2026 ASCO/æ ŒGFH375%< GFS202A ¦/ü6â4à[U]m Œ

2026/æ68z

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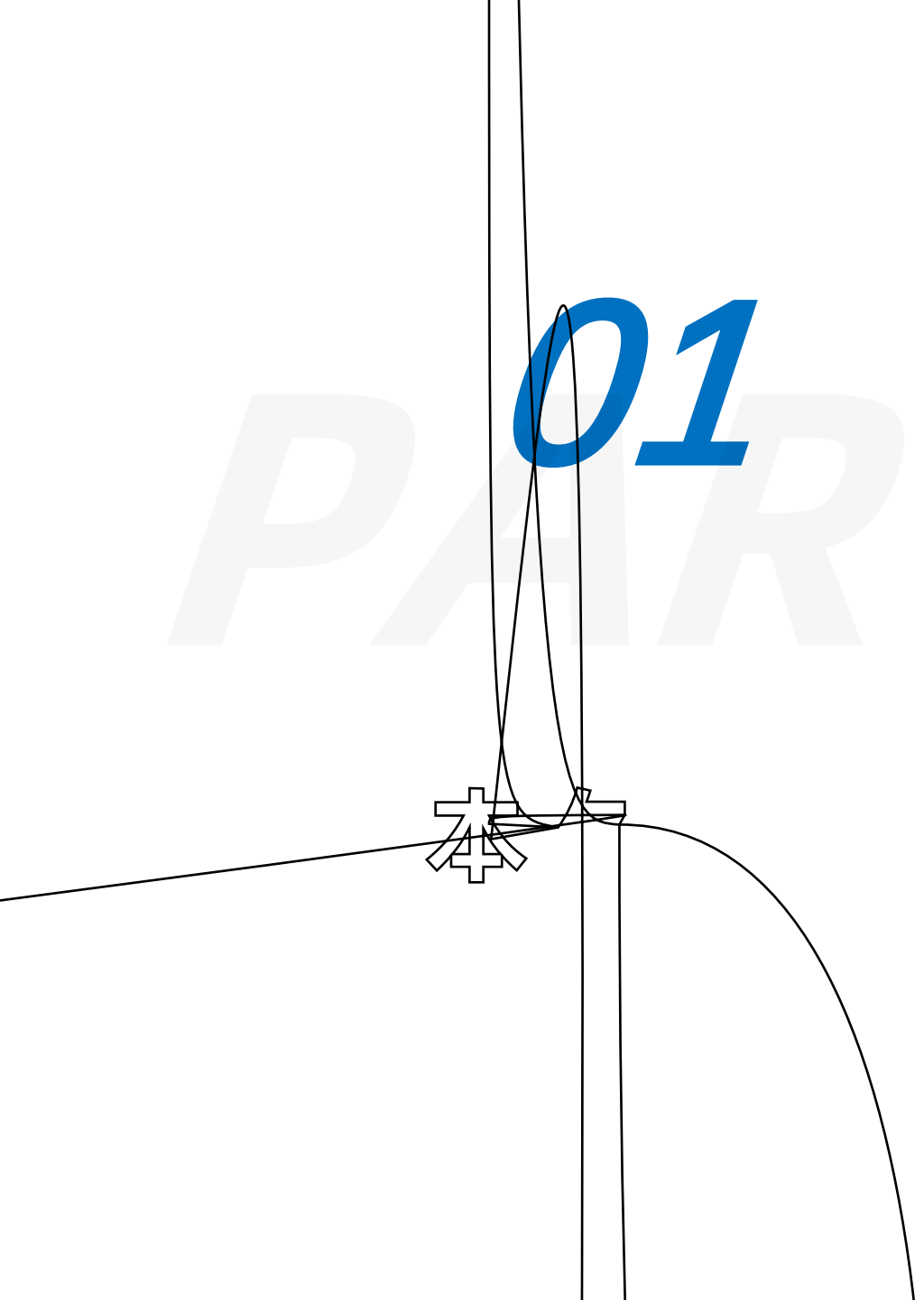
PART

01



GFH375 ¦/üI†Kè6â4àaPP_(M‹“"×a{(` ÅÒ UªcAr[À

GFH3753,Tá1™S\%-/æ,Ø8¡ Œ] 4 %¼%€aM r<×là]

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)	9 (6.3)
			0	

GFH375(šIà- 1™)II² |Gö8f*™&¸ ŒKìgf

- KRAS G12D is the most frequent KRAS mutation (29%) driving cancer development, accounting for 5.8 –10.8% in CCAand 10.6– 19.2% in CRC[1~4]
- –

