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SYNOPSIS

Study Title: A Phase 1 Dose Escalation and Expansion Study Evaluating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Anti Tumor Activity of PF-07062119 in Patients With Advanced Gastrointestinal Tumors

Study Number:C3861001

Regulatory Agency or Public Disclosure Identifier Number: US IND Number: 143416; ClinicalTrials.gov ID: NCT04171141

Study Phase: Phase 1

Name of Study Intervention: PF-07062119

Name of Sponsor/Company: Pfizer Inc.

CSR Version and Report Date: Final CSR (Last Patient Last Visit [LPLV] Date: 28 November 2023) Version 1.0, 28 June 2024

Number of Study Center(s) and Investigator(s):

A total of 99 participants were screened at 10 centers in 3 countries (US, Australia, Japan). A list of study centers and investigators involved in this study is provided in Appendix 16.1.4.1.

Publications:

None.

Study Period:

Study Initiation Date (First Participant First Visit [FPFV]): 19 November 2019

Study Completion (LPLV) Date: 28 November 2023

This study enrollment was terminated on 10 October 2023.

Rationale:

PF-07062119 is an anti-Guanylyl Cyclase 2C (anti-GUCY2c)/anti-CD3 bispecific Fc diabody targeting CD3 on T cells with one binding domain and GUCY2c with the other binding domain. PF-07062119 acts as a T cell redirecting bispecific for the treatment of gastrointestinal tumors including colorectal, gastric and esophageal adenocarcinomas.

Study C3861001 was a first-in-human, Phase 1, dose escalation and expansion study evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and anti-tumor activity of PF-07062119 in patients with advanced gastrointestinal tumors known

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to express GUCY2c and for whom no standard therapy is available. This study was designed to contain 2 parts: Part 1 dose escalation of PF-07062119, with and without a priming dose, as a monotherapy (Part 1A) and in combination with an anti-PD-1 or anti-vascular endothelial growth factor (VEGF) agent (Part 1B) and Part 2 dose expansion.

This study was terminated on 10 October 2023. Study termination was due to a strategic decision but not any safety concerns or requests from any regulatory authorities. This CSR presents the study results of dose escalation phase (Part 1) collected by the study completion date. Dose expansion phase (Part 2) of the study was not conducted due to the study termination.

Objectives, Endpoints, and Statistical Methods:

Objectives and Endpoints

Dose Escalation (Part 1)

Type	Objective	Endpoints
Primary		
Safety	• To assess safety and tolerability of increasing dose levels of PF-07062119 with and without priming dose administered in participants with advanced gastrointestinal tumors, including colon, gastric, and esophageal adenocarcinomas, for whom no standard therapy is available in order to estimate the MTD and select the RP2D as a monotherapy in Part 1A and in combination therapy in Part 1B with select tumor(s).	• First cycle DLTs; • Adverse Events as characterized by type, frequency, severity (as graded by [NCI CTCAE] version 5), timing, seriousness, and relationship to study therapy; • Laboratory abnormalities as characterized by type, frequency, severity (as graded by NCI CTCAE version [version 5.0]), and timing.

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Dose Escalation (Part 1)

Type	Objective	Endpoints
Secondary		
PK	• To characterize the single and multiple dose PK of PF-07062119;	PK parameters of PF-07062119: • Cycle 1 and Cycle 4 PK parameters maximum concentration (C_{max}), time to achieve C_{max} (T_{max}), area under the concentration versus time curve from time zero to the last quantifiable concentration (AUC_{last}). If data permits, other PK parameters will be derived such as apparent clearance (CL/F), terminal half-life ($t_{1/2}$), and the area under the plasma concentration-time profile from time zero extrapolated to infinite time (AUC_{inf}); • Predose trough concentrations after multiple doses of PF-07062119.
Immunogenicity	• To evaluate the immunogenicity of PF-07062119;	• Incidence, titers of ADA and NAb PF-07062119.
Immunogenicity	• To evaluate the immunogenicity of PF-06801591 and bevacizumab-Pfizer[a] given in combination with PF-07062119 (Part 1B);	• Incidence and titers of ADA and NAb against PF-06801591 and bevacizumab-Pfizer[a] given in combination with PF-07062119 (Part 1B).
PD / Biomarkers	• To evaluate immune cells in archival tumor biopsies and/or pre and post treatment tumor biopsies (if available);	• Assessment of levels of intra-tumor T cells (eg, CD8 IHC).
Efficacy	• To evaluate preliminary anti-tumor activity.	• Objective response, as assessed using RECIST version 1.1.

