (D)1.9(T)-4.9 21.5i;CC5.9 (ogyg)-5.9 (l)-5.9 ( )socarion all surviatpons M(R

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Patient Baseline Characteristics

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

- 70% were intrahepatic cholangiocarcinoma and 30% were extrahepatic cholangiocarcinoma at diagnosis

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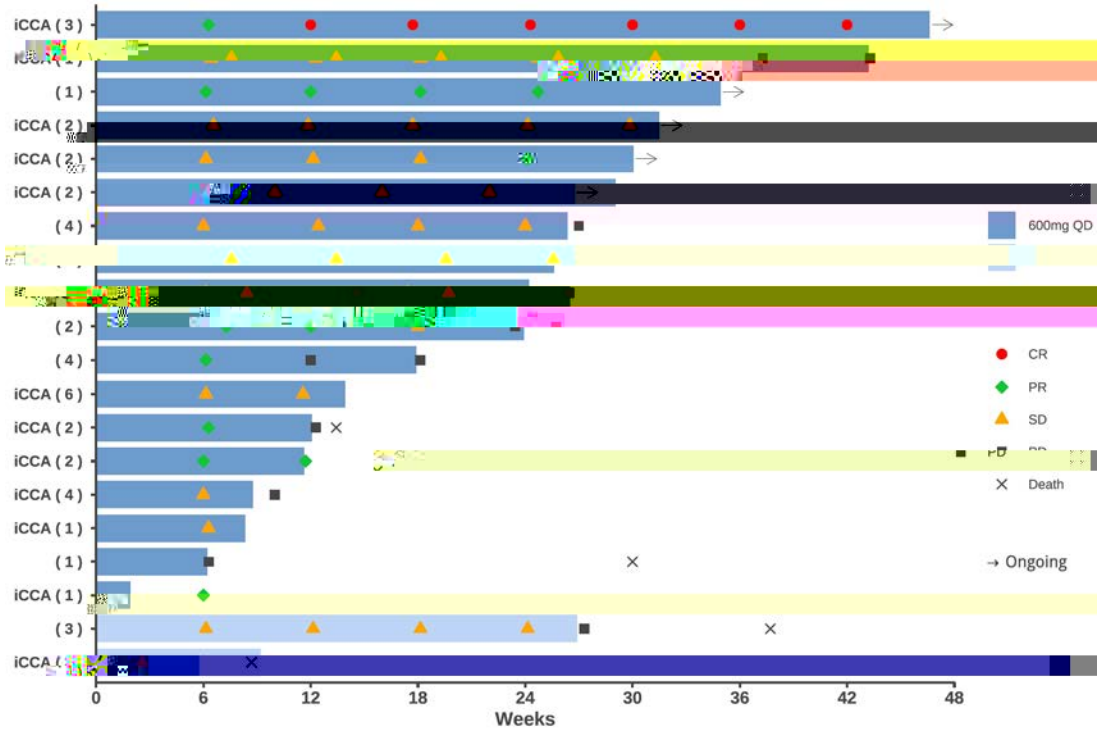
Efficacy in CCA

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.