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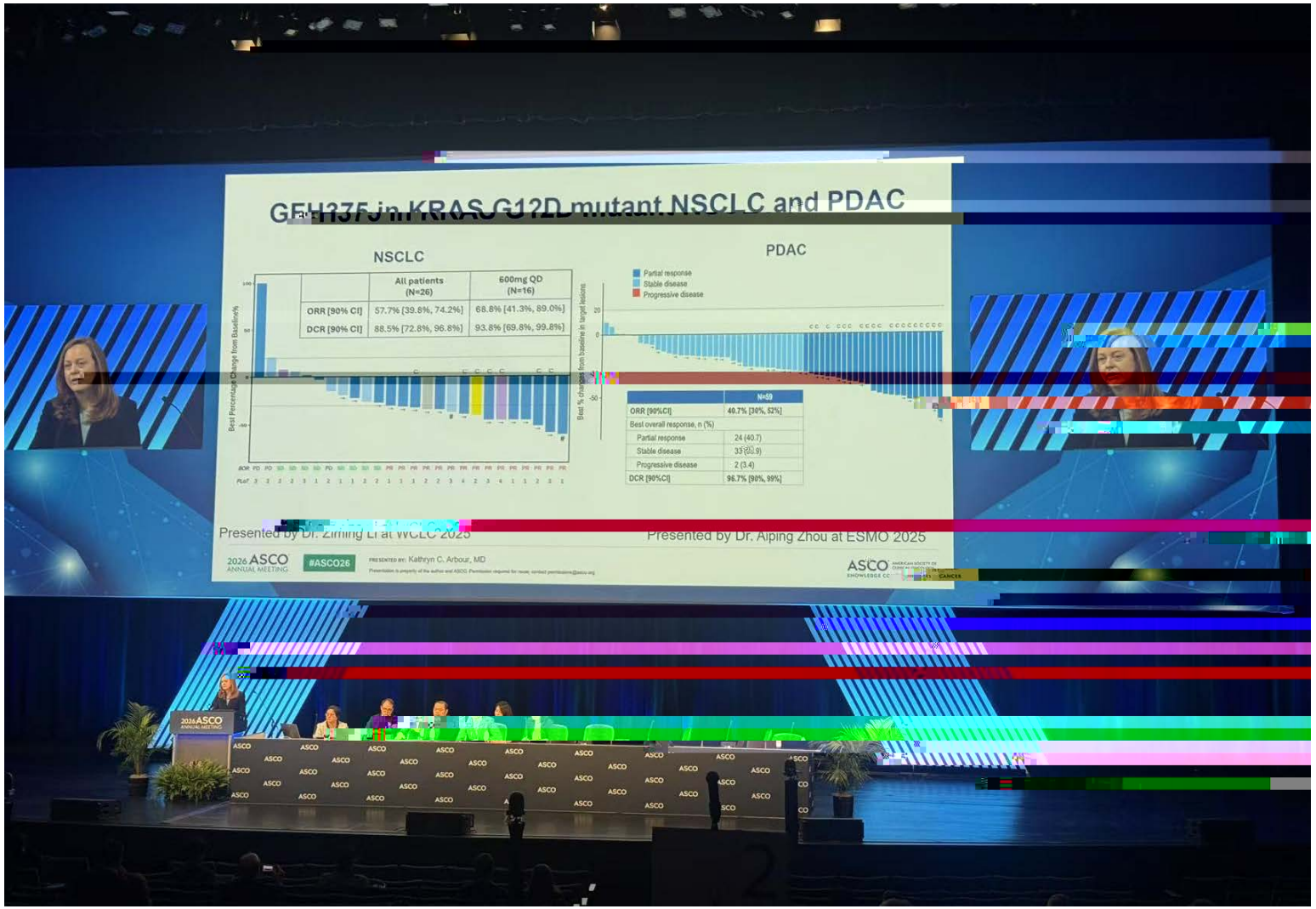

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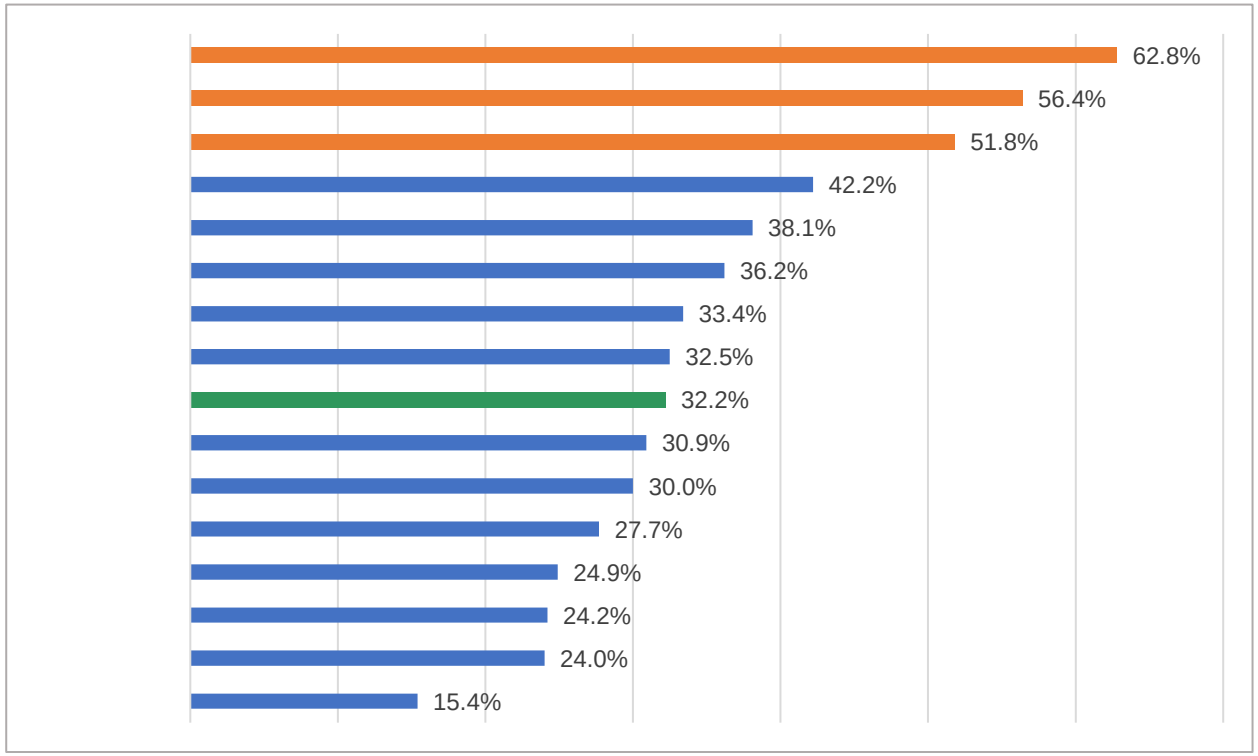
- 37.0%
- (62.8%) (56.4%) (51.8%)
- 32.2%