Abbreviations: ADA = antidrug antibodies; AUC_{inf} = AUC from time zero extrapolated to infinite time; AUC_{last} = AUC from time zero to the last quantifiable concentration; CL/F = apparent clearance; C_{max} = maximum observed concentration; CTCAE = Common Terminology Criteria for Adverse Event; DLT = dose limiting toxicity; MTD = maximum tolerated dose; NAb = neutralizing antibodies; NCI = National Cancer Institute; PK = pharmacokinetic(s); RECIST = Response Evaluation Criteria in Solid Tumors; RP2D = recommended Phase 2 dose; $t_{½}$ = terminal half-life; T_{max} = time to maximum concentration.
a. No data reported in this report

Dose expansion phase (Part 2) of the study was not conducted due to the study termination.

Statistical Methods

There were no formal hypothesis testing in this study.

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The data were summarized by cohort defined by the initial dose of the study drug. DLT rates at the study dose levels were presented via mean and medians and a Bayesian credible interval based on the posterior density from the full probability model and were used for the dose escalation decision meetings.

The following analysis sets were defined for this study:

Population	Description
Full analysis set	The full analysis set includes all enrolled participants.
Per protocol analysis set (Evaluable for MTD)	The per protocol analysis set includes all enrolled participants who had at least one dose of study treatment and either experienced DLT or do not have major treatment deviations during the DLT observation period.
Safety set	The safety analysis set includes all enrolled participants who receive at least one dose of study treatment. Unless otherwise specified the safety analysis set will be the default analysis set used for all analyses.
Modified Intent to Treat	The modified intent to treat is the analysis population that will follow the ITT principle and include participants receiving at least 1 dose of study medication with baseline assessment and at least 1 post baseline assessment, disease progression, or death before the first tumor assessment. The mITT population may be used for interim analysis and conference presentations when the study is still ongoing.
PK analysis	The PK parameter analysis population is defined as all enrolled participants treated who do not have protocol deviations influencing PK assessment, and have sufficient information to estimate at least 1 of the PK parameters of interest. The PK concentration population is defined as all enrolled participants who are treated and have at least 1 analyte concentration.
Response Evaluable	The response evaluable population will include all participants who received at least one dose of study treatment and had baseline disease and at least one post baseline disease assessment.
PD/Biomarker	The PD/Biomarker analysis population is defined as all enrolled participants with at least 1 of the PD/Biomarkers evaluated at pre and/or post dose.
Immunogenicity analysis set	The immunogenicity analysis set includes all enrolled participants who receive at least one dose of study treatment and have at least one sample tested for ADA.