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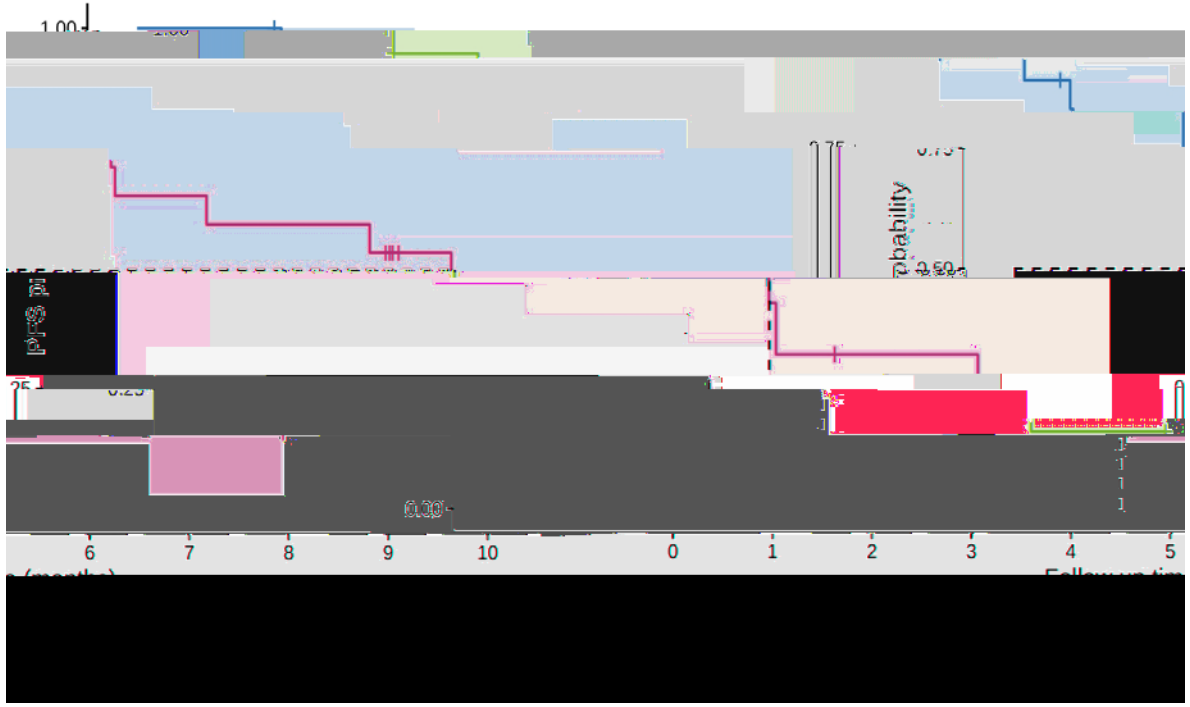
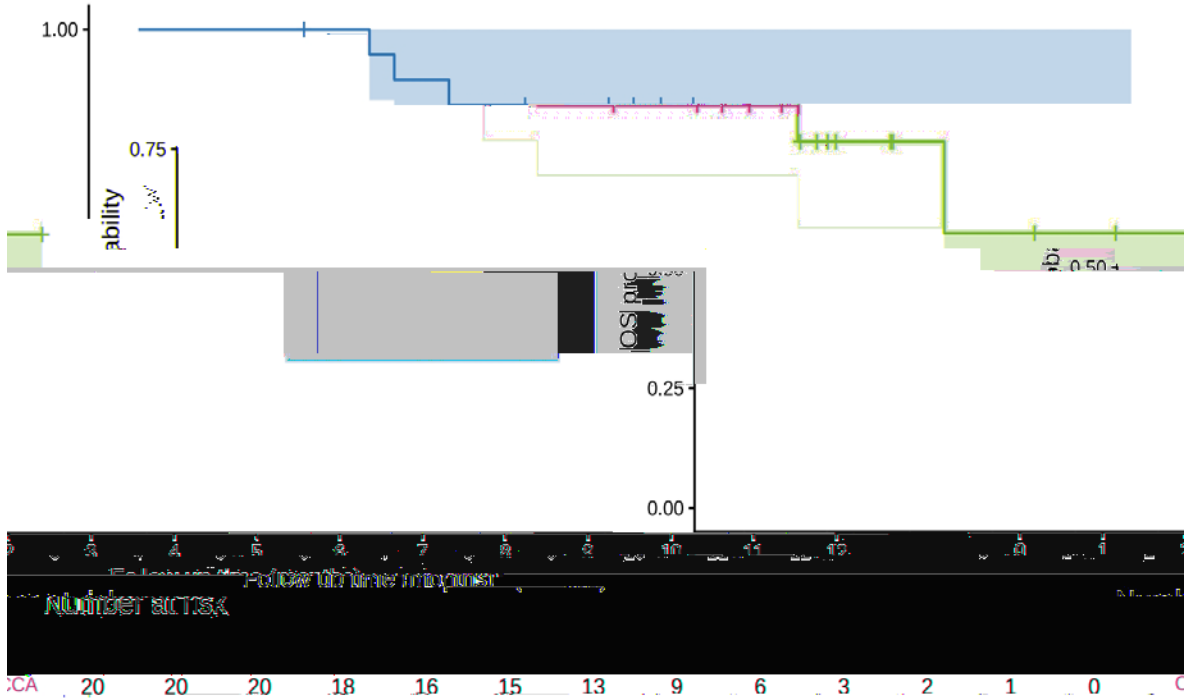
PFS and OS in CCA