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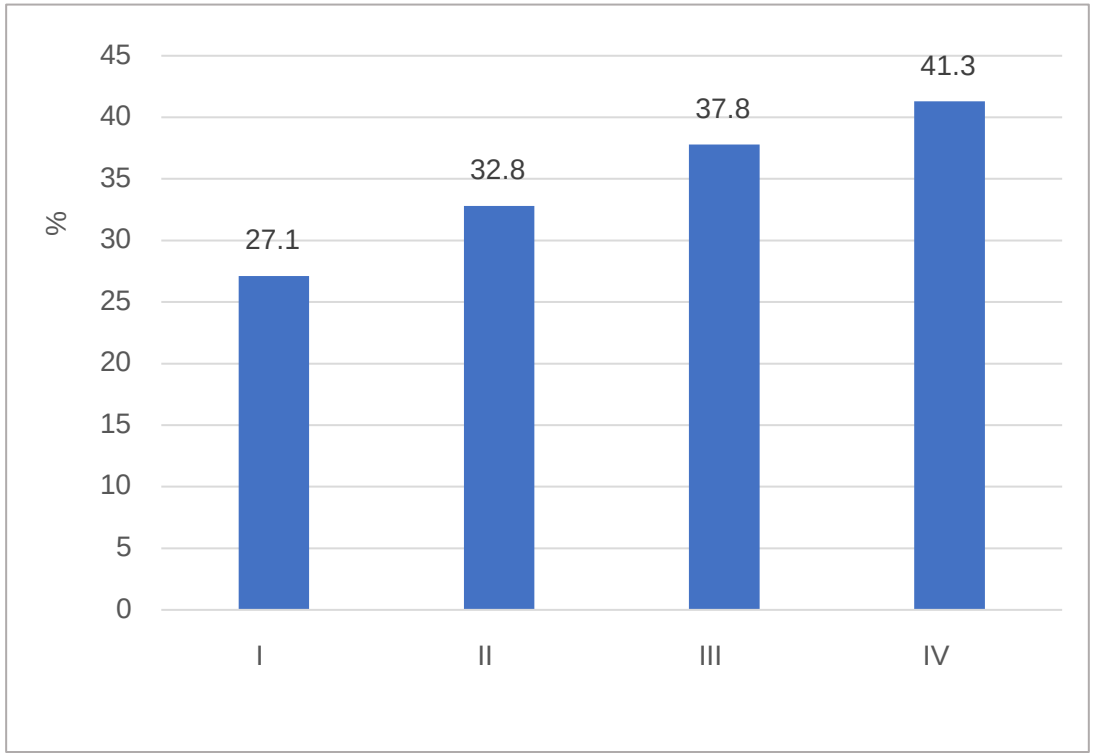

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1. Li, Xiangrui , et al.. Precision Nutrition 1(1):10.1097/PN9.0000000000000008, June 2022. 2. Han B, et al. 2024;4(1):47-53. 2024 Feb 2.

- 12

1èG7^š8‘R1G–2 Qw5 %Iponsegromab100mg [1] [1]

2026 AS

PART 02

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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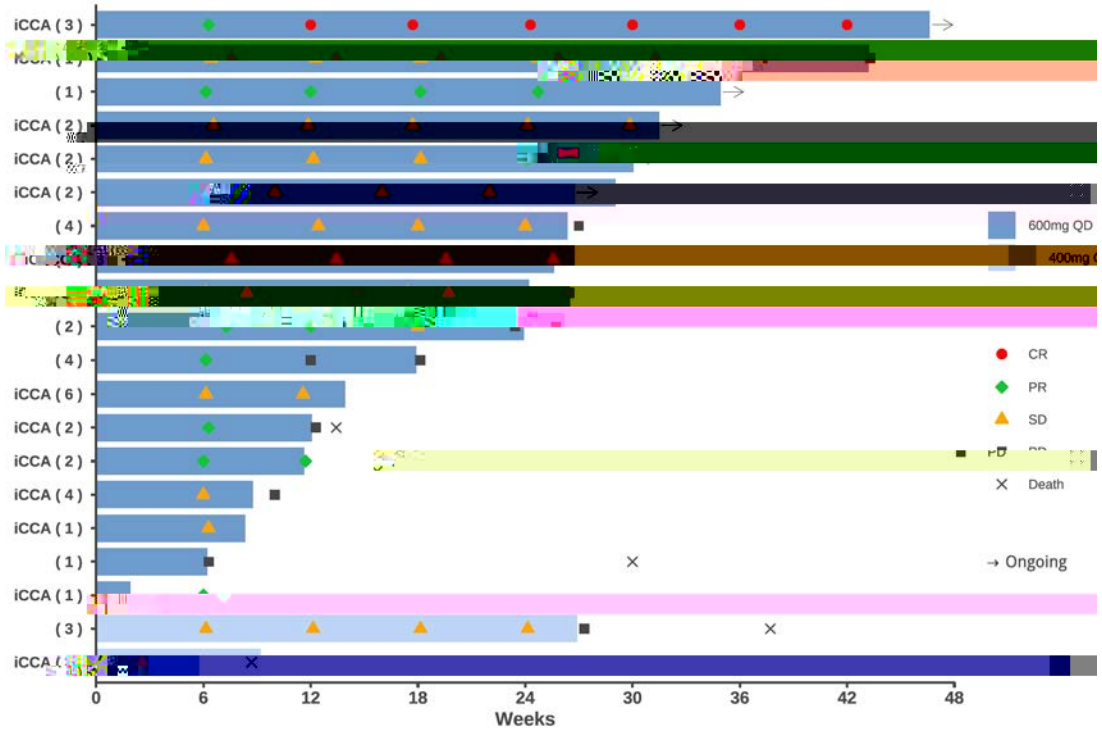
Efficacy in CCA

