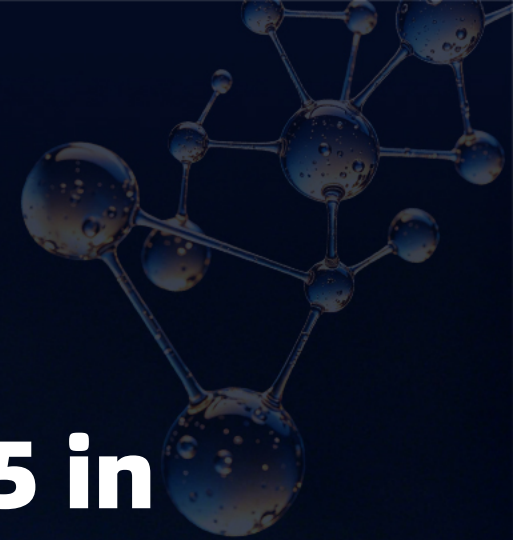




# **Preliminary Data Review of GFH375 in Combination with Cetuximab in Solid Tumors**

**Oct. 2026**



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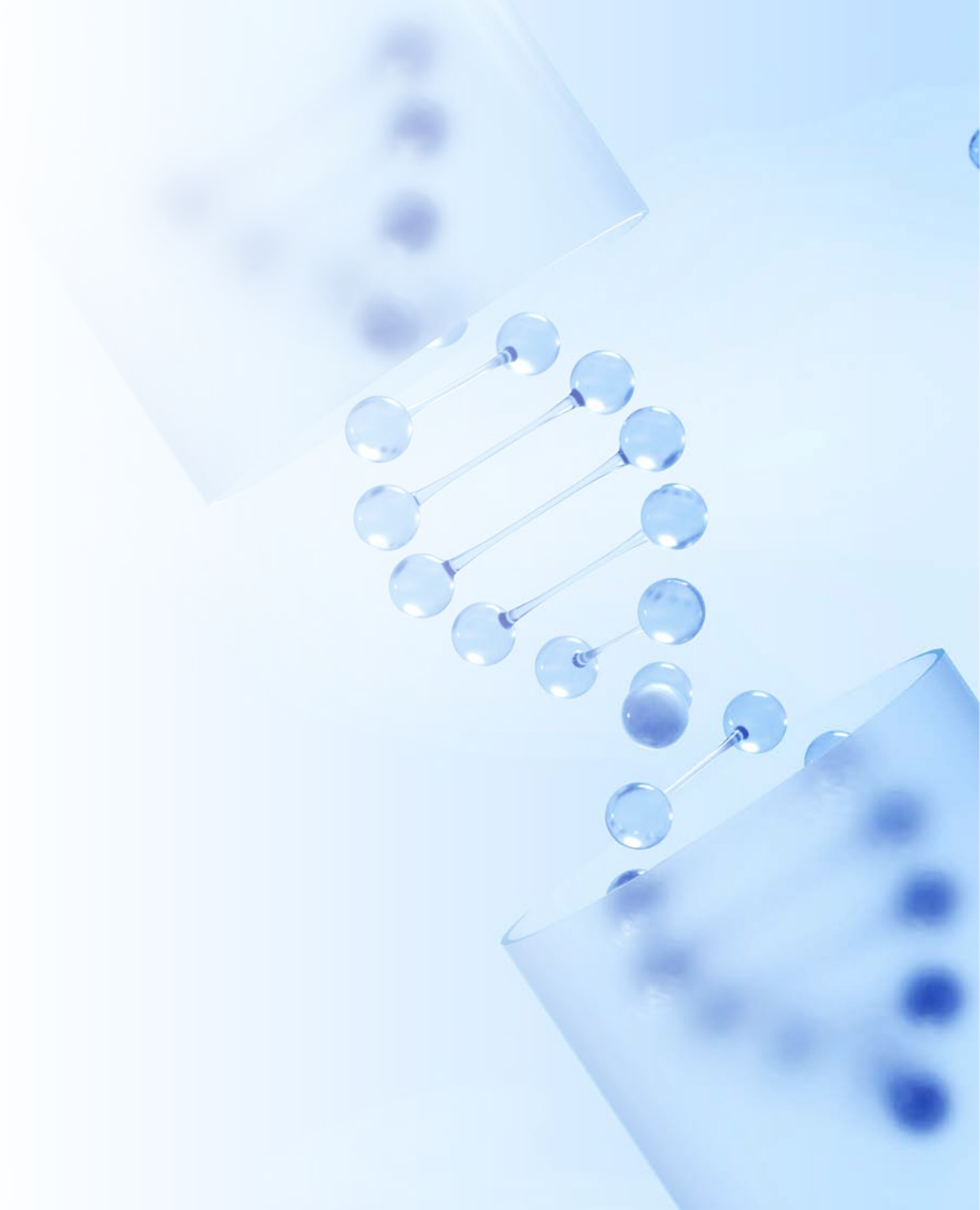
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# *PART* **01**