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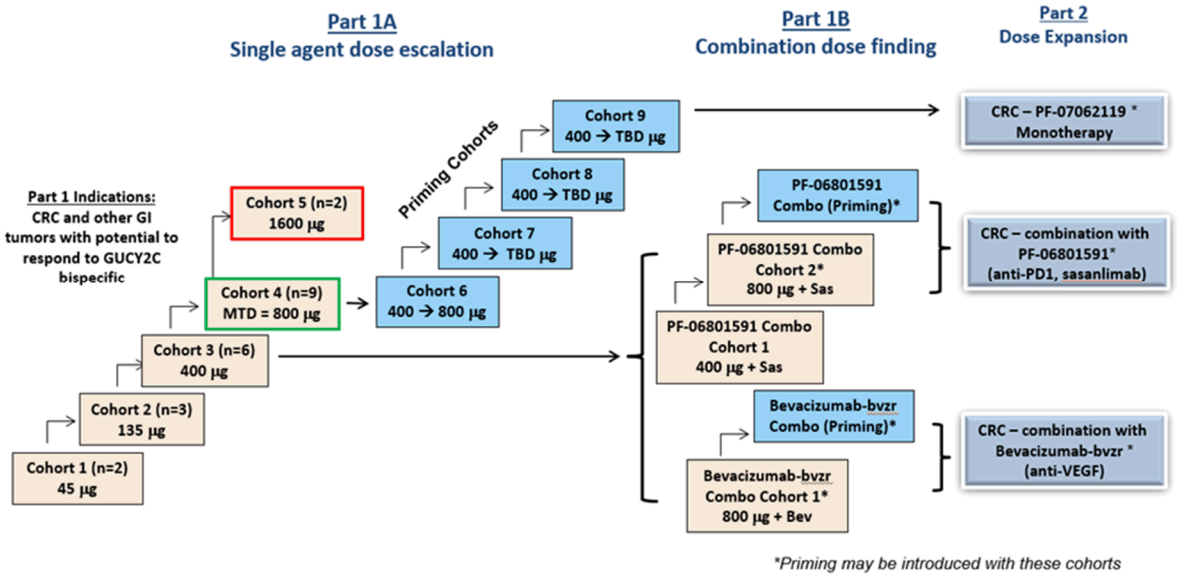
Methodology:

This was a Phase 1, open-label, multi-center, multiple-dose, study to evaluate safety, tolerability, PK, PD and anti-tumor activity of PF-07062119 in participants with selected advanced or metastatic gastrointestinal tumors. This study contained 2 parts: Part 1 dose escalation of PF-07062119, with and without a priming dose, as a monotherapy (Part 1A) and in combination with an anti-PD-1 or anti-VEGF agent (Part 1B) and Part 2 dose expansion (Figure 1). The PF-07062119 administration regimen for Parts 1A, 1B, and 2 were planned to be guided by subcutaneous (SC) dose priming escalation cohorts and all available data were planned to be used to make a decision on future dose regimens.

Figure 1. C3861001 Study Schema



Number of Participants (planned and analyzed):

Approximately 35 participants each were planned to be enrolled in the Part 1A (monotherapy) and Part 1B (combination) dose escalation portions of the study.

In the study, 79 participants were assigned and treated with PF-07062119. All treated participants (79) were included in the safety analysis set and full analysis set, and all participants were with evaluable PK and included in the PK concentration analysis set and PK parameter analysis set. A total of 77 participants were included in the PD/Biomarker analysis set and PF-07062119 immunogenicity analysis set. Sixty-three participants were included in the per protocol analysis set.

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Diagnosis and Main Criteria for Inclusion and Exclusion:

Enrolled in this study were participants with diagnosis of advanced/metastatic colorectal, gastric, or esophageal adenocarcinoma that was resistant to standard therapy or for which no local regulatory approved standard therapy was available.

Study Interventions, Dose, Mode of Administration, and Batch Number(s):

PF-07062119 was treated as monotherapy and in combination with PF-06801591 or bevacizumab, with and without a priming dose.

PF-07062119

PF-07062119 was administered via SC injection, without adjustment for body size, Q2W at every cycle. One cycle was defined as 28 days. Priming and premedication with both the priming dose and initial full dose of PF-07062119 for all participants was implemented into this study to further improve tolerability and participant experience in Protocol Amendment 5 dated 16 March 2021. Priming dose of 400 μg was given on Cycle 1 Day 1, followed by full doses on Cycle 1 Day 15. Premedication included Acetaminophen 650 mg (or equivalent), oral; Diphenhydramine 25 mg, oral or IV; and Dexamethasone 12 mg (or equivalent), oral or IV. Premedications were given approximately 1 hour before PF-07062119.