- 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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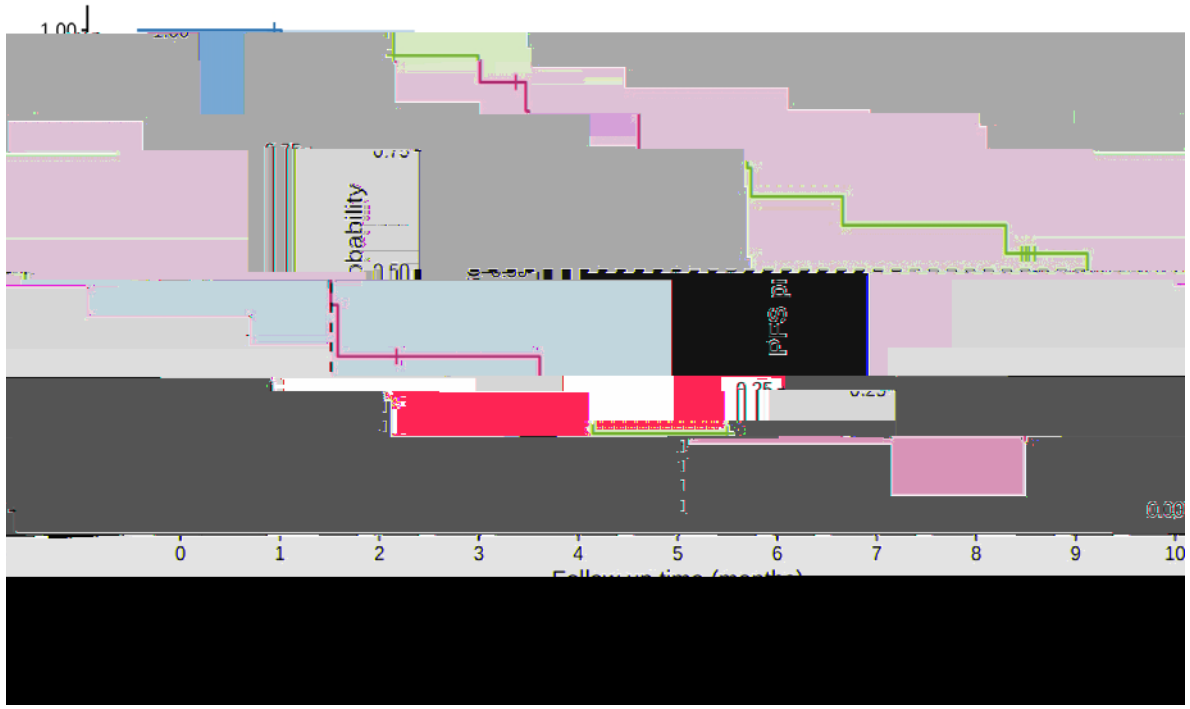
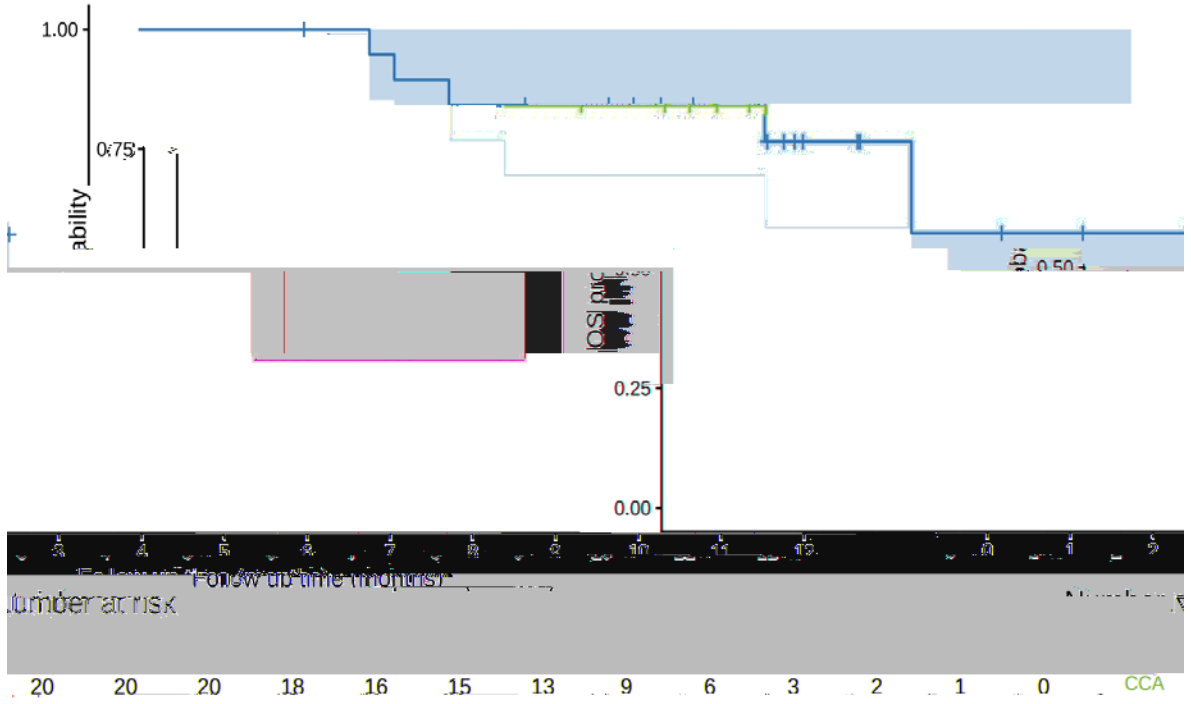
PFS and OS in CCA

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

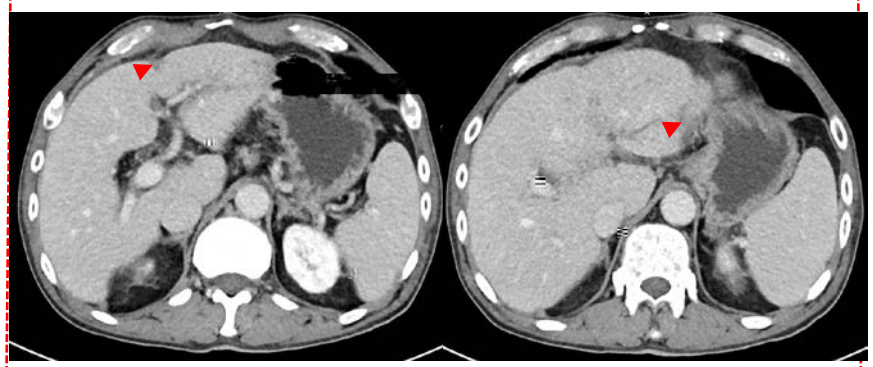
- 1st line: GEMOX, 6 cycles, 2024.10- 2025.1
- 2nd line: FOLFIRI, 3 cycles, 2025.2- 2025.3
- 3rd line: Lenvatinib + Cadonilimab, 2025.4- 2025.4
- Disease progressed 2025.5

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 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.