**Study background of  
GFH375 across tumor types**



# GFH375 Leads KRAS G12D Inhibitor Development in Global Landscape with Most Complete Mono & Combo Data

## GenFleet's study momentum in China: druggability, execution and results

2024

**2024.7 FPI**

First patient dosed in  
China's study

Start Point of  
Clinical Development

**D+11Months**

2025

**2025.6 ASCO Oral**

66 pts' data in solid-tumor trial

**2025.9 WCLC Oral**

142 pts data in solid-tumor trial

**2025.10 ESMO Oral &  
combo initiation**

PhII PDAC data granted ESMO LBA

Study initiation of combo with  
chemo or cetux

**2025.11 PDAC phase III initiation**  
**World's first phIII trial of an oral  
KRAS G12Di (D+16M)**

2026

**2026.2 NSCLC BTD**

**First in China to have received BTD for  
oral KRAS G12Di**

**2026.4 PDAC BTD**

**Oral KRAS G12Di for pancreatic cancer**

**2026.6 ASCO Oral**

World's first dedicated data of RASi for CCA

**2026.7 NSCLC PhIII initiation**

**GFH375's 2<sup>nd</sup> PhIII study (D+24M)**

**2026.8 Multiple novel combos initiation**

1L NSCLC, RAS doublet, RAS+cachexia

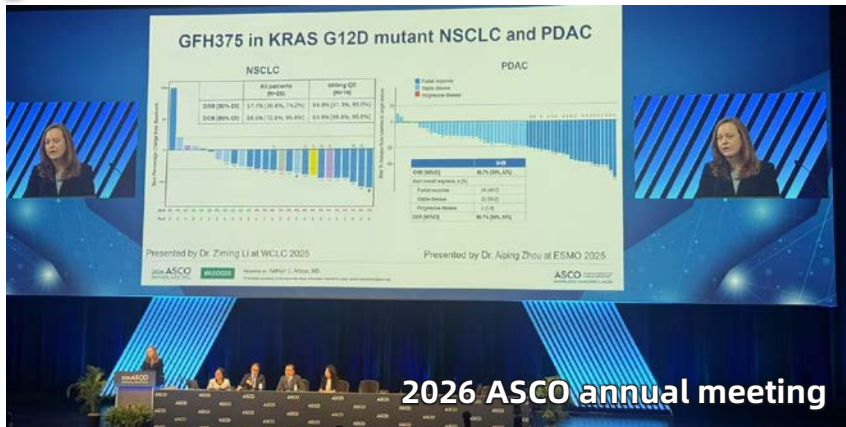
**2026.9 WCLC Oral & CRC BTD**

Phase II NSCLC data selected for WCLC oral

**CRC BTD: in combination with cetux**



# Robust Druggability Supported by Consistent Efficacy and Safety Profile



## GFH375's promising efficacy across multiple malignancies earns commentator recognition at 2026 ASCO

*We see a truly impressive response rate in CCA, a refractory disease. And I will mention that we saw data earlier for this agent in NSCLC and pancreatic cancer, with response rates presented at the same dose 600 mg QD as clearly an active agent.*

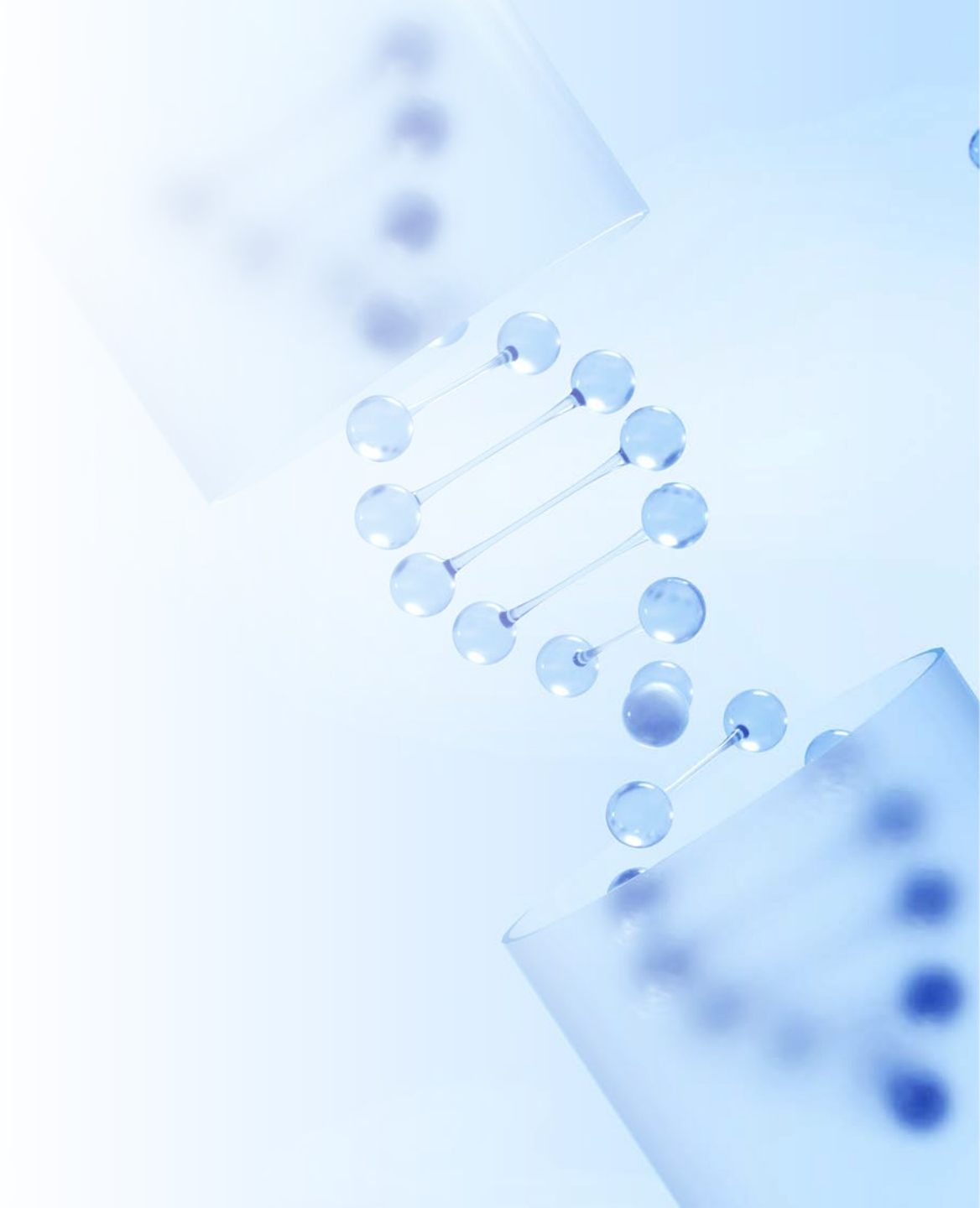
*It is not surprising the response rate is lower in CRC. I really credit the authors for even presenting the data here. We have to understand what the baseline is and to know how much benefit we're really adding to these combos, which will likely be required.*