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.

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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

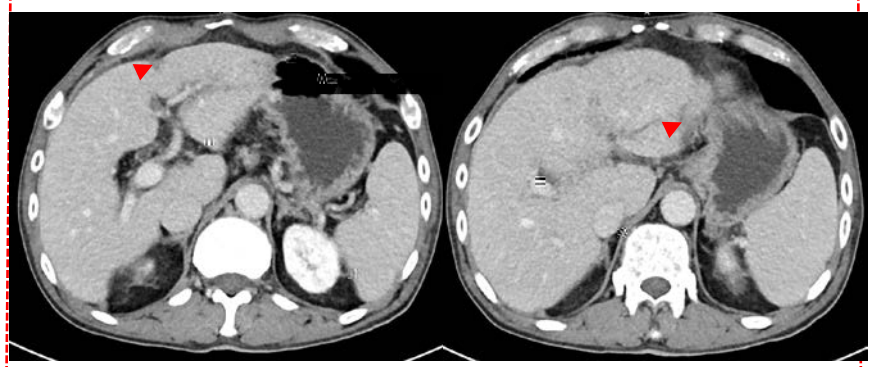
1st line: GEMOX, 6 cycles, 2024.10- 2025.1
2nd line: FOLFIRI, 3 cycles, 2025.2- 2025.3
3rd line: Lenvatinib + Cadonilimab, 2025.4- 2025.4
Disease progressed 2025.5

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 uPR (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.

