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FRESCO-2: A global phase 3 multiregional clinical trial evaluating the efficacy and safety of fruquintinib in patients with refractory metastatic colorectal cancer

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Declaration of Interests

Arvind Dasari

- **Grants to Institution**
  - AAA/Novartis, Crinetics, Eisai, Guardant Health, HUTCHMED, Natera

- **Advisory Boards**
  - AAA/Novartis, Crinetics, HUTCHMED, Personalis, Voluntis

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Introduction

- The VEGF pathway is a key mediator of angiogenesis, which is necessary for tumor growth and metastasis[1]
- Fruquintinib is a highly selective and potent oral tyrosine kinase inhibitor of VEGFRs-1, -2, and -3[2]
- The phase 3 FRESCO study showed the efficacy and safety of fruquintinib in Chinese patients with mCRC in a 3L+ setting[3]
  - mOS improvement of 2.7 months with fruquintinib vs placebo (9.3 m vs 6.6 m; HR=0.65 [95% CI, 0.51-0.83]; $p<0.001$)
  - mPFS improvement of 1.9 months with fruquintinib vs placebo (3.7 m vs 1.8 m; HR=0.26 [95% CI, 0.21-0.34]; $p<0.001$)
  - Fruquintinib was approved in China in 2018 for 3L+ mCRC
  - Standard of care for mCRC in China differed from global patterns when FRESCO was conducted
- There remains an unmet need for effective treatment options for patients with refractory mCRC
- FRESCO-2 is a global phase 3 study evaluating the efficacy and safety of fruquintinib in more heavily pretreated mCRC patients reflective of current global treatment practices

1. Hicklin DJ et al. *J Clin Oncol* 2005; 2. Sun Q et al. *Cancer Biol Ther* 2014. 3. Li J et al. *JAMA* 2018.

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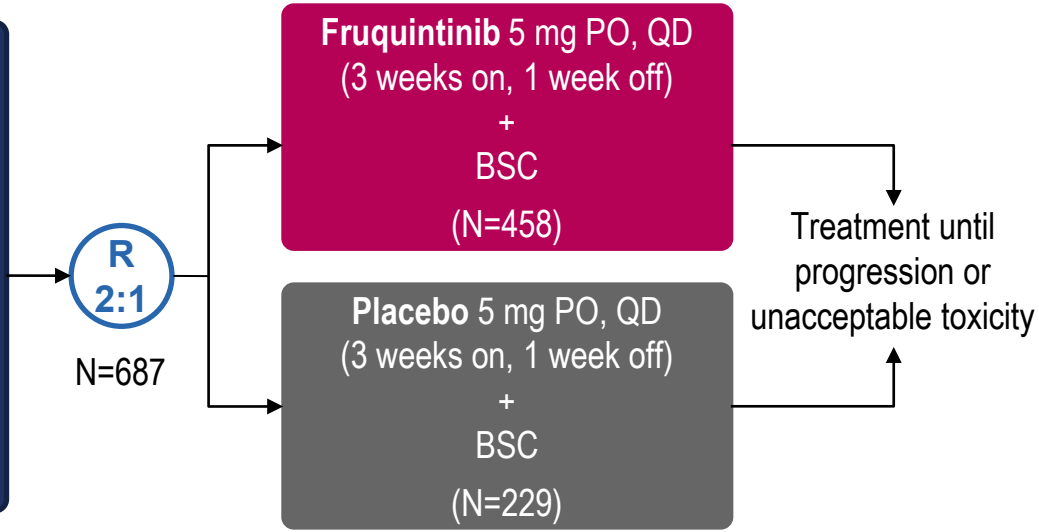
FRESCO-2 Study Design

Patient Eligibility

- Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and, if *RAS* wild type, an anti-EGFR therapy
- Progression on, or intolerance to, TAS-102 and/or regorafenib
- Prior treatment with an immune checkpoint inhibitor or BRAF inhibitor if indicated



Stratification Factors

- Prior therapy (TAS-102 vs regorafenib vs TAS-102 and regorafenib)
- *RAS* mutational status (wild-type vs mutant)
- Duration of metastatic disease (≤18 months vs >18 months)

Note: To ensure the patient population is reflective of clinical practice, the number of patients treated with prior regorafenib was limited to 344 patients (50%)

BSC, best supportive care.
NCT04322539.