*By commentator Kathryn Arbor, M.D., Memorial Sloan Kettering Cancer Center*

|          |                 | NSCLC                    | CRC                      |                                      | PDAC                     |                                  | Other tumor type             |
|----------|-----------------|--------------------------|--------------------------|--------------------------------------|--------------------------|----------------------------------|------------------------------|
|          |                 | mono<br>(pretreated pts) | mono<br>(pretreated pts) | combo with cetux<br>(pretreated pts) | mono<br>(pretreated pts) | combo with cetux<br>(1L setting) | CCA mono<br>(pretreated pts) |
| Efficacy | 600 mg QD       | N=71                     | N=28                     | N=54                                 | N=59                     | N=24                             | N=18                         |
|          | ORR             | 59.2% (cORR 52.1%)       | 11%                      | 44%                                  | 40.7%                    | 71%                              | 44.4%                        |
|          | DCR             | 93.0%                    | 71%                      | 89%                                  | 96.7%                    | 100%                             | 94.4%                        |
|          | Data cutoff     | Sept. 4, 2026            | Apr, 20, 2026            | Sept. 16, 2026                       | Sept. 27, 2025           | Sept. 16, 2026                   | Apr, 20, 2026                |
| Safety   |                 | 600 mg QD(N=75)          | 400-750 mg QD(N=41)      | 600 mg QD(N=54)                      | 600mg QD(N=66)           | 600 mg QD(N=24)                  | 400-600 mg QD(N=20)          |
|          | TRAEs ≥G3       | 41.3%                    | 26.8%                    | 26%                                  | 31.8%                    | 21%                              | 40%                          |
|          | Discontinuation | 4%                       | 4.9%                     | 0                                    | 3%                       | 0                                | 0                            |
|          | Interruption    | 37.3%                    | 24.4%                    | 22%                                  | 27.3%                    | 17%                              | 40%                          |
|          | SAEs            | 21.3%                    | 9.8%                     | 7%                                   | 13.6%                    | 8%                               | 5%                           |
|          | Data cutoff     | Jun. 17, 2026            | Dec. 12, 2025            | Jul.22, 2026                         | Aug. 27, 2025            | Jul.22, 2026                     | Dec. 12, 2025                |

# *PART* **02**

**Preliminary data review of  
GFH375 in combination with  
cetuximab**



# GFH375 in combination with Cetuximab: Demographics and Baseline Characteristics

## CRC

- All patients had metastatic disease at baseline.
- 94% (51/54) of patients were treated in 3L+ setting; 50% (27/54) previously received 3 or more lines of anti-cancer therapy.

## PDAC

- 96% (23/24) of patients had metastatic disease at baseline.
- All patients were treatment-naïve.

|                                                                          | CRC (N=54)         | PDAC (N=24)        |
|--------------------------------------------------------------------------|--------------------|--------------------|
| <b>Median age, years (range)</b>                                         | <b>58 (33, 82)</b> | <b>68 (47, 78)</b> |
| <b>Male, n(%)</b>                                                        | <b>25 (46)</b>     | <b>14 (58)</b>     |
| <b>ECOG PS, n(%)</b>                                                     |                    |                    |
| 0                                                                        | 11 (20)            | 3 (12)             |
| 1                                                                        | 43 (80)            | 21 (88)            |
| <b>Metastasis at baseline, n(%)</b>                                      | <b>54 (100)</b>    | <b>23 (96)</b>     |
| Lung                                                                     | 31 (57)            | 3 (14)             |
| Liver                                                                    | 27 (50)            | 14 (58)            |
| Peritoneum                                                               | 25 (46)            | 7 (29)             |
| Bone                                                                     | 5 (9)              | 2 (8)              |
| <b>Number of prior anti-cancer therapies in metastatic setting, n(%)</b> |                    |                    |
| <b>Median (range)</b>                                                    | <b>2.5 (1, 6+)</b> | <b>0</b>           |
| 0                                                                        | 0                  | 24 (100)           |
| 1                                                                        | 3 (6)              | 0                  |
| 2                                                                        | 24 (44)            | 0                  |
| ≥ 3                                                                      | 27 (50)            | 0                  |

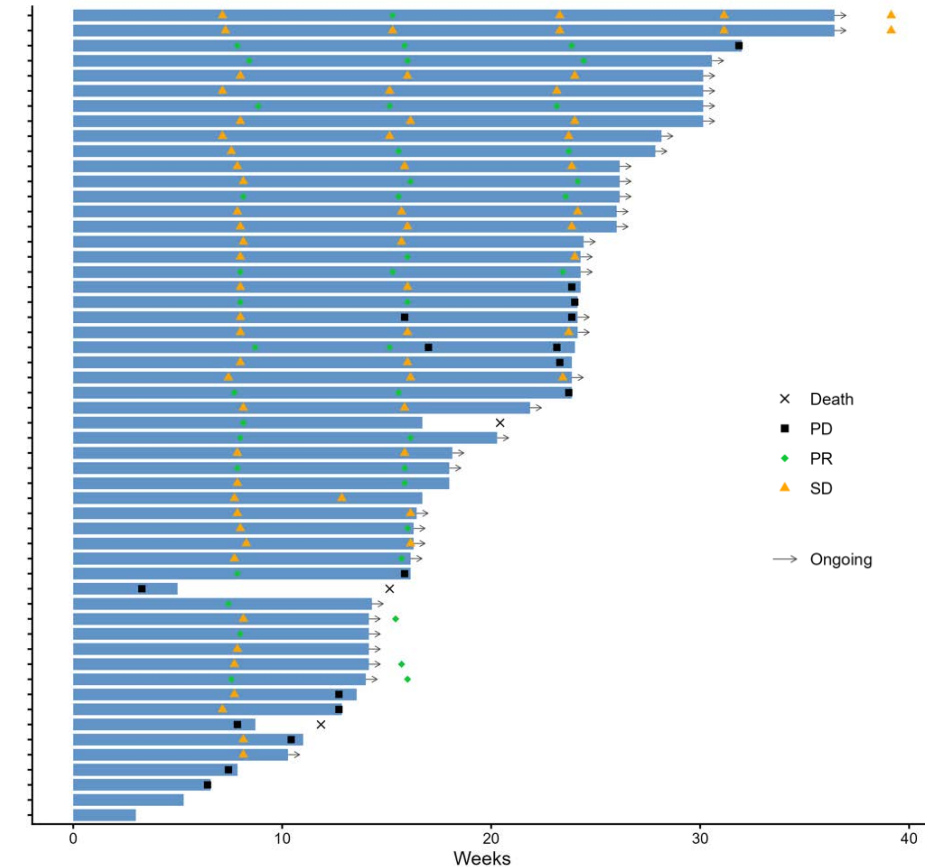
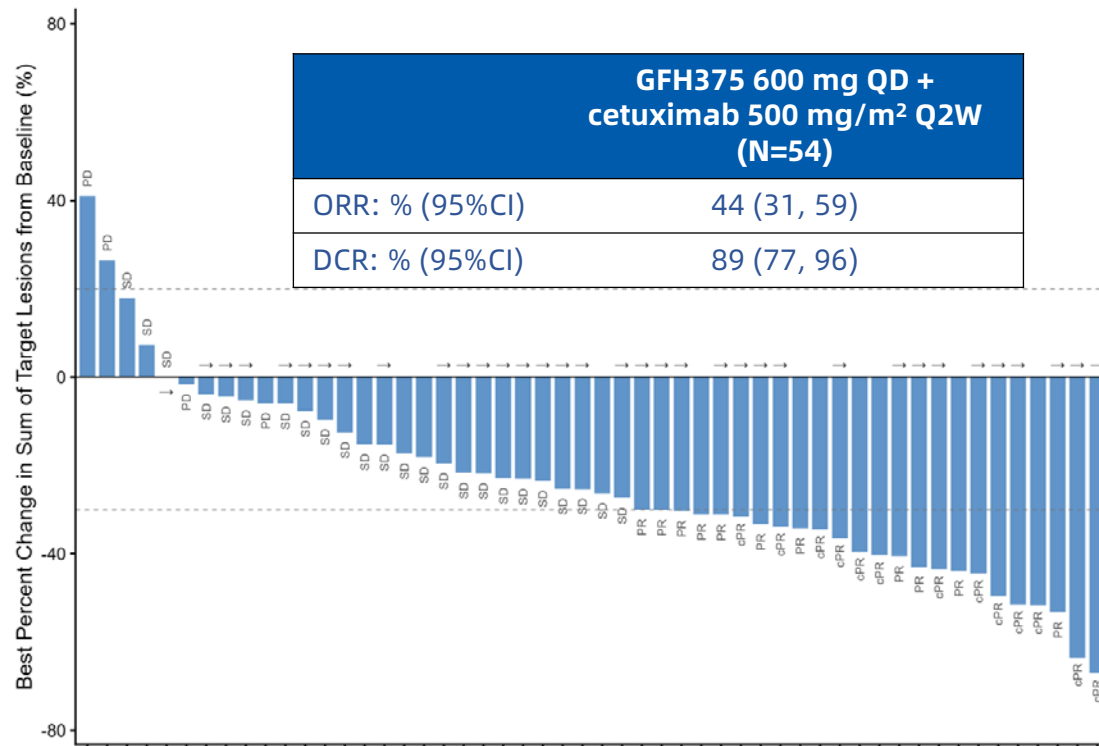
Enrollment cut-off date: 24-Jun-2026.