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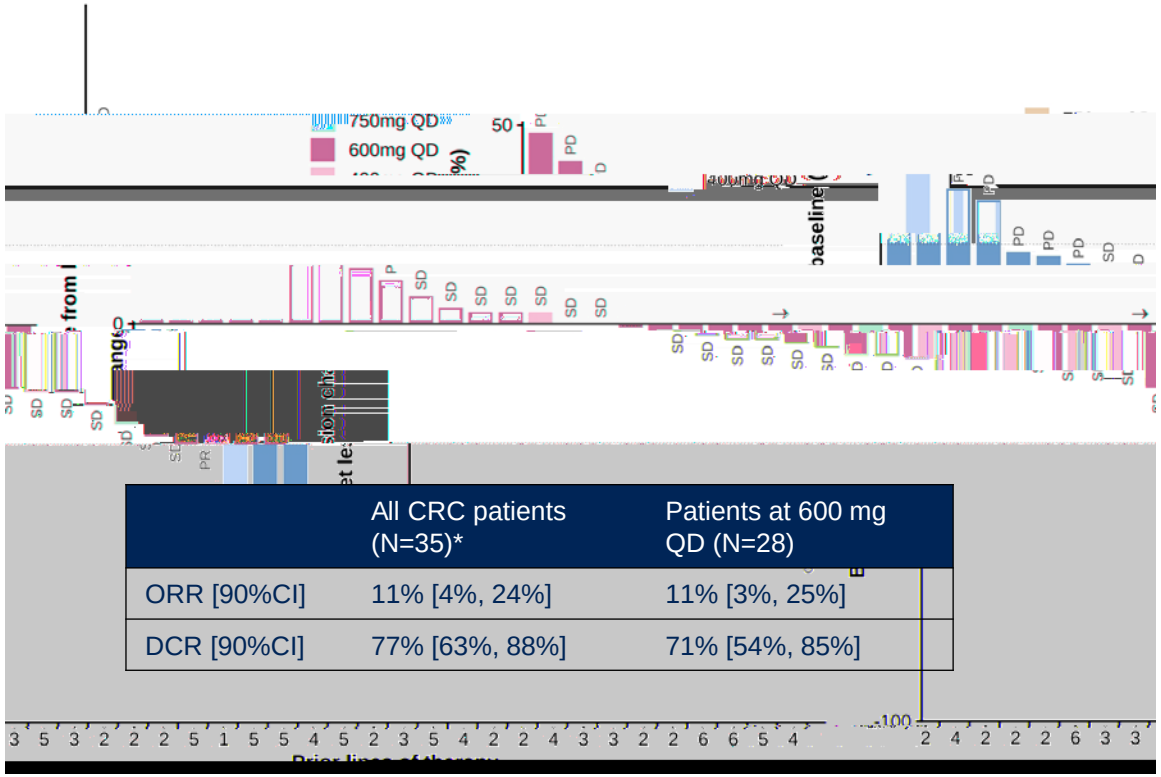
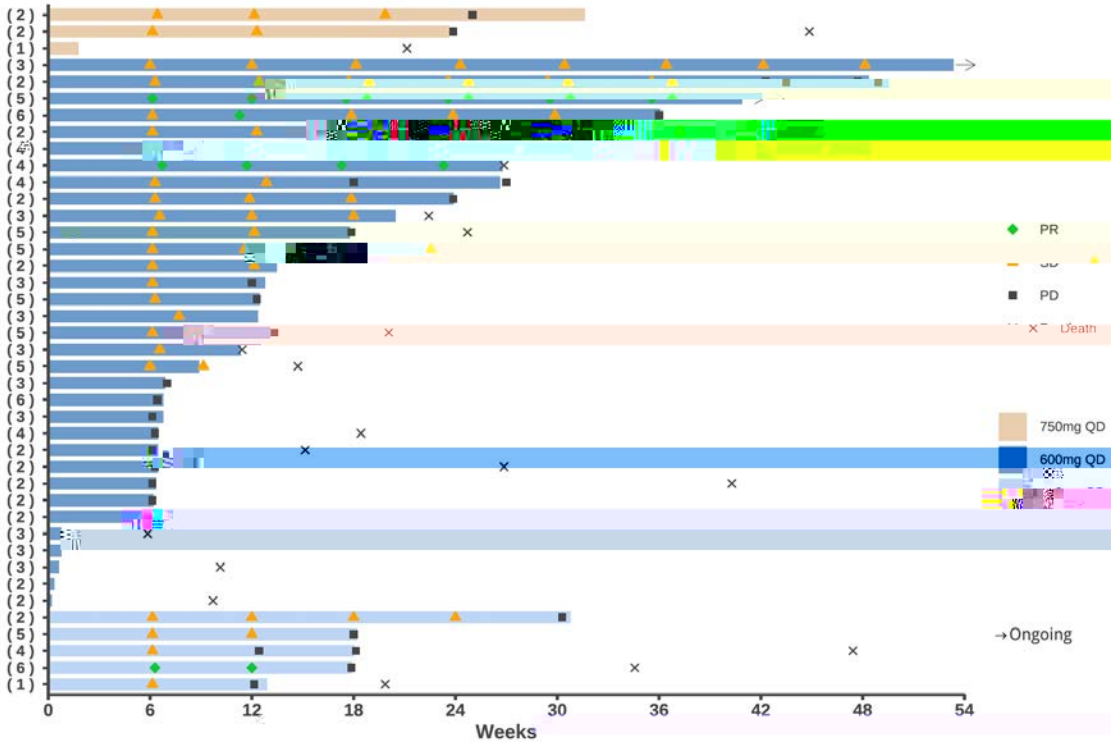
Efficacy in CRC

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-

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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.