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Study Objectives and Statistical Assumptions

- Objectives
  - **Primary: Overall Survival**
  - Key Secondary: Progression-Free Survival
  - Other Secondary: Objective Response Rate, Disease Control Rate, Safety
- Sample Size
  - 687 patients (480 OS events) would provide 90% power to detect a difference in OS with a HR of 0.73 at a 2-sided α of 0.05
  - Median OS assumption in the placebo arm is 5.0 months and median OS in fruquintinib arm is 6.8 months
  - Non-binding interim futility analysis at one-third (160) of OS events
- Safety monitored by independent data monitoring committee

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Patient and Disease Characteristics

ITT Population
Enrollment: Sep 2020 to Dec 2021
Data Cutoff: 24 June 2022

Characteristic, n (%)		Fruquintinib (N=461)	Placebo (N=230)
Age, y	Median (range) ≥ 65	64 (25, 82) 214 (46.4)	64 (30, 86) 111 (48.3)
Sex	Female Male	216 (46.9) 245 (53.1)	90 (39.1) 140 (60.9)
Region	North America Europe Asia Pacific	82 (17.8) 329 (71.4) 50 (10.8)	42 (18.3) 166 (72.2) 22 (9.6)
ECOG PS	0 1	196 (42.5) 265 (57.5)	102 (44.3) 128 (55.7)
Primary site at 1st diagnosis	Colon left Colon right Colon left and right Colon unknown Rectum only	192 (41.6) 97 (21.0) 4 (0.9) 25 (5.4) 143 (31.0)	92 (40.0) 53 (23.0) 2 (0.9) 13 (5.7) 70 (30.4)
Liver metastases	Yes	339 (73.5)	156 (67.8)

Characteristic, n (%)		Fruquintinib (N=461)	Placebo (N=230)
Duration of metastatic disease	≤ 18 mo > 18 mo	37 (8.0) 424 (92.0)	13 (5.7) 217 (94.3)
RAS status	WT Mutant	170 (36.9) 291 (63.1)	85 (37.0) 145 (63.0)
BRAF V600E mutation	No Yes Other/Unknown	401 (87.0) 7 (1.5) 5 (11.5)	198 (86.1) 10 (4.3) 22 (9.6)
Number of prior treatment lines in metastatic disease	Median (range) ≤ 3 > 3	5 (2, 16) 125 (27.1) 336 (72.9)	5 (2, 12) 64 (27.8) 166 (72.2)
Prior therapies	VEGF inhibitor EGFR inhibitor	445 (96.5) 180 (39.0)	221 (96.1) 88 (38.3)
Prior TAS-102 and/or regorafenib	TAS-102 Regorafenib Both	240 (52.1) 40 (8.7) 181 (39.3)	121 (52.6) 18 (7.8) 91 (39.6)