CRC, colorectal cancer; PDAC, pancreatic ductal adenocarcinoma; ECOG PS, Eastern Cooperative Oncology Group Performance Status.

# Efficacy in Pretreated KRAS G12D-mutant mCRC

- Median follow-up: 5.7 months (range: 2.8, 9.2).
- ORR: 44% (24/54), 11 uPR (8 patients remaining on treatment, 3 EOT).

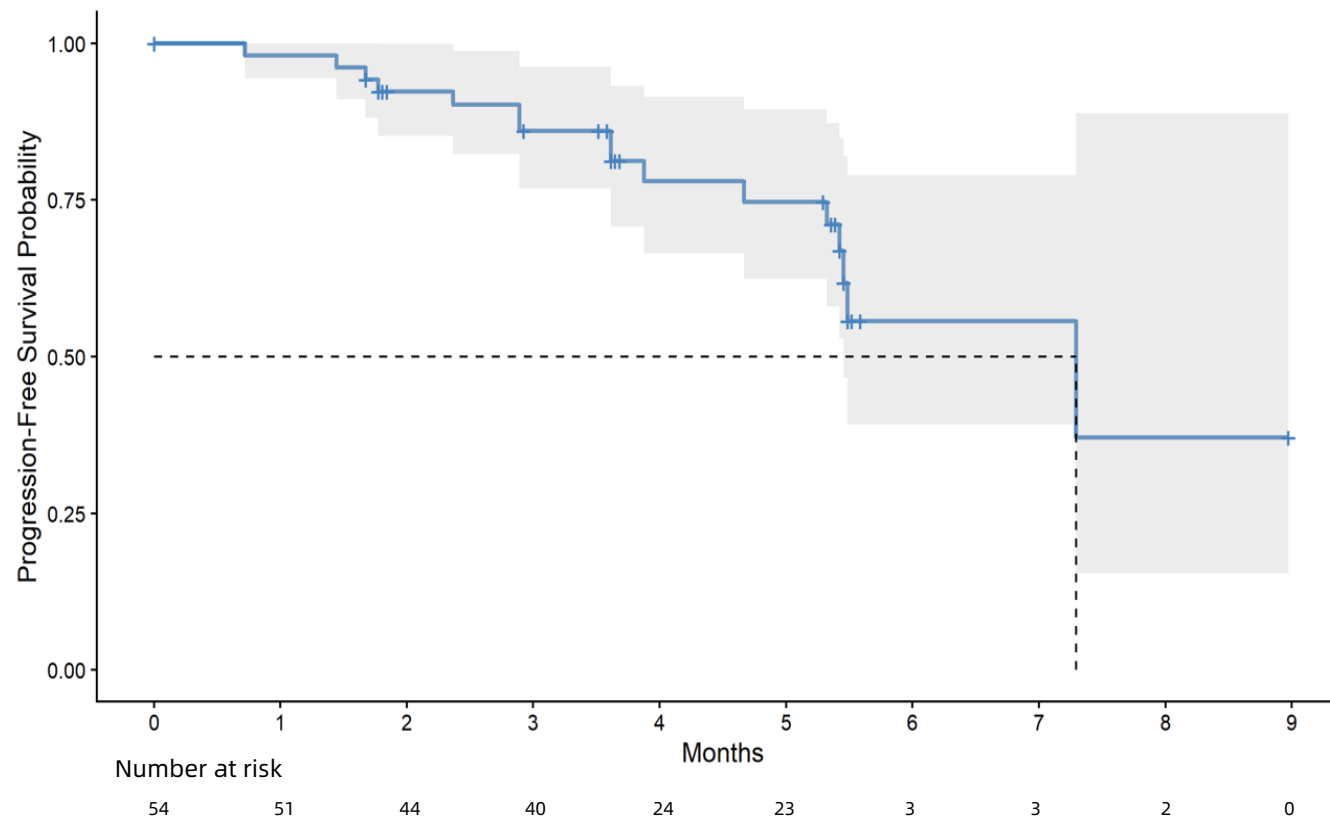
- 65% (35/54) of patients remain on treatment.



Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Two patients with CRC who lack post-baseline tumor assessments are not displayed in the waterfall but included in the denominator for ORR. Three patients with uPR discontinued treatment: 1 due to PD, 1 per patient decision, and 1 to initiate a new anticancer therapy. CI, confidence interval; cPR, confirmed partial response; CRC, colorectal cancer; DCR, disease control rate; ORR, overall response rate; PD, progressive disease; PFS, progression-free survival; PR, partial response; QD, once daily; Q2W, Quaque 2 weeks; SD, stable disease; uPR, unconfirmed partial response.

# PFS in Pretreated KRAS G12D-mutant CRC

- PFS events: n=16, 35 remain on treatment.
- Median PFS was 7.3 months with median follow-up time of 5.4 months.
- 4-months PFS rate, % (95%CI): 78 (62, 88).

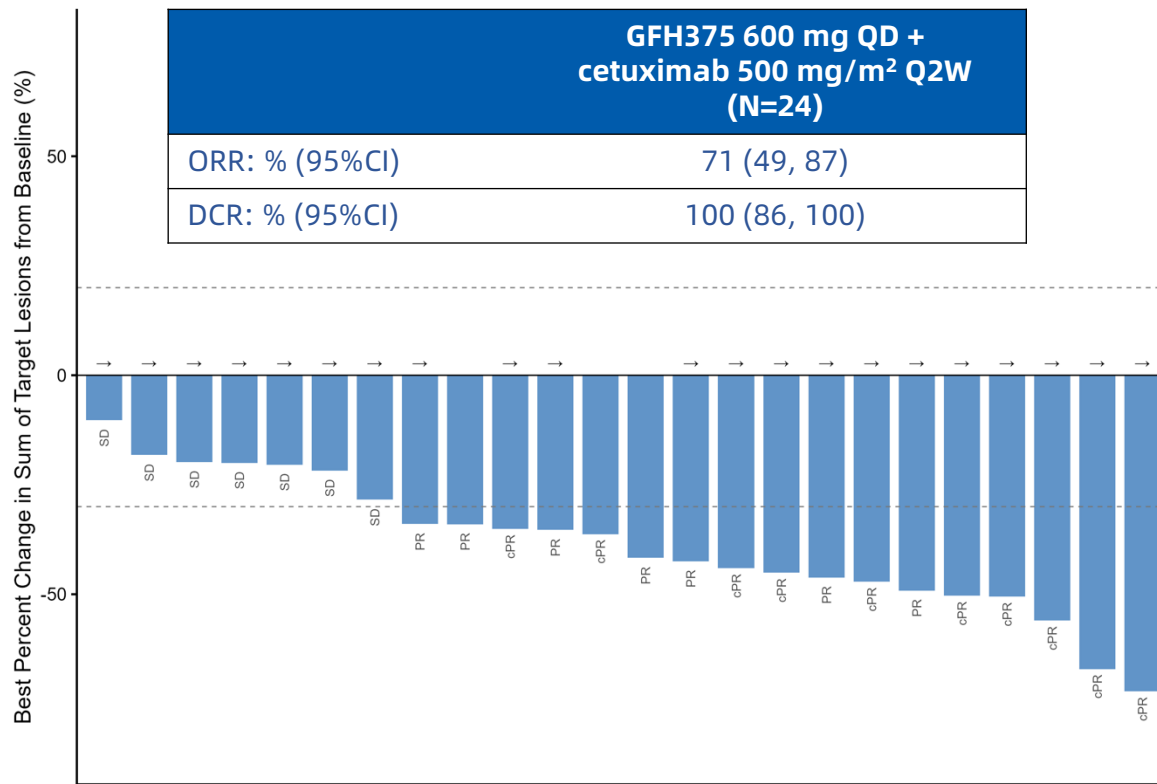


Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Four patients dropped out early, including 3 per patient decision and 1 per investigator decision.

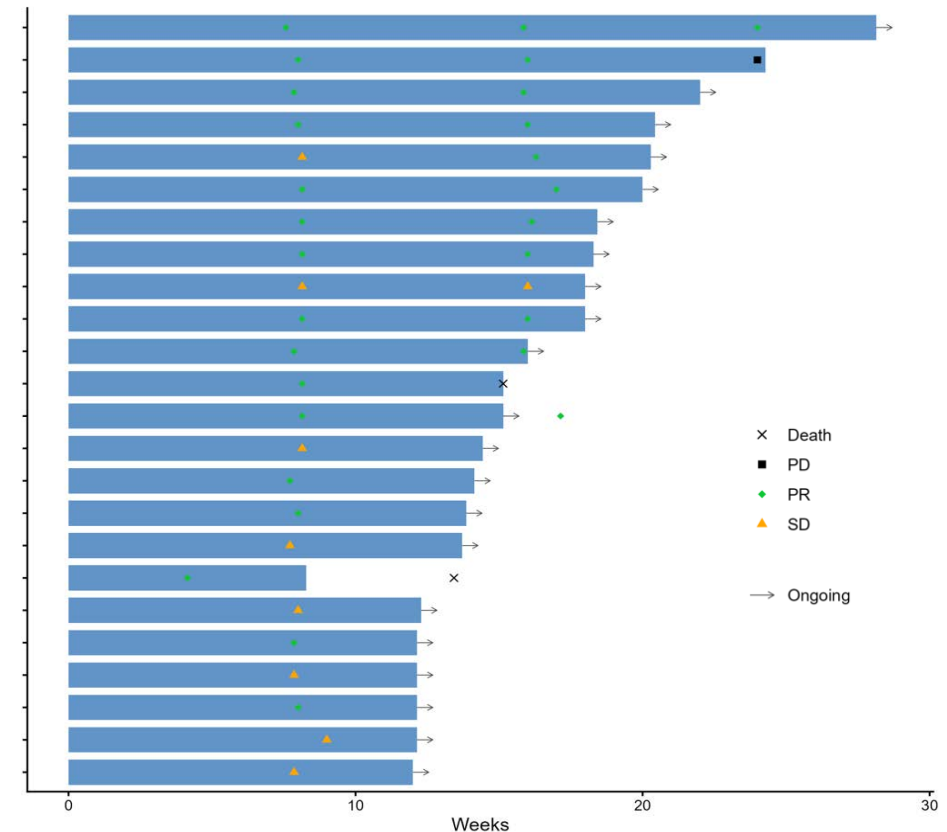
CI, confidence interval; CRC, colorectal cancer; PD, progressive disease; PFS, progression-free survival.