PF-06801591 (Sasanlimab)

In the investigational combination therapy with PF-07062119, PF-06801591 300 mg (50 mg/mL), was administered SC Q4W.

Bevacizumab-Pfizer

For participants treated with the investigational therapy with PF-07062119, bevacizumab-Pfizer was administered via IV infusion Q2W based on 5 mg/kg of body weight.

The manufacturing lot numbers for the study intervention(s) dispensed in this study are provided in Table S1.

Table S1. Study Intervention(s) Administered

Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
Bevacizumab-bvzr 25 mg/mL Vial Injection for Intravenous Use 400 mg / 16 mL	DK0250	20-002658	25 mg/mL	Solution for Infusion
Diluent Solution for Injection; Histidine, Sucrose, PS80, EDTA - External	1-FIN-3461	19-003282	0 mg/mL	Solution

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Table S1. Study Intervention(s) Administered

Investigational Product Description	Vendor Lot No.	Pfizer Lot No.	Strength/Potency	Dosage Form
Diluent Solution for Injection; Histidine, Sucrose, PS80, EDTA - External	1-FIN-3984	21-DP-00807	0 mg/mL	Solution
PF-06801591 Solution for Injection, 50 mg/mL (2 mL)	19-DP-00060	19-003154	50 mg/mL	Solution for Injection
PF-07062119 Powder for Solution for Injection, 5 mg/vial	CK1126	19-003307	5 mg	Lyophile
PF-07062119 Powder for Solution for Injection, 5 mg/vial	FE8780	21-DP-00920	5 mg	Lyophile
Bevacizumab-bvzr 25mg / mL Vial Injection for Intravenous Use 400 mg / 16 mL	PA2087743	20-AE-00050	25 mg/mL	Solution for Infusion
Bevacizumab-bvzr 25mg / mL Vial Injection for Intravenous Use 400 mg / 16 mL	DK0250	20-AE-00050	25 mg/mL	Solution for Infusion
PF-06801591 Solution for Injection, 50 mg/mL (2 mL)	N/A	18-000607	50 mg/mL	Solution for Injection
Bevacizumab-bvzr 25mg / mL Vial Injection for Intravenous Use 400 mg / 16 mL	EN6402	21-AE-00143	25 mg/mL	Solution for Infusion
Bevacizumab-bvzr 25mg / mL Vial Injection for Intravenous Use 400 mg / 16 mL	GC7723	22-AE-00622	25 mg/mL	Solution for Infusion

Duration of Study Intervention:

For active treatment phase, 1 cycle was 28 days in duration.

Treatment with study intervention were planned to continue until either disease progression, participant refusal, or unacceptable toxicity occurs, whichever to be earliest, unless the investigator and medical monitor to agree to treatment beyond disease progression based on individual benefit/risk assessments.

Summary of Results:

Demographic and Other Baseline Characteristics:

Overall, of the 79 treated participants, 49 (62.0%) were male and 30 (38.0%) were female. The majority of participants were White (46 [58.2%] participants) and Asian (25 [31.6]) participants). The median (range) age was 56.0 (29 - 81) years.

Exposure:

In Part 1A, the median (range) duration of treatment with PF-07062119 was 43.0 (1, 322) days. A total of 14 (23.3%) participants received 1 cycle of study treatment, 29 (48.3%)

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participants received 2 cycles, 3 (5.0%) participants received 3 cycles, and 14 (23.3%) participants received >3 cycles, respectively.

In Part 1B, the median (range) duration of treatment with PF-07062119 was 59.0 (1, 576) days. A total of 2 (10.5%) participants received 1 cycle of study treatment, 8 (42.1%) participants received 2 cycles, 2 (10.5%) participants received 3 cycles, and 7 (36.8%) participants received >3 cycles, respectively.

Efficacy Results:

79 patients were evaluated for objective response (OR). Totally, 2 of 79 (2.5%) patients achieved OR (complete response [CR]: 0, partial response [PR]: 2).