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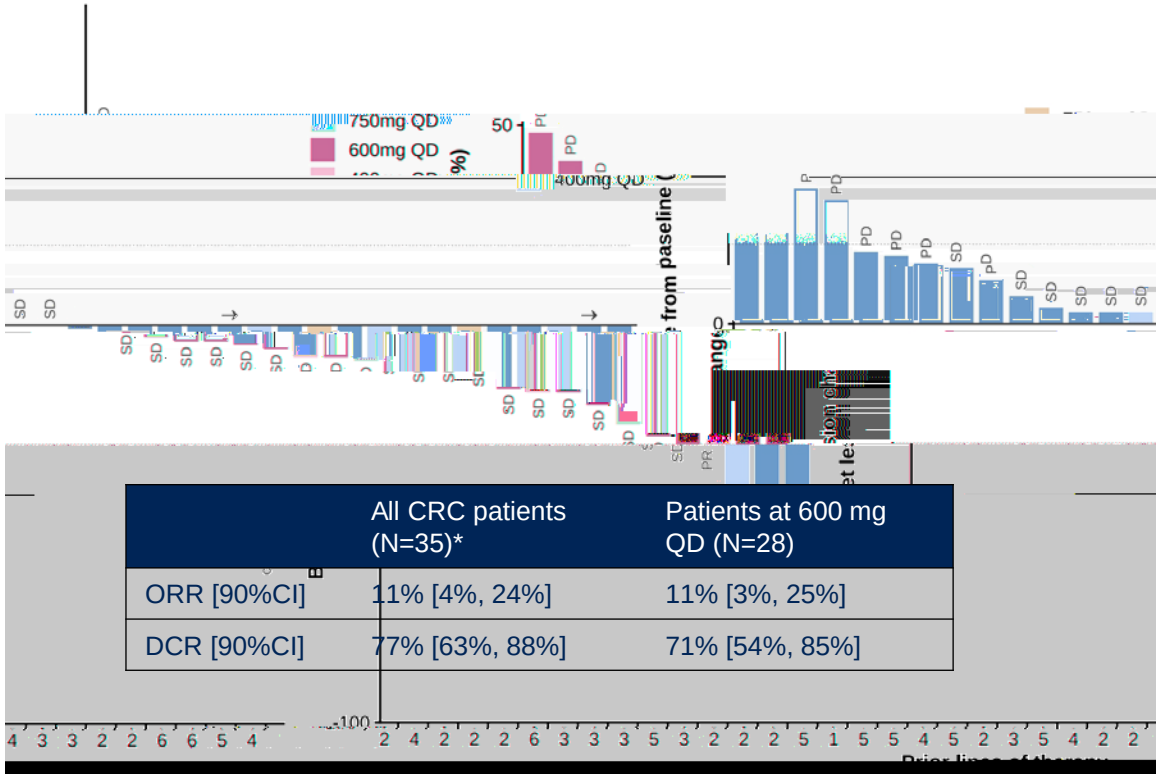
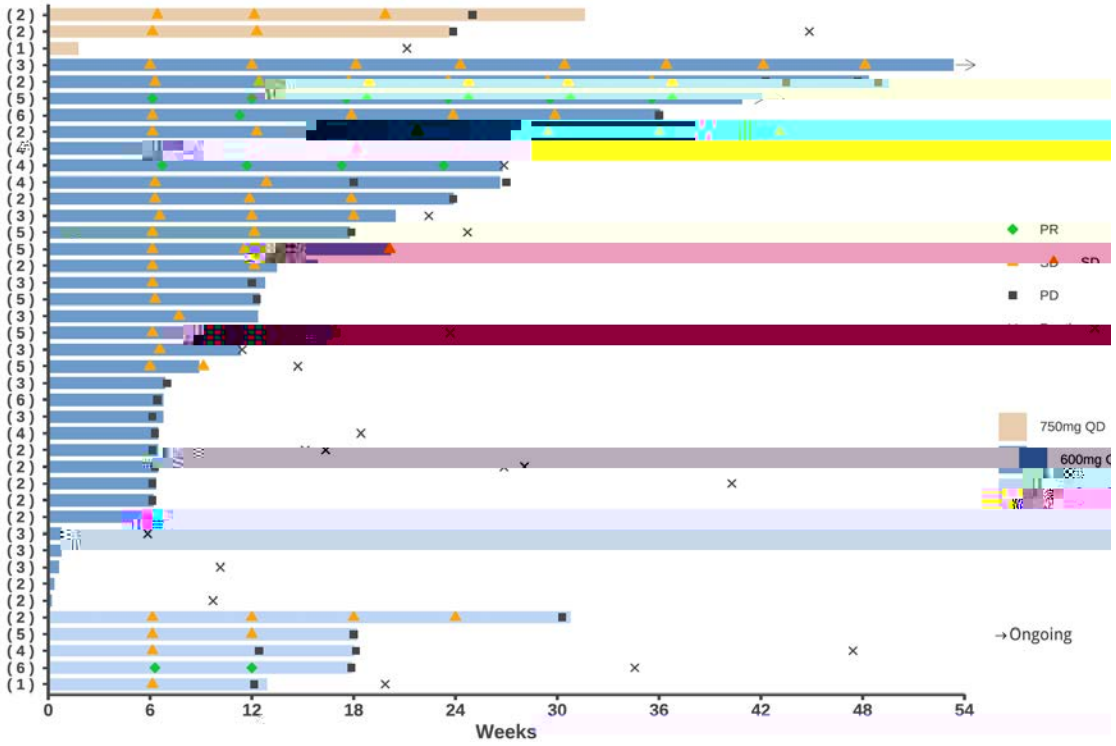
Efficacy in CRC