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Adverse Events in •10% of Patients

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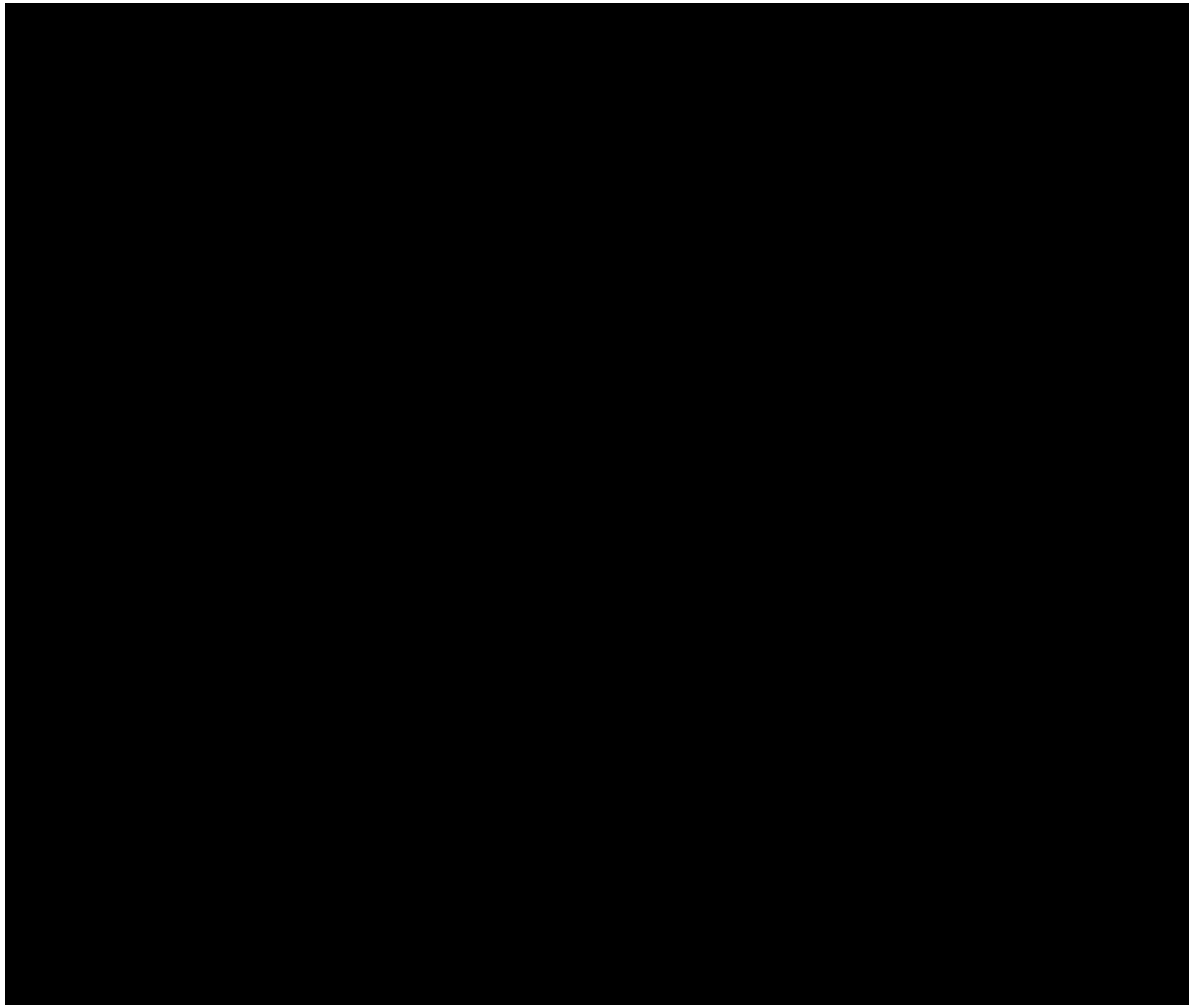
The safety profile in CCA and CRC was consistent with prior reports[1,2,3], without new safety signals observation.

Common TRAEs were gastrointestinal, hematological AEs and transaminitis; most were grade 1 or 2 and recovered with supportive treatment.



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.