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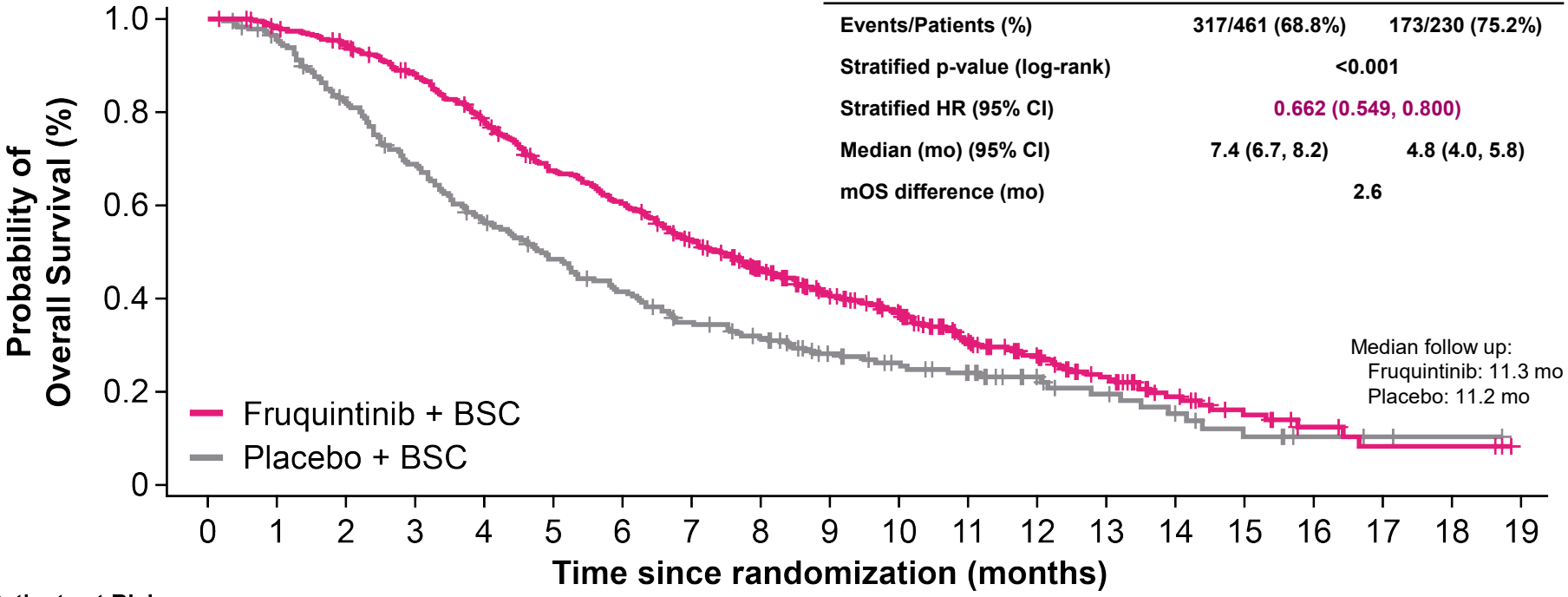
Primary Endpoint: Overall Survival

ITT Population



	Fruquintinib	Placebo
Events/Patients (%)	317/461 (68.8%)	173/230 (75.2%)
Stratified p-value (log-rank)	<0.001	
Stratified HR (95% CI)	0.662 (0.549, 0.800)	
Median (mo) (95% CI)	7.4 (6.7, 8.2)	4.8 (4.0, 5.8)
mOS difference (mo)	2.6	

Median follow up:
Fruquintinib: 11.3 mo
Placebo: 11.2 mo

Patients at Risk

Fruquintinib	461	449	429	395	349	297	266	224	184	143	113	79	58	41	23	14	7	4	4	0
Placebo	230	216	184	153	125	105	89	73	63	45	37	31	20	15	10	6	3	2	1	0

Subsequent anti-cancer medication balanced between the two arms: **29.4% fruquintinib arm** vs. **34.3% placebo arm**

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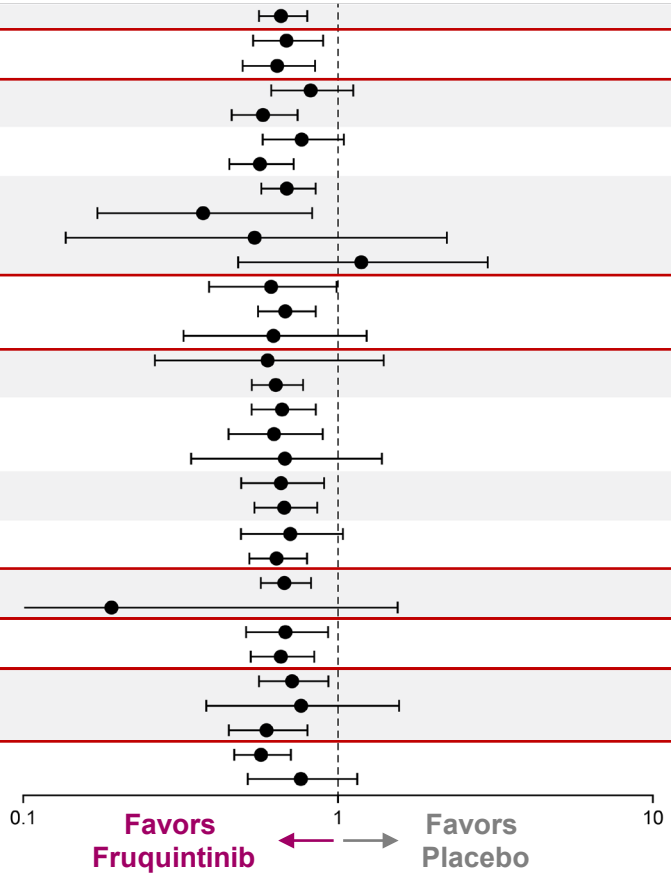
OS Subgroup Analysis