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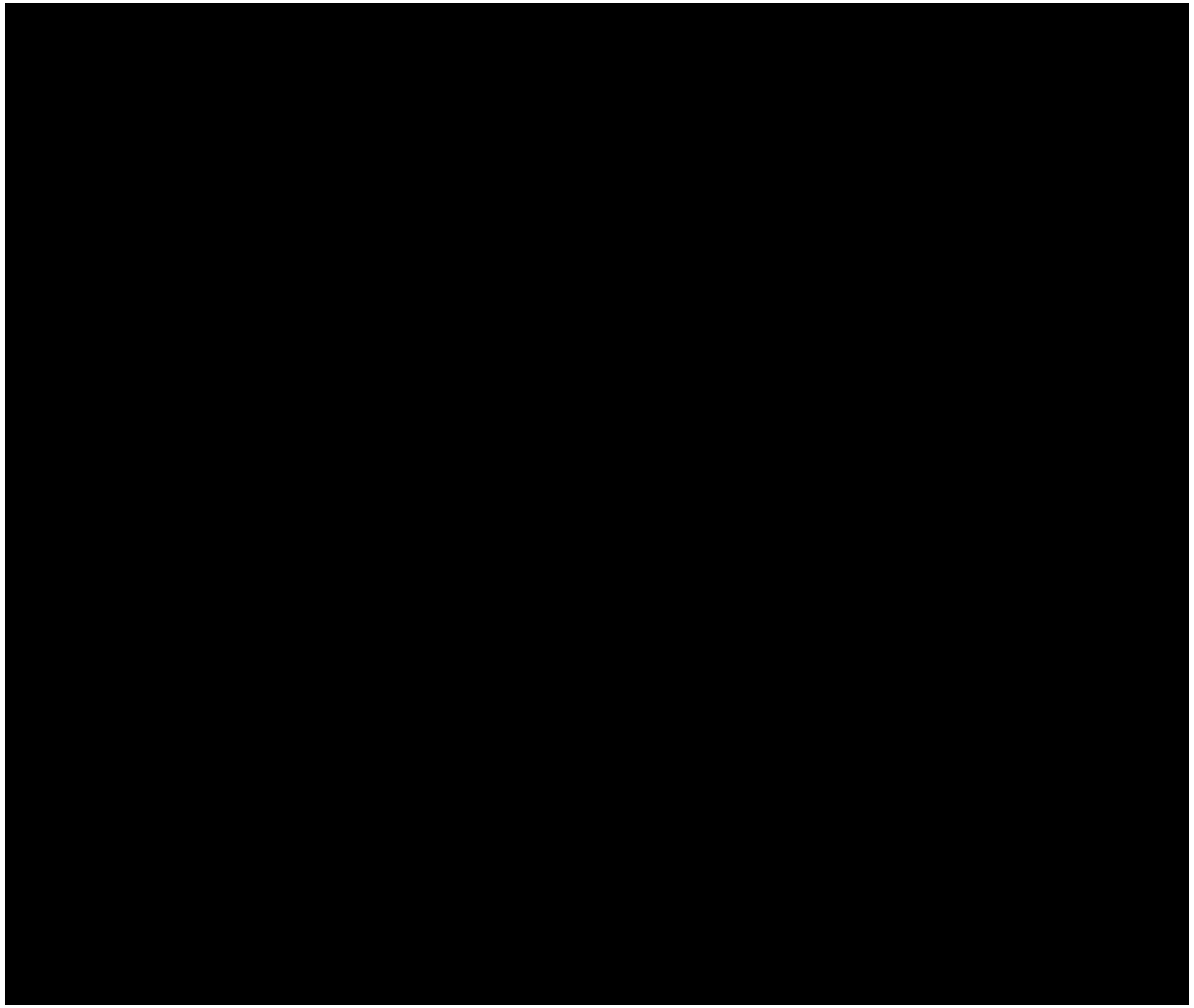
- The safety profile in CCA and CRC was consistent with prior reports[1,2,3], without new safety signals observation.
- Common TRAEs were gastrointestinal, hematological AEs and transaminitis; most were grade 1 or 2 and recovered with supportive treatment.



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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PART 03