# Preliminary Efficacy in 1L KRAS G12D-mutant mPDAC

- Median follow-up: 3.8 months (range: 2.9, 6.5).
- ORR: 71% (17/24), 7 uPRs (5 patients remaining on treatment, 2 EOT).



- 88% (21/24) of patients remain on treatment.
- PFS events: n=3.



Data cutoff: 16-Sep-2026. All patients received a first dose of GFH375 in combination with cetuximab at least 12 weeks prior to data cutoff date. Two patients with uPR discontinued treatment: 1 per investigator decision and 1 death due to disease progression.

1L, first line; CI, confidence interval; cPR, confirmed partial response; DCR, disease control rate; ORR, overall response rate; PDAC, pancreatic ductal adenocarcinoma; PFS, progression-free survival; PR, partial response; QD, once daily; Q2W, Quaque 2 weeks; SD, stable disease; uPR, unconfirmed partial response.

# GFH375 + Cetuximab: Design of GFH375X1202

|                                                                | 2L+ CRC (N = 54) |                | 1L PDAC (N = 24) |               | Total (N = 78)  |                |
|----------------------------------------------------------------|------------------|----------------|------------------|---------------|-----------------|----------------|
|                                                                | Any Grade        | Grade 3        | Any Grade        | Grade 3       | Any Grade       | Grade 3        |
| <b>Any study drug-related AE, n (%)</b>                        | <b>54 (100)</b>  | <b>14 (26)</b> | <b>24 (100)</b>  | <b>5 (21)</b> | <b>78 (100)</b> | <b>19 (24)</b> |
| <b>TRAEs in ≥20% of all patients, n (%)</b>                    |                  |                |                  |               |                 |                |
| Diarrhea                                                       | 46 (85)          | 4 (7)          | 14 (58)          | 0             | 60 (77)         | 4 (5)          |
| Nausea                                                         | 34 (63)          | 0              | 10 (42)          | 0             | 44 (56)         | 0              |
| Rash                                                           | 24 (44)          | 1 (2)          | 15 (63)          | 0             | 39 (50)         | 1 (1)          |
| Vomiting                                                       | 30 (56)          | 0              | 7 (29)           | 0             | 37 (47)         | 0              |
| Decreased appetite                                             | 22 (41)          | 1 (2)          | 9 (38)           | 1 (4)         | 31 (40)         | 2 (3)          |
| Weight decreased                                               | 18 (33)          | 0              | 9 (38)           | 0             | 27 (35)         | 0              |
| Asthenia                                                       | 15 (28)          | 0              | 9 (38)           | 0             | 24 (31)         | 0              |
| Anaemia                                                        | 15 (28)          | 0              | 8 (33)           | 1 (4)         | 23 (30)         | 1 (1)          |
| Dermatitis acneiform                                           | 20 (37)          | 1 (2)          | 1 (4)            | 0             | 21 (27)         | 1 (1)          |
| Alanine aminotransferase increased                             | 13 (24)          | 0              | 7 (29)           | 0             | 20 (26)         | 0              |
| Lipase increased                                               | 17 (32)          | 1 (2)          | 2 (8)            | 1 (4)         | 19 (24)         | 2 (3)          |
| Amylase increased                                              | 14 (26)          | 1 (2)          | 3 (13)           | 0             | 17 (22)         | 1 (1)          |
| Hypoalbuminaemia                                               | 9 (17)           | 0              | 8 (33)           | 0             | 17 (22)         | 0              |
| <b>Treatment related SAEs, n (%)</b>                           | <b>4 (7)</b>     |                | <b>2 (8)</b>     |               | <b>6 (8)</b>    |                |
| <b>Dose modification of any study drug due to TRAEs, n (%)</b> |                  |                |                  |               |                 |                |
| Dose interruption                                              | 12 (22)          |                | 4 (17)           |               | 16 (21)         |                |
| Dose reduction                                                 | 3 (6)            |                | 1 (4)            |               | 4 (5)           |                |
| Dose discontinuation                                           | 0                |                | 0                |               | 0               |                |

- No Grade 4/5 TRAEs.
- No dose discontinuation due to TRAEs.
- TRAEs were predominantly cutaneous and gastrointestinal toxicities, mostly Grade 1/2.
- Grade 3 TRAEs occurred in 24%; no individual Grade 3 TRAE exceeded 5% (most commonly diarrhea).
- Less frequency and severity of hepatic and hematologic TRAEs comparing to GFH375 monotherapy.