- In Part 1A (PF-07062119 monotherapy), 1 of 60 (1.7%) participants had PR. This participant This participant was primarily diagnosed as lung metastasis and was assigned to receive PF-07062119 2100 µg with a priming dose.

- In Part 1B (PF-07062119 combination therapy), 1 of 19 (5.3%) participants had PR. This participant was primarily diagnosed as lung metastasis and was assigned to receive PF-07062119 1200 µg + bevacizumab 5 mg/kg with a priming dose.

Safety Results:

DLTs

A total of 63 participants were evaluable for DLTs. Six (9.5%) participants had DLTs, and all 6 participants received PF-07062119 monotherapy.

DLTs by participant are summarized below:

- One participant on dose level of 800 µg without a priming dose reported Cytokine release syndrome and Colitis;

- One participant on dose level of 800 µg without a priming dose reported Diarrhoea;

- One participant on dose level of 1600 µg without a priming dose reported Diarrhoea;

- One participant on dose level of 1600 µg without a priming dose reported Diarrhoea and Colitis;

- One participant on dose level of 800 µg with a priming dose reported Rash;

- One participant on dose level of 2800 µg with a priming dose reported Rash maculo-papular.

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Adverse Events (AEs)

All-causality TEAEs:

- All participants treated in the study experienced at least 1 TEAEs. The most frequently reported all-causality TEAEs (≥20% of participants) by PT were Diarrhoea (73.4%), Cytokine release syndrome (48.1%), Injection site erythema (46.8%), Nausea (43.0%) Fatigue (38.0%), Vomiting (38.0%), Injection site reaction (29.1%), Decreased appetite (25.3%), Injection site pruritus (25.3%), Constipation (21.5%), Rash (21.5%) and Pyrexia (20.3%).

- Grade 3 or 4 all-causality TEAEs were reported in 42 (53.2%) participants. The most frequently reported Grade 3 TEAE (≥10% of participants) was Diarrhoea (14 [17.7%] participants). Only 1 (1.3%) participant reported Grade 4 TEAE (PT: Hypomagnesaemia). Four (5.1%) participants reported Grade 5 TEAEs: Disease progression (1 [1.3%] participant), Malignant neoplasm progression (1 [1.3%] participant) and Neoplasm progression (2 [2.5%] participants).

- Seven (8.9%) participants discontinued from the study due to TEAEs. Nine (11.4%) discontinued PF-07062119 due to TEAEs. Dose reductions and interruptions of PF-07062119 due to TEAEs were reported in 2 (2.5%) and 24 (30.4%) participants, respectively.

- Thirty (38.0%) participants experienced SAEs, of whom, 22 (27.8%) participants experienced SAEs of Grade 3 and higher. The most frequently reported all-causality SAEs (≥3%) by PT were Cytokine release syndrome (7 [8.9%] participants) and Diarrhoea (6 [7.6%] participants).

Treatment-related TEAEs:

- All participants treated in the study experienced at least 1 treatment-related TEAEs. The most frequently reported treatment-related TEAE (≥20% of participants) by PT was Diarrhoea (69.6%), Cytokine release syndrome (48.1%), Injection site erythema (46.8%), Nausea (36.7%), Vomiting (31.6%), Fatigue (31.6%), Injection site reaction (27.8%), Injection site pruritus (25.3%), Pyrexia (20.3%) and Rash (20.3%).

- Grade 3 or 4 treatment-related TEAEs were reported in 27 (34.2%) participants. The most frequently reported treatment-related Grade 3 TEAE (≥10% of participants) was Diarrhoea (14 [17.7%] participants). No Grade 4 TEAEs were reported, and no Grade 5 TEAEs were reported.

- No participants discontinued the study due to treatment-related TEAEs. Two (2.5%) discontinued PF-07062119 due to treatment-related TEAEs. Dose reductions and interruptions of PF-07062119 due to treatment-related TEAEs were reported in 2 (2.5%) and 19 (24.1%) participants, respectively.