研究结果重点及解读
——GFS202A

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

Primary Endpoints

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

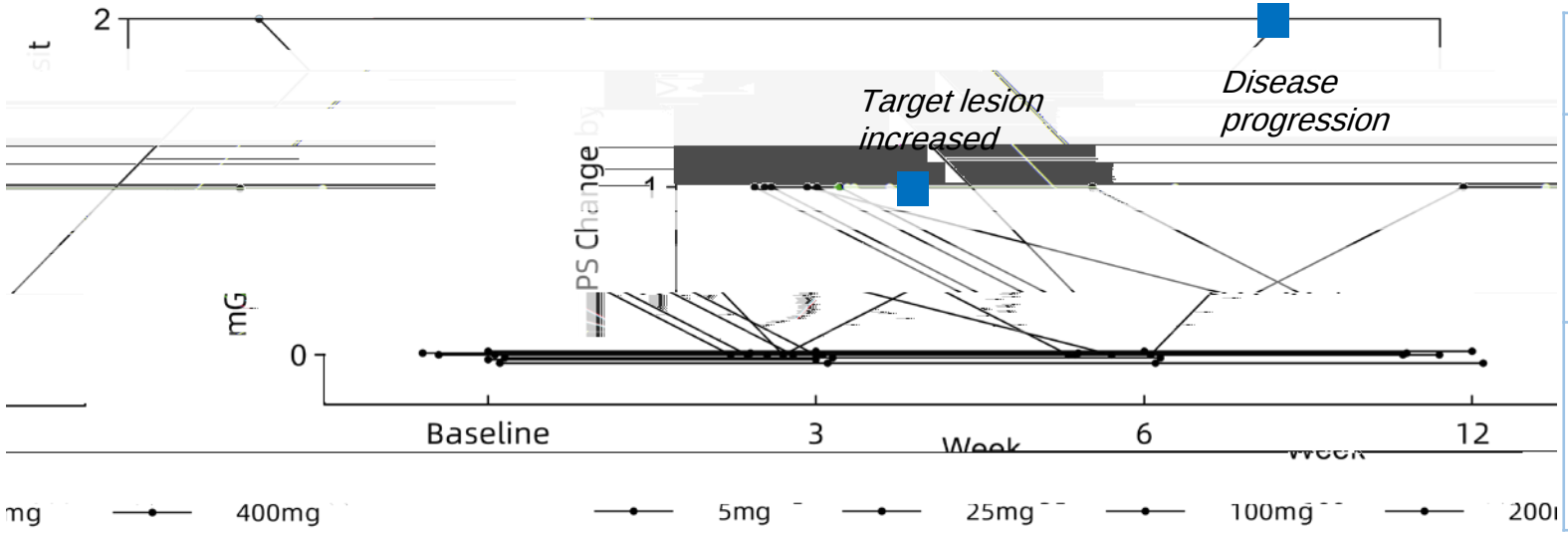
Secondary Endpoints

- Pharmacokinetics
- GDF15 and CRP

Pre-cachexia and Cachexia Patients: Baseline Characteristics and Demographics

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

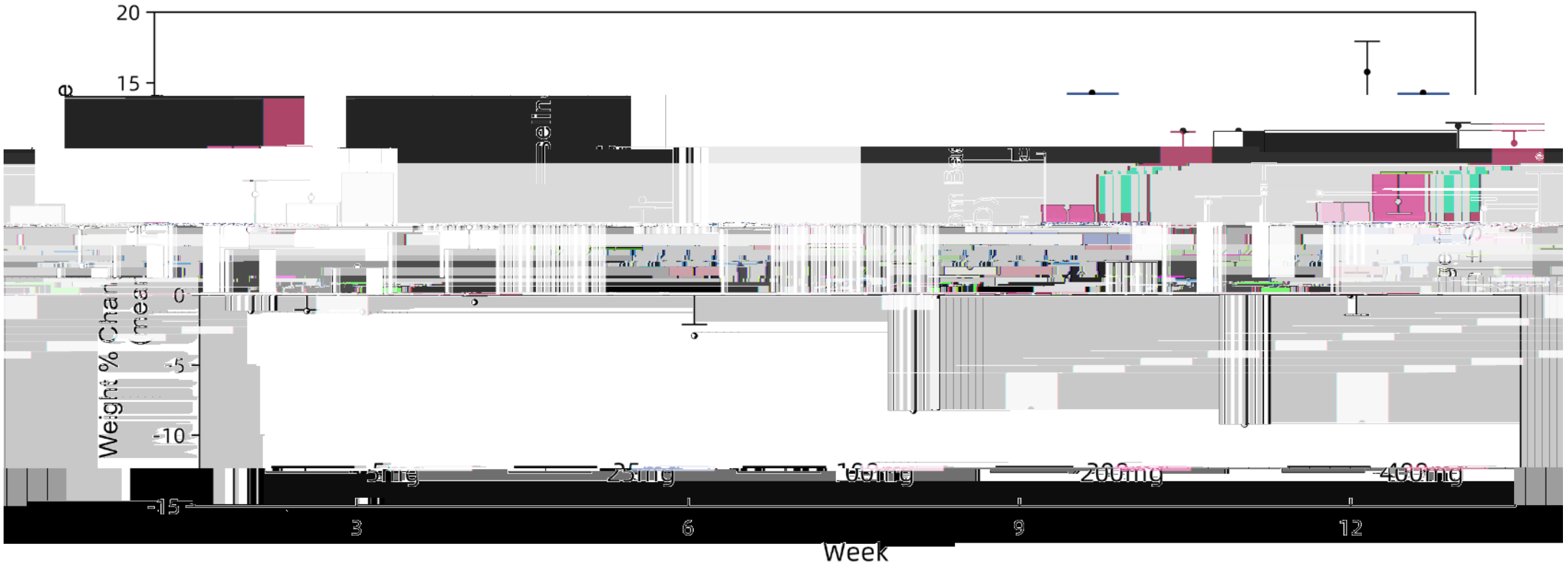
Crucial inflammation- based prognostic index that predicts survival and clinical outcome