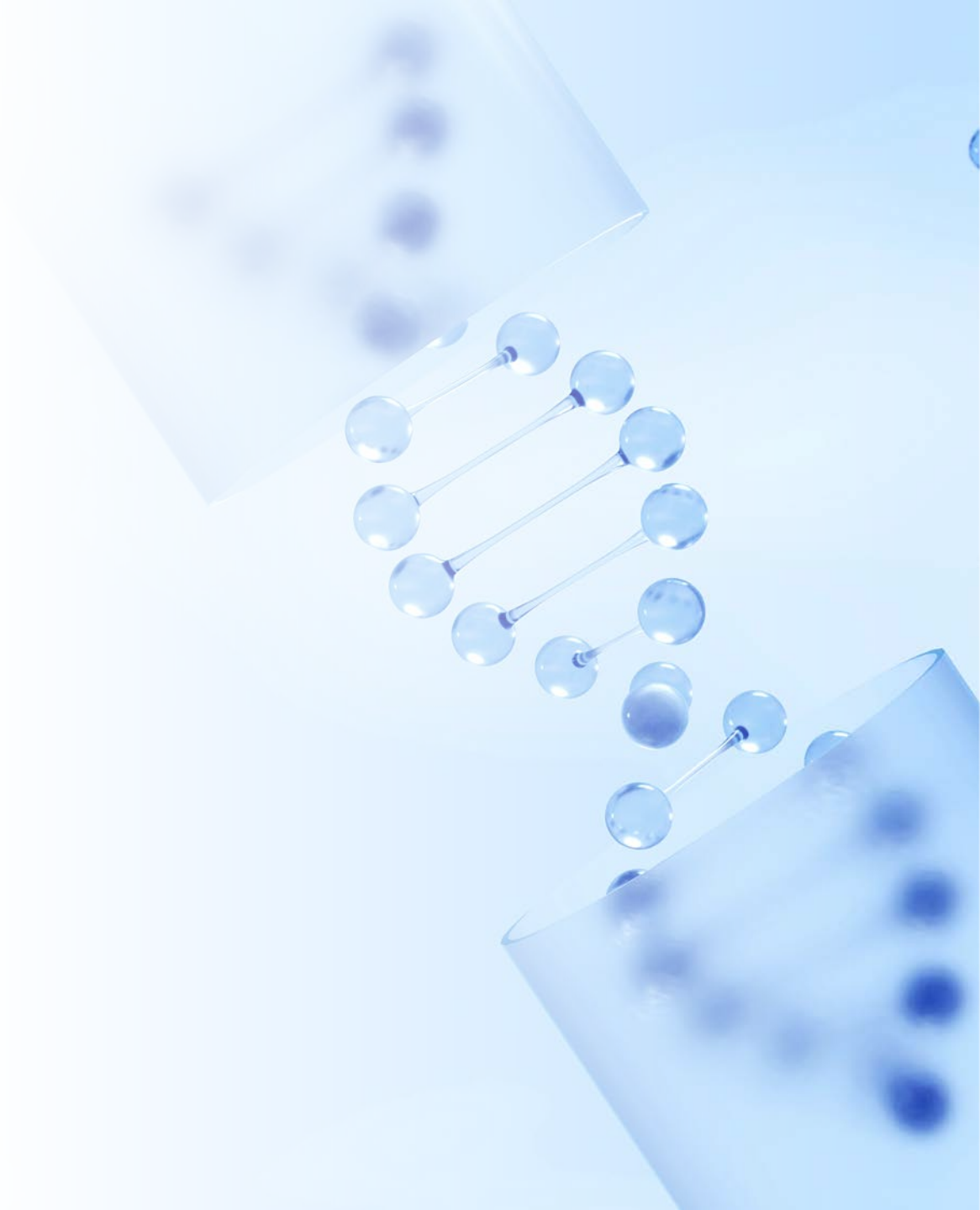
Data cutoff: 22-Jul-2026. All patients received a first dose of GFH375 600 mg QD in combination with cetuximab 500 mg/m<sup>2</sup> Q2W at least 4 weeks prior to data cutoff date.

CRC, colorectal cancer; PDAC, pancreatic ductal adenocarcinoma; QD, once daily; Q2W, Quaque 2 weeks; SAE, serious adverse event; TRAE, treatment related adverse event.