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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

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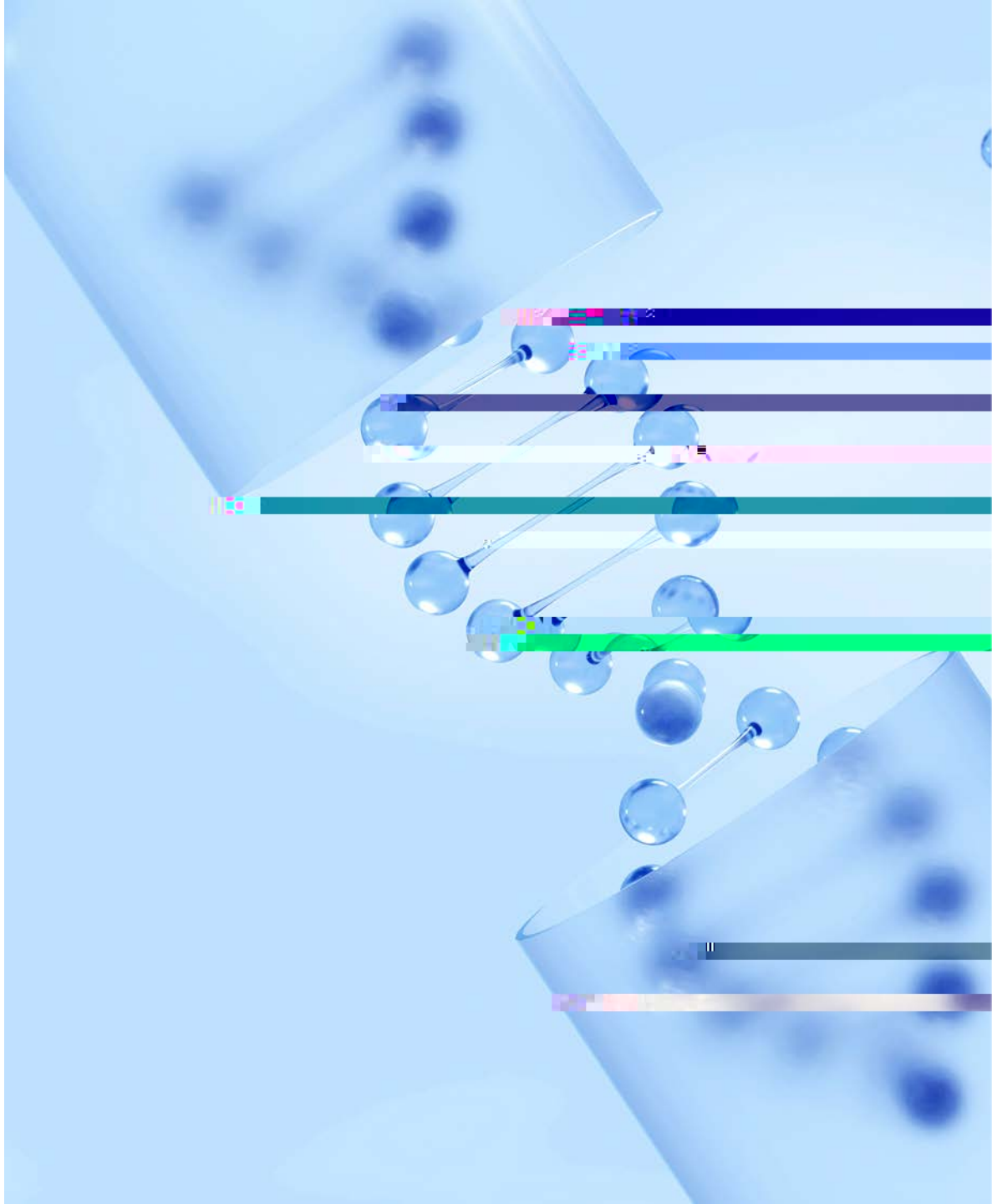