ITT Population

Subgroup		Fruquintinib n/N	Placebo n/N	HR (95% CI)
ITT population		317/461	173/230	0.662 (0.549, 0.800)
Age	< 65	171/247	89/119	0.694 (0.534, 0.903)
	≥ 65	146/214	84/111	0.648 (0.494, 0.851)
Sex	Female	149/216	61/90	0.828 (0.609, 1.125)
	Male	168/245	112/140	0.584 (0.456, 0.749)
ECOG PS	0	121/196	67/102	0.775 (0.573, 1.050)
	1	196/265	106/128	0.571 (0.499, 0.728)
Race	Caucasian	260/367	145/192	0.696 (0.567, 0.854)
	Asian	24/43	14/18	0.377 (0.171, 0.833)
	African American	7/13	5/7	0.550 (0.135, 2.231)
	Other	26/38	9/13	1.199 (0.478, 3.008)
Region	North America	50/82	29/42	0.620 (0.387, 0.995)
	Europe	237/329	130/166	0.688 (0.554, 0.855)
	Asia Pacific	30/50	14/22	0.631 (0.321, 1.241)
Duration of metastatic disease	≤ 18 mo	30/37	8/13	0.605 (0.260, 1.406)
	> 18 mo	287/424	165/217	0.642 (0.529, 0.779)
Primary tumor site at 1st diagnosis	Colon	195/279	109/137	0.672 (0.528, 0.855)
	Rectum	99/143	49/70	0.633 (0.446, 0.900)
	Colon and Rectum	23/39	15/23	0.686 (0.339, 1.388)
RAS status	WT	119/170	62/85	0.667 (0.489, 0.909)
	Mutant	198/291	111/145	0.683 (0.539, 0.865)
# of prior treatment lines in metastatic disease	≤ 3	80/125	45/64	0.714 (0.488, 1.043)
	>3	237/336	128/166	0.645 (0.519, 0.802)
Prior VEGFi	Yes	306/445	167/221	0.683 (0.565, 0.827)
	No	11/16	6/9	0.193 (0.024, 1.557)
Prior EGFRi	Yes	127/180	64/88	0.689 (0.507, 0.936)
	No	190/281	109/142	0.666 (0.524, 0.846)
Prior TAS-102 and Regorafenib	TAS-102	165/240	88/121	0.723 (0.557, 0.938)
	Regorafenib	25/40	12/18	0.772 (0.379, 1.573)
	Both	127/181	73/91	0.600 (0.447, 0.805)
Liver metastases	Yes	255/339	132/156	0.576 (0.465, 0.713)
	No	62/122	41/74	0.771 (0.513, 1.158)