# *PART*

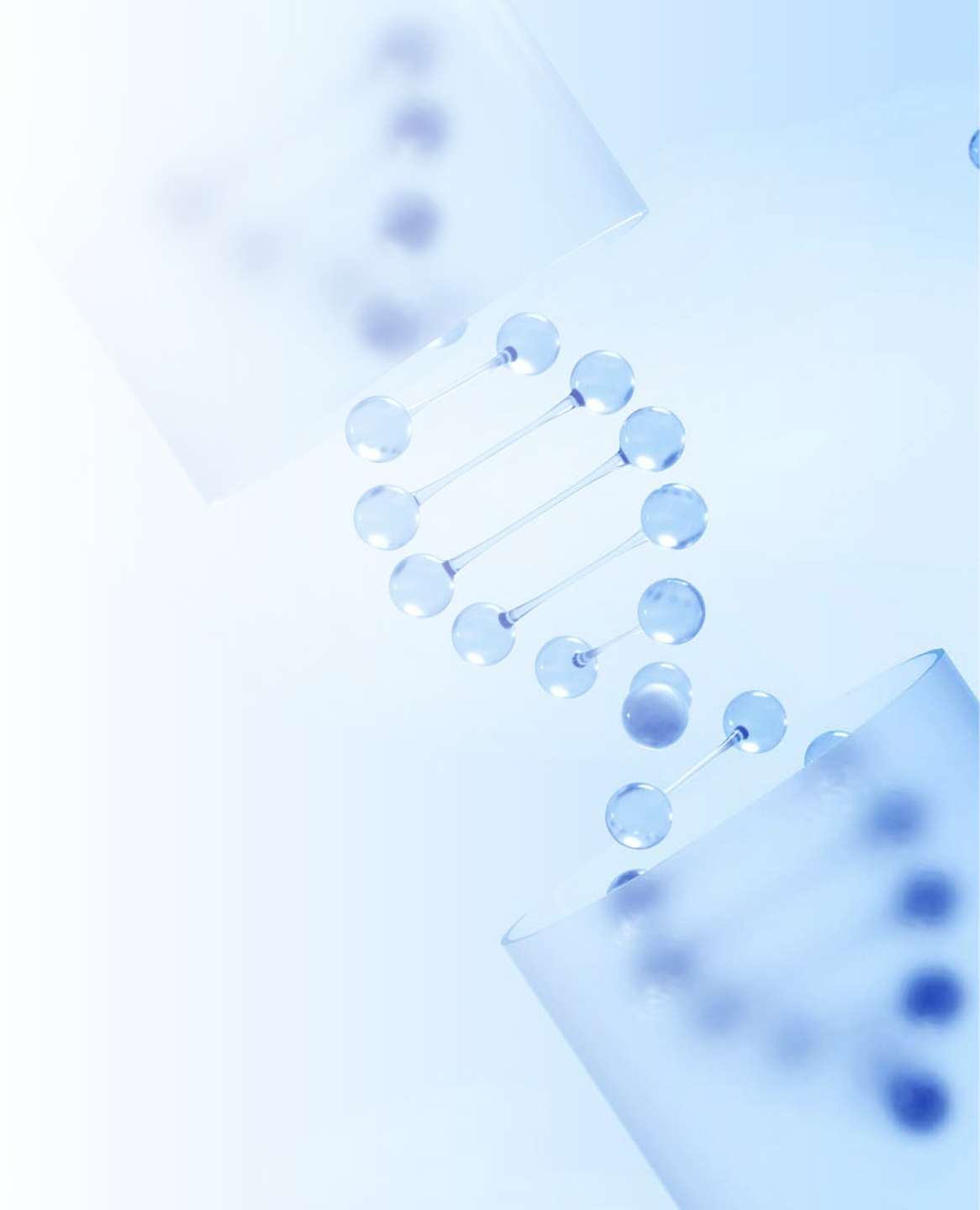
## *03*

**Q&A**



# *04* *PART*

## **Summary and outlook**



BTDs Granted in China for Three Major KRAS G12D-mutant Solid Tumors

| 突破性治疗申请公示详细信息 |                                   | BTD Notice from<br>CENTER FOR DRUG<br>EVALUATION,<br>China's National<br>Medical Products<br>Administration |            |                   |            |
|---------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------|------------|-------------------|------------|
| 受理号           | CXHL2400328                       | 药品名称                                                                                                        | GFH375片    |                   |            |
| 药品类型          | 化药                                | 注册分类                                                                                                        | 1          |                   |            |
| 申请日期          | 2026-01-30                        | 承办日期                                                                                                        | 2024-04-03 | GFH375片           |            |
| 公示日期          | 2026-02-13                        | 公示截止日期                                                                                                      | 2026-02-27 | 1                 | GFH375片    |
| 是否为罕见病药物      | 否                                 |                                                                                                             |            | 2024-04-03        | 1          |
|               |                                   |                                                                                                             |            | 2026-04-08        | 2025-07-11 |
| 拟定适应症（或功能主治）  | 至少接受过一种系统性治疗并具有KRAS G12D突变的非小细胞肺癌 |                                                                                                             | NSCLC      |                   | 2026-09-24 |
|               | 拟定适应症（或功能主治）                      | 至少接受过一种系统性治疗并具有KRAS G12D突变的转移性胰腺癌                                                                           |            | Pancreatic cancer |            |
|               | 拟定适应症（或功能主治）                      | 联合西妥昔单抗用于携带KRAS G12D突变的既往奥沙利铂、氟尿嘧啶类和伊利替康为基础的化疗失败的转移性结直肠癌                                                    |            | CRC               |            |

## Six Launches in 2026/2027 Support Solid Commercialization Prospects

### GFH375 (KRAS G12D inhibitor)

#### PDAC

Late-line, mono

1st-line, combo with chemo

#### NSCLC

Late-line, mono

#### CRC

3rd-line, combo with cetux

### GFH276 (Pan RAS inhibitor)

#### PDAC

Late-line, mono

1st-line, combo with chemo

# ESMO LBA: Preliminary Study Data of GFH276 in RAS-mutant Solid Tumors

MADRID  
2026 **ESMO** congress

**MADRID SPAIN**  
**23-27 OCTOBER 2026**



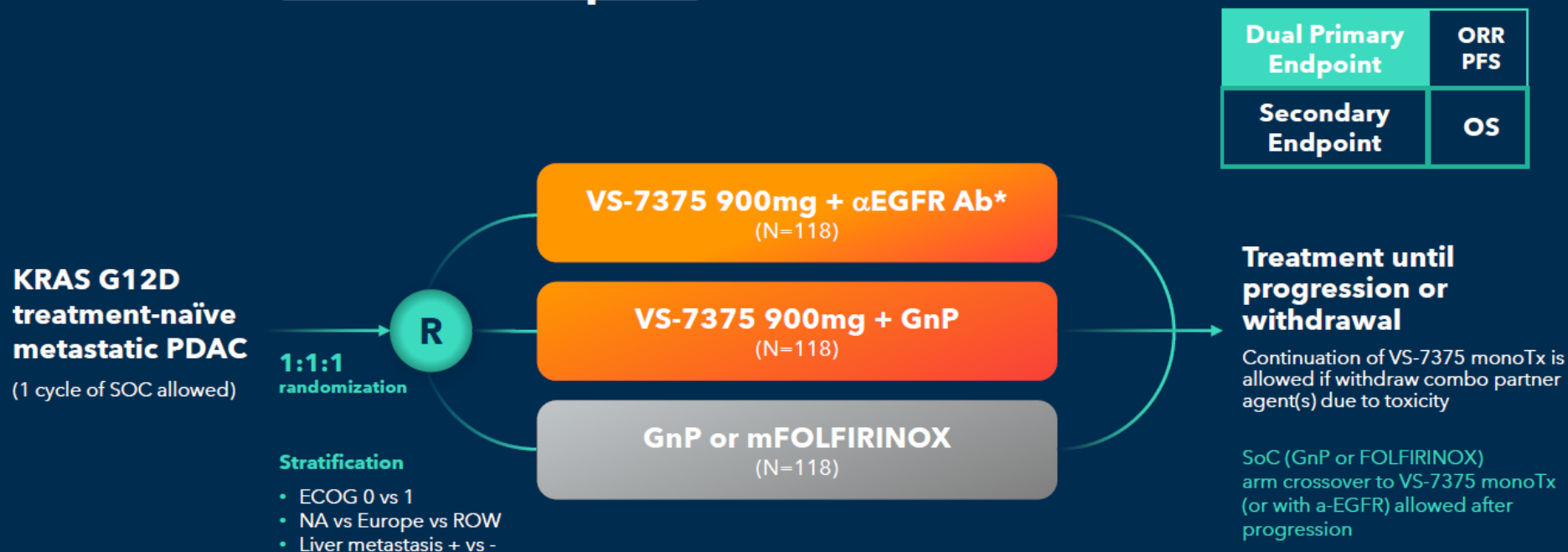
*LBA title: Safety and efficacy of GFH276 monotherapy in previously treated RAS-mutated advanced solid tumors*

*Session: 8:30-10:00 a.m. Oct. 25, 2026, local time  
(Developmental Therapeutic)*



# VS-7375 Expected to Enter 1L Phase III PDAC Combo Study by Year End

## VS-7375 1L PDAC Phase 3: TARGET-D 301 Study Schema - Potential for Chemo Free Option



**REACHED ALIGNMENT ON PROTOCOL WITH FDA -  
PLAN TO OPEN PHASE 3, 1L mPDAC TRIAL BY END OF 2026**



**Innovation, in expedition**