Study Plan for GFS202A h World's First Bispecific Antibody for Cachexia

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

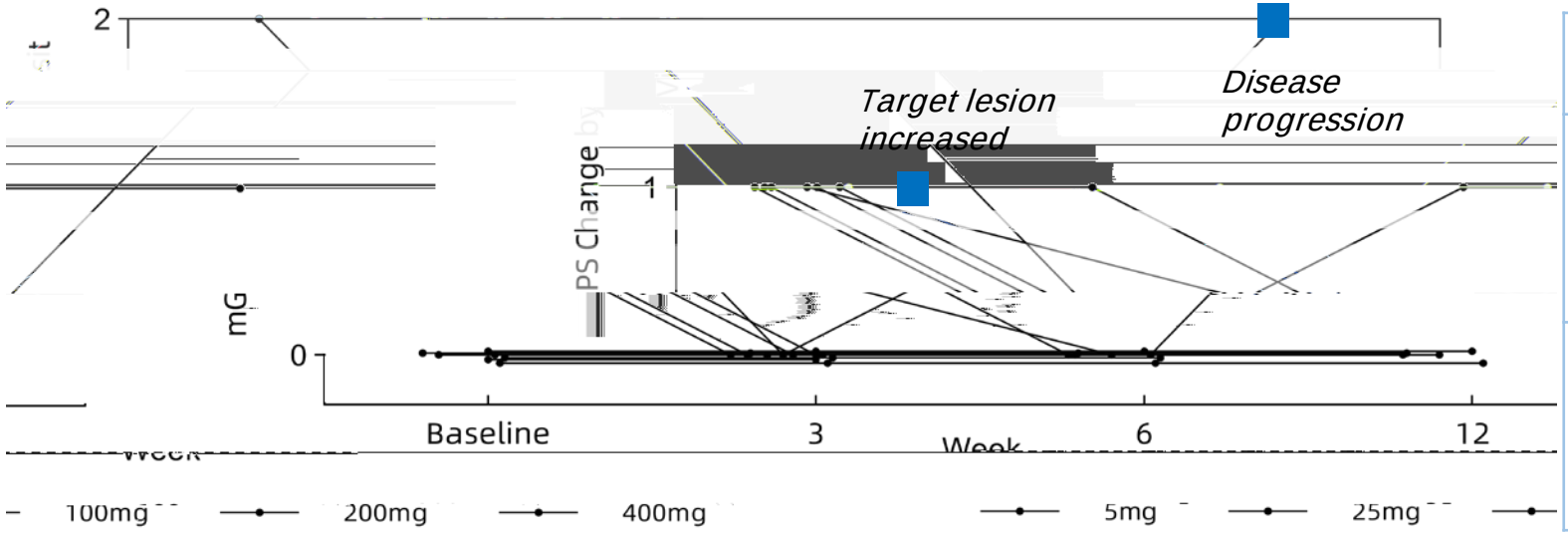
PK/PD: Dose-dependent Suppression of GDF15

PK exposure increased with escalating dose levels

with a 3.2-7.5 days $T_{1/2}$.