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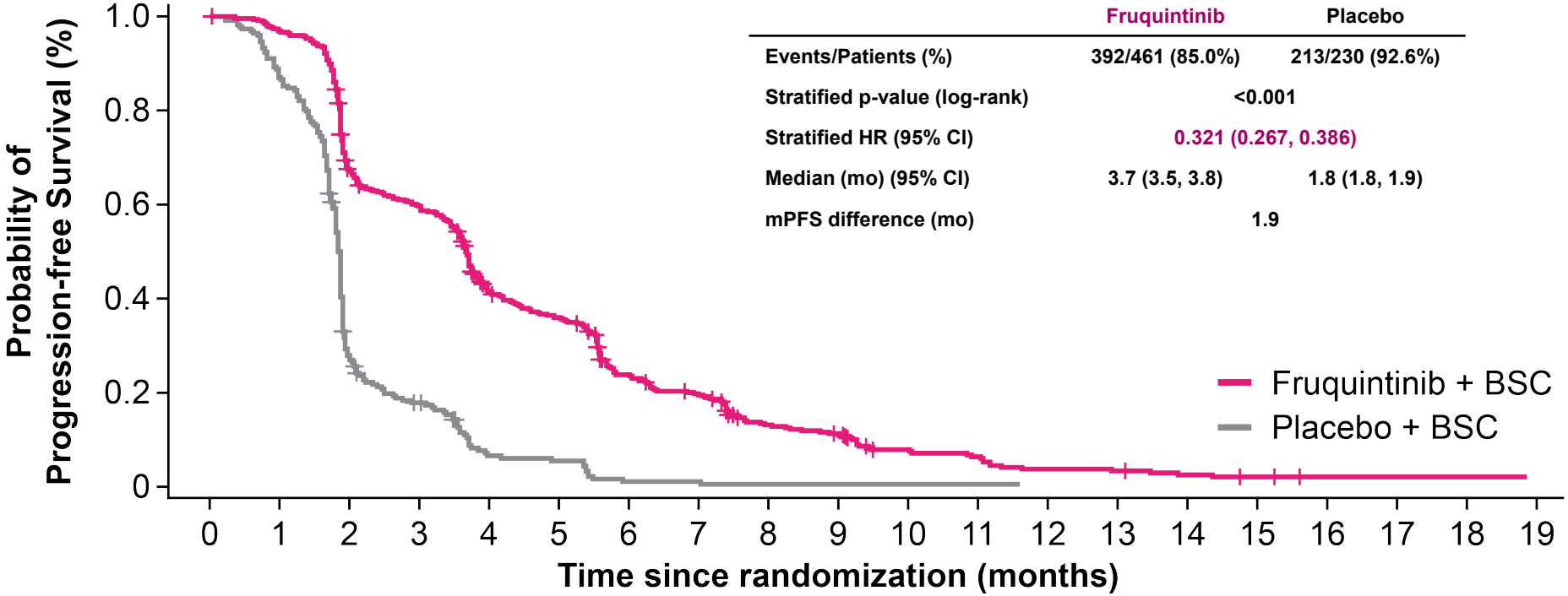
Progression-Free Survival

ITT Population



	Fruquintinib	Placebo
Events/Patients (%)	392/461 (85.0%)	213/230 (92.6%)
Stratified p-value (log-rank)	<0.001	
Stratified HR (95% CI)	0.321 (0.267, 0.386)	
Median (mo) (95% CI)	3.7 (3.5, 3.8)	1.8 (1.8, 1.9)
mPFS difference (mo)	1.9	

Patients at Risk

Fruquintinib	461	430	291	256	170	146	89	71	43	36	21	17	10	9	6	4	2	2	2
Placebo	230	194	60	36	12	10	2	2	1	1	1	1	0						

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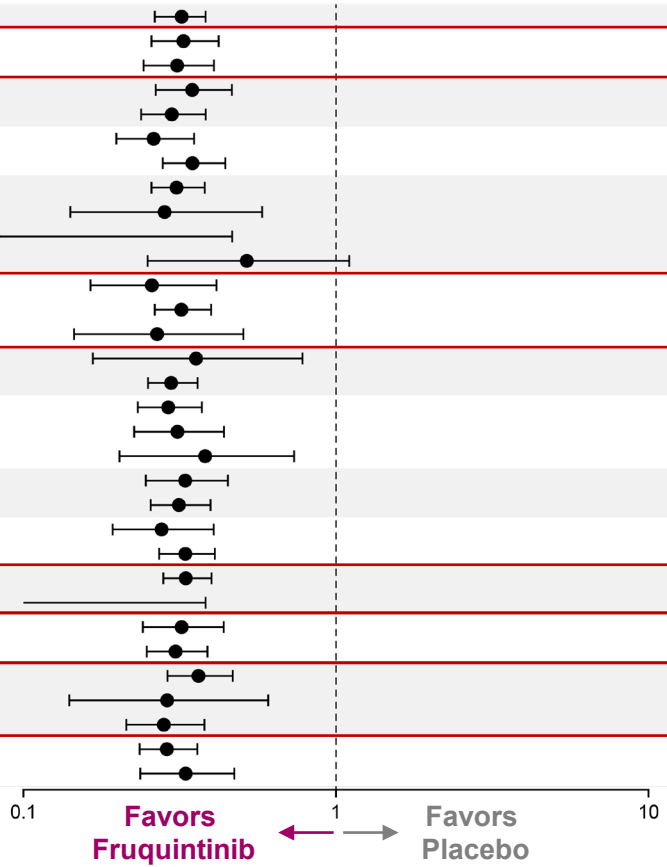
PFS Subgroup Analysis