	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

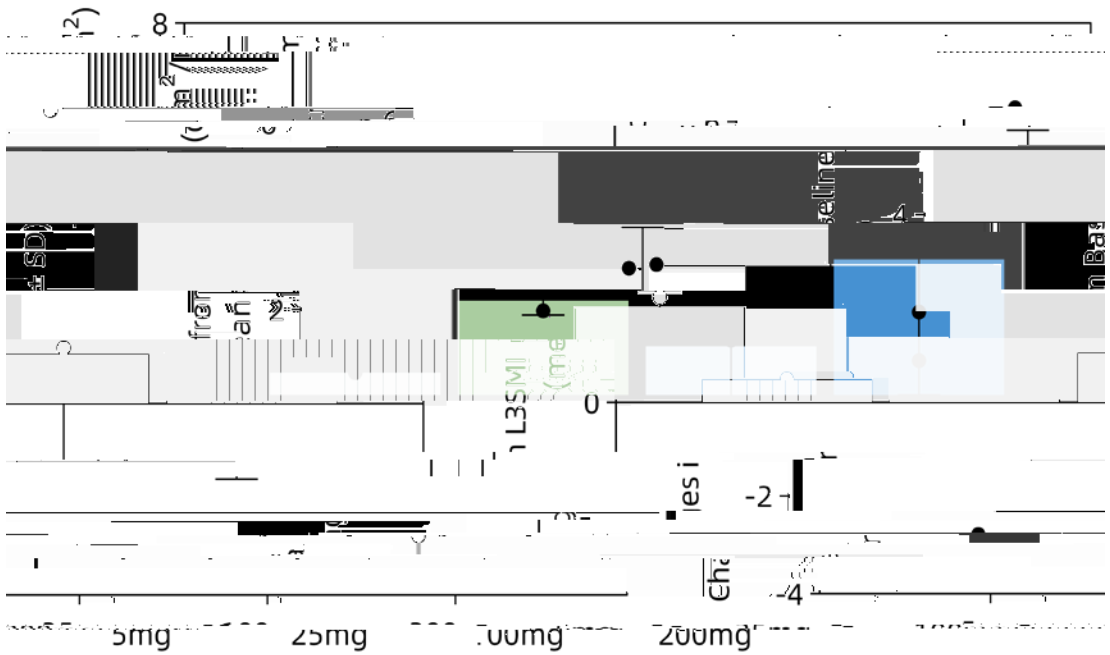
- mGPS= 2: CRP≥10mg/L & ALB<35g/L
- mGPS= 1 CRP≥10mg/L & ALB≥35g/L,
- mGPS= 0: CRP<10mg/L & any ALB

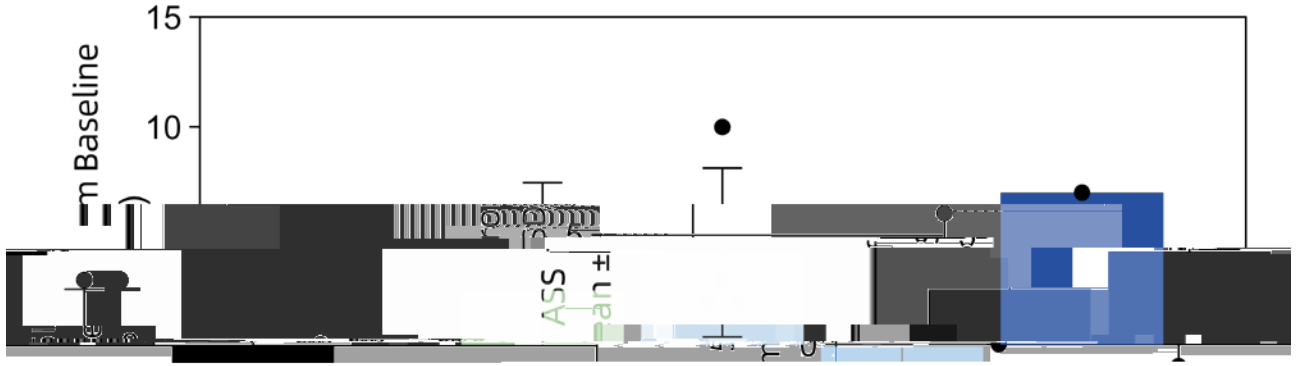
Dose-dependent Increase Observed in Body Weight



- *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 .*

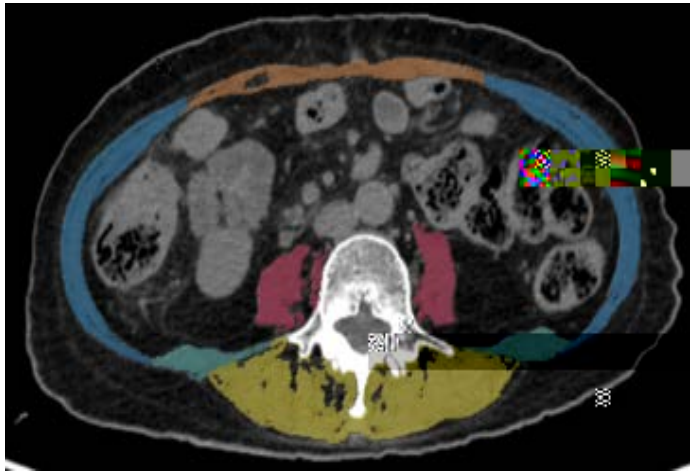
Improvements in Skeletal Muscle Mass and Appetite

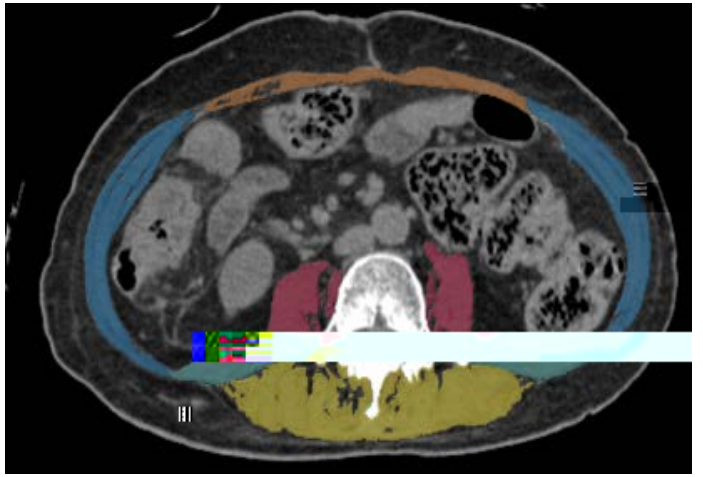




- *Data points indicate values of individual patients ; bars indicate mean values .*
- *L3SMI was calculated centrally using Independent Review Committee (IRC). FAACT-5 IASS was collected using paper form . Abbreviations : TL, target lesion.*

Case Study (GFS202A 100mg Q3W)





Favorable Overall Safety and Tolerability

- GFS202A showed a favorable safety profile and promising efficacy, and compared to

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III

QÆ%z$ˆG >-G RbRìG¾
Ib/II