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- Fourteen (17.7%) participants experienced treatment-related SAEs, of whom, 6 (7.6%) participants experienced SAEs of Grade 3 and higher. The most frequently reported treatment-related SAEs (≥3%) by PT were Cytokine release syndrome (7 [8.9%] participants) and Diarrhoea (5 [6.3%] participants).

During the treatment period (including 28 days after the last dose of study treatment), 4 (5.1%) participants died due to disease progression (Grade 5 TEAEs, not related to the study treatment)

Clinical Laboratory Evaluation

Grade 3 hematological test abnormalities were White blood cell decreased (reported in 2 [2.6%] participants), Hemoglobin increased (3 [3.8%] participants), Anemia (reported in 5 [6.3%]) participants), and Lymphocyte count decreased (17 [21.5%] participants). Grade 4 hematological test abnormalities were Platelet count decreased (1 [1.3%] participants) and Lymphocyte count decreased (2 [2.5%] participants).

Grade 3 chemical test abnormalities were Alkaline phosphatase increased, Creatinine increased and Hypermagnesemia (reported in 1 [1.3%] participant); Aspartate aminotransferase increased (2 [2.5%] participants); Alanine aminotransferase increased, and Blood bilirubin increased (3 [3.8%]) participants each); Hypokalemia, and Serum amylase increased (4 [5.1%] participants each); Hyponatremia (5 [6.3%] participants); and Lipase increased (11 [4.3%] participants). Grade 4 hematological test abnormalities were Aspartate aminotransferase increased, Blood bilirubin increased, Hypomagnesemia, and Serum amylase increased (reported in 1 [1.3%] participant each); and Lipase increased (7 [9.1%] participants).

Pharmacokinetic Results:

Priming Cohorts

In Part 1A, following SC administration of PF-07062119 at 400 ug priming dose, C_{max} was reached with a median T_{max} of 165 to 222 hours. Following SC administration of PF-07062119 full dose at doses ranging from 800 ug to 3700 ug, T_{max} ranged from 128 to 162 hours on Cycle 1 Day 15 and from 19.0 to 144 hours on Cycle 4 Day 1, where it could be determined.

In Part 1B, following SC administration of PF-07062119 at 400 ug priming dose in combination with PF-06801591 300 mg or bevacizumab 5 mg/kg, C_{max} was reached with a median T_{max} of 166 to 167 hours. Following SC administration of PF-07062119 at Q2W doses ranging from 800 ug to 1200 ug in combination with Q4W PF-06801591 300 mg or bevacizumab 5mg/kg, C_{max} was reached within a median T_{max} of 73.2 to 167 hours on Cycle 1 Day 15, and 67.4 to 141 hours on Cycle 4 Day 1, where it could be determined.

Systemic exposure based on AUC_{tau}, AUC_{168} and C_{max} values appeared to increase in a dose related manner across the doses on Cycle 1 Day 1 and 15 and Cycle 4 Day 1. It appears steady state has been reached by Cycle 4 Day 1.

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Non-priming Cohorts

In Part 1A, following SC administration of PF-07062119 at doses ranging from 45 ug to 1600 ug, C_{max} was reached within a median T_{max} of 93.3 to 186 hours on Cycle 1 Day 1, and ranging from 24.0 to 167 hours, on Cycle 4 Day 1.

In Part 1B, following SC administration at Q2W doses ranging from 400 ug to 800 ug in combination with a Q4W PF-06801591 300 mg or bevacizumab 5mg/kg, C_{max} was reached within a median T_{max} of 94.0 to 170 hours on Cycle 1 Day 1 and 23.4 to 96.2 hours on Cycle 4 Day 1.

Systemic exposure based on AUC_{tau}, AUC_{168} and C_{max} values appeared to increase in a dose related manner across the doses on Cycle 1 Day 1 and Cycle 4 Day 1. It appears steady state has been reached by Cycle 4 Day 1.