ITT Population

Subgroup		Fruquintinib n/N	Placebo n/N	HR (95% CI)
ITT population		392/461	213/230	0.321 (0.267, 0.386)
Age	< 65	214/247	111/119	0.329 (0.255, 0.424)
	≥ 65	178/214	102/111	0.314 (0.241, 0.410)
Sex	Female	190/216	81/90	0.351 (0.263, 0.468)
	Male	202/245	132/140	0.302 (0.237, 0.385)
ECOG PS	0	169/196	90/102	0.264 (0.197, 0.354)
	1	223/265	123/128	0.351 (0.277, 0.446)
Race	Caucasian	312/367	176/192	0.313 (0.255, 0.383)
	Asian	37/43	17/18	0.286 (0.140, 0.584)
	African American	9/13	7/7	0.081 (0.014, 0.468)
	Other	34/38	13/13	0.525 (0.248, 1.110)
Region	North America	64/82	36/42	0.261 (0.163, 0.417)
	Europe	283/329	158/166	0.324 (0.261, 0.401)
	Asia Pacific	45/50	19/22	0.271 (0.144, 0.509)
Duration of metastatic disease	≤ 18 mo	35/37	11/13	0.361 (0.166, 0.787)
	> 18 mo	357/424	202/217	0.300 (0.249, 0.363)
Primary tumor site at 1st diagnosis	Colon	241/279	127/137	0.294 (0.231, 0.375)
	Rectum	118/143	64/70	0.315 (0.225, 0.441)
	Colon and Rectum	33/39	22/23	0.386 (0.202, 0.739)
RAS status	WT	145/170	76/85	0.333 (0.245, 0.454)
	Mutant	247/291	137/145	0.318 (0.254, 0.399)
# of prior treatment lines in metastatic disease	≤ 3	108/125	57/64	0.280 (0.192, 0.409)
	>3	284/336	156/166	0.334 (0.270, 0.412)
Prior VEGFi	Yes	377/445	206/221	0.335 (0.278, 0.402)
	No	15/16	7/9	0.020 (0.001, 0.385)
Prior EGFRi	Yes	154/180	79/88	0.325 (0.239, 0.440)
	No	238/281	134/142	0.310 (0.247, 0.391)
Prior TAS-102 and Regorafenib	TAS-102	210/240	111/121	0.367 (0.287, 0.470)
	Regorafenib	29/40	16/18	0.292 (0.139, 0.611)
	Both	153/181	86/91	0.285 (0.212, 0.382)
Liver metastases	Yes	297/339	149/156	0.291 (0.234, 0.362)
	No	95/122	64/74	0.334 (0.235, 0.476)



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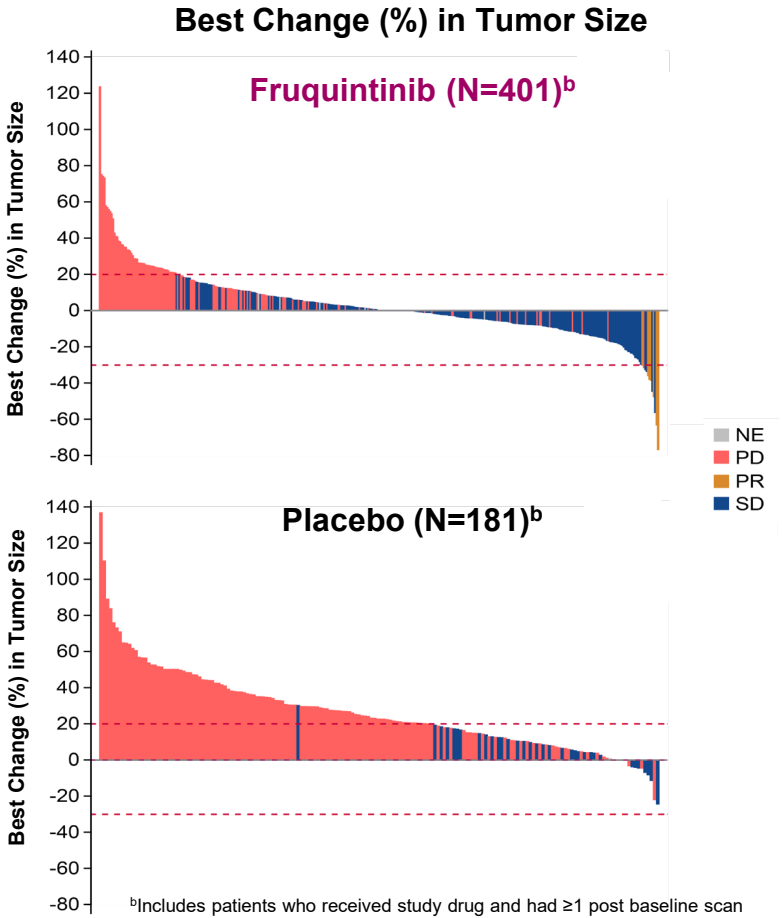
Anti-Tumor Activity