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

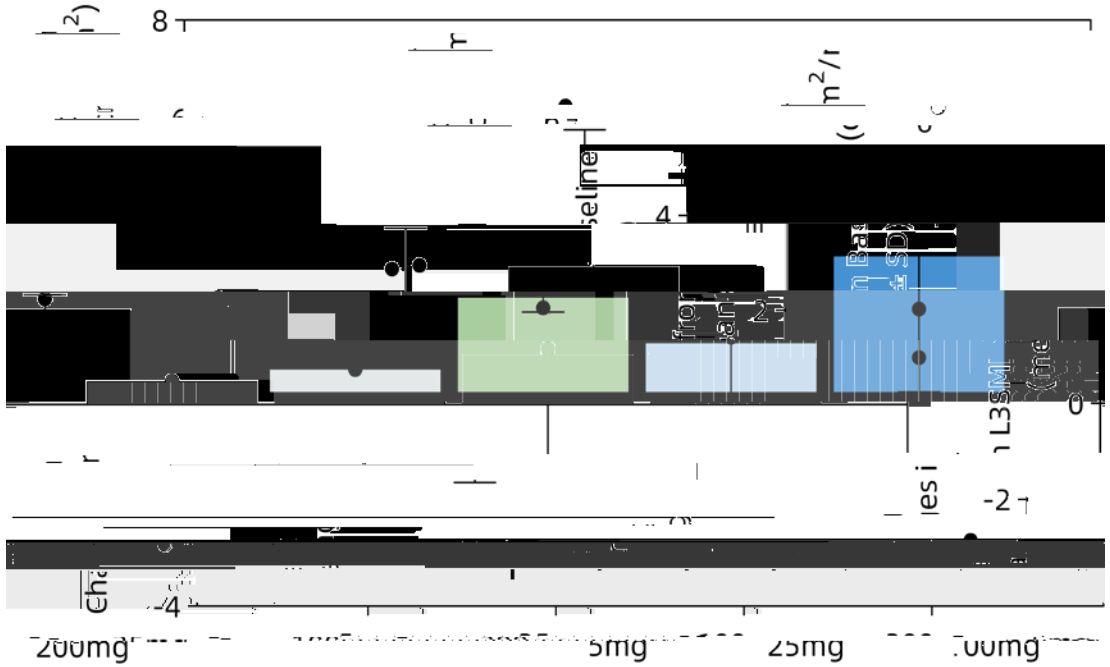
Crucial inflammation-based prognostic index that predicts survival and clinical outcome

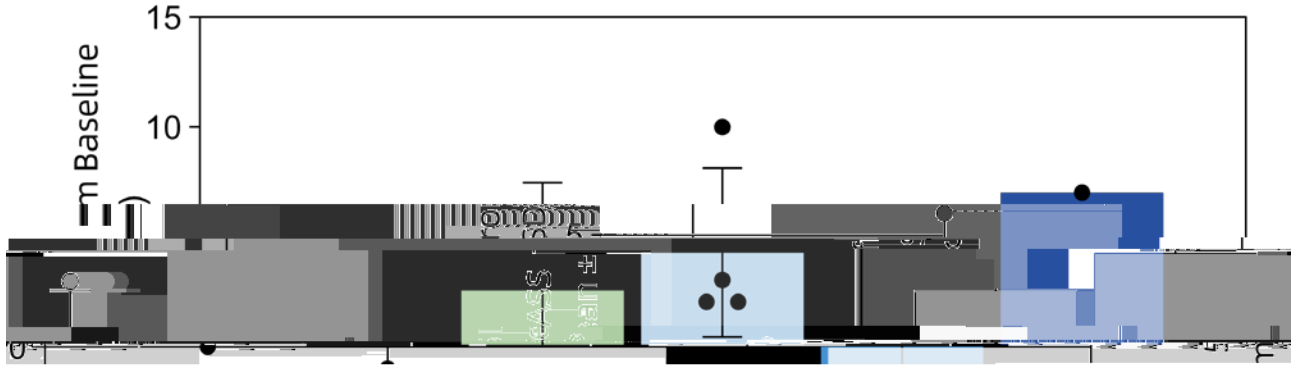


	Week 6	Week 12
Mean decrease of C-reactive protein	39.81 mg/L	49.42 mg/L
Mean increase of albumin	3.4 g/L	2.8 g/L

mGPS & 5 3 r P&JALB<35g/L
mGPS= 1 j & 5 3 r P J &/ $ / % r J, /
mGPS= 0: CRP<10mg/L & any ALB

Improvements in Skeletal Muscle Mass and Appetite





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.

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)

The G3 patient

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.

Summary and Outlook

Ongoing trials with expected progress

Mono in pancreatic cancer
Phase III registrational study

Combo with chemo in pancreatic cancer
Phase Ib/II, 1L

Combo with cetuximab in solid tumors
Phase Ib/II, 1L+

GFH375
KRAS G12D (ON/OFF) inhibitor

Recent CDE disclosure of new trials and IND applications

GFH375+GFS202A
Phase II combo IND application accepted

Innovation, in Expedition