Other Results:

Biomarkers

Immune biomarkers (CD3, CD8, PD-L1) and changes in immune biomarkers in pretreatment (screening) and on-treatment (Cycle 3 Day 1) paired tumor biopsies from 5 participants are summarized in the study tables. Three out of 5 participants had increased immune biomarkers in the on-treatment tumor biopsies and are summarized below:

- One participant had a 482.21% change from baseline in CD3+ cells/mm^2, a 1378.52 % change from baseline in CD8+ cells/mm^2, and a 700% change from baseline in PD-L1 positive immune cells per tumor area in the Cycle 3 Day 1 biopsy.
- One participant had an 89.14% change from baseline in CD3+ cells/mm^2, a 290.74% change from baseline in CD8+ cells/mm^2, and a -20 % change from baseline in PD-L1 positive immune cells per tumor area in the Cycle 3 Day 1 biopsy.
- One participant had an 822.76% change from baseline in CD3+ cells/mm^2 and a 3405.31% change from baseline in CD8+ cells/mm^2 in the Cycle 3 Day 1 biopsy.

Immunogenicity

A total of 77 participants were evaluable for ADA against PF-07062119. At baseline, all participants were ADA negative, except 1 participant was ADA-positive. Overall, the incidence of ADA positive was 14.3% (11 of 77). Out of these, 13.0% (10 of 77) was treatment induced, and the median time to detection of ADA across dose cohorts ranged from 29 to 447 days. Five ADA-positive participants who had ≥16 weeks of post-treatment ADA results were assessed for the duration of response, 40% (2 of 5) participants had persistent response.

A total of 77 participants were evaluable for NAb against PF-07062119. At baseline, all participants were NAb negative. Overall, the incidence of NAb positive was 10.4% (8 of 77),

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and all were treatment induced, with the median time to detection of NAb across dose cohorts ranging from 55 to 280 days. Three NAb-positive participants who had ≥16 weeks of post-treatment NAb results were assessed for the duration of response, 33.3% (1 of 3) participants had persistent response.

Conclusions:

In the Phase 1 Study C3861001, PF-07062119, a bispecific Fc diabody targeting anti-GUCY2c and anti-CD3, was evaluated for its efficacy in advanced/metastatic gastrointestinal tumors, specifically focusing on 3L+ MSS colorectal cancer.

Part 1A - Dose Escalation and MTD: The dose escalation phase, Part 1A, ranged from 45 µg to 1600 µg. This phase led to the identification of the MTD at 800 µg. The DLTs observed at this level were Grade 3 CRS, Colitis, and Diarrhea. PK exposures of PF-07062119, measured by AUC_{tau}, AUC_{168}, and C_{max}, appeared to increase proportionally with the dose.

Following these findings, a priming dose of 400 µg, along with premedication, was introduced. This strategy successfully reduced the incidence of CRS to Grade 2 or higher, enabling a dose increase up to 3700 µg. The RDE was established at 2100 µg, with the DLT at this level being Grade 3 Rash. However, the priming approach did not mitigate the frequency of Diarrhea, which persisted as the primary clinically significant toxicity. Diarrhea remained the most common TEAE, the most frequent Grade 3/4 TEAE, the most common SAE, and the leading cause of dose interruption and discontinuation.

Part 1B - Combination Dose Escalation: Part 1B of the study explored dose escalation in combination with sasanlimab and bevacizumab. This combination did not result in any significant additional toxicity.

Efficacy and Anti-Tumor Activity: As a monotherapy and in combination therapy, PF-07062119 demonstrated modest anti-tumor activity, with only 2 ORs observed across all cohorts. One response occurred at the 2100 µg dose level, and the other in combination with bevacizumab at a study drug dose of 1200 µg.

In conclusion, PF-07062119 exhibited a relatively favorable benefit-risk profile and modest clinical activity in advanced/metastatic gastrointestinal tumors. However, the comprehensive PK, safety, and efficacy data do not support a transformational profile that would justify further clinical development towards registration.

The Phase 1 study C3861001 was terminated by the sponsor due to strategic business decisions.