Category	Fruquintinib N=461	Placebo N=230
Confirmed ORR (CR + PR)[a]	7 (1.5)	0
Adjusted difference (95% CI)	1.5 (0.4, 2.7)	
Two-sided p-value	0.059	
Disease Control Rate (CR + PR + SD)	**256 (55.5)**	**37 (16.1)**
Adjusted difference (95% CI)	39.4 (32.8, 46.0)	
Two-sided p-value	< 0.001	

[a]No CR reported

- Tumor assessments were performed every 8 weeks until disease progression



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Study Drug Exposure

Category	Fruquintinib (N=456)[a]	Placebo (N=230)[a]
Cycles received, median (Q1, Q3)	3.00 (2.00, 6.00)	2.00 (1.00, 3.00)
Relative dose intensity (%), median (Q1, Q3)	91.63 (74.13, 99.52)	97.62 (86.67, 100.00)
Number of patients with drug interruption, n (%)	312 (68.4)	110 (47.8)
Number of patients with any dose reduction, n (%)	121 (26.5)	10 (4.3)
Reduction from 5mg to 4mg	121 (26.5)	10 (4.3)
Reduction from 4mg to 3mg	45 (9.9)	0

[a]Of 5 patients assigned to the fruquintinib arm, 3 did not receive fruquintinib treatment and 2 patients received placebo instead. Two patients assigned to the placebo arm did not receive treatment.

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Overview of TEAEs

Category, n (%)	Fruquintinib (N=456)	Placebo (N=230)
Any TEAE	**451 (98.9)**	**213 (92.6)**
Grade ≥ 3	286 (62.7)	116 (50.4)
Treatment-related Grade ≥ 3	164 (36.0)	26 (11.3)
Leading to Death	48 (10.5)	45 (19.6)
Any Serious TEAE	**171 (37.5)**	**88 (38.3)**
Grade ≥ 3	162 (35.5)	85 (37.0)
TEAEs leading to dose modifications		
Dose interruption	247 (54.2)	70 (30.4)
Dose reduction	110 (24.1)[a]	9 (3.9)
Dose discontinuation	93 (20.4)[b]	49 (21.3)

[a]Most common TEAEs leading to dose reduction in the fruquintinib arm: hand-foot syndrome (5.3%), hypertension (3.7%), and asthenia (3.5%).
[b]Most common TEAE leading to dose discontinuation in the fruquintinib arm: asthenia (1.5%)

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Most Common TEAEs
(Any Grade ≥ 15% in Either Arm)

TEAE, n (%)	Fruquintinib (N=456)		Placebo (N=230)	
	Any Grade	Grade ≥ 3	Any Grade	Grade ≥ 3
Patients with ≥1 TEAE	451 (98.9)	286 (62.7)	213 (92.6)	116 (50.4)
Hypertension	168 (36.8)	62 (13.6)	20 (8.7)	2 (0.9)
Asthenia	155 (34.0)	35 (7.7)	52 (22.6)	9 (3.9)
Decreased appetite	124 (27.2)	11 (2.4)	40 (17.4)	3 (1.3)
Diarrhea	110 (24.1)	16 (3.5)	24 (10.4)	0
Hypothyroidism	94 (20.6)	2 (0.4)	1 (0.4)	0
Fatigue	91 (20.0)	18 (3.9)	37 (16.1)	2 (0.9)
Hand-foot syndrome	88 (19.3)	29 (6.4)	6 (2.6)	0
Abdominal pain	83 (18.2)	14 (3.1)	37 (16.1)	7 (3.0)
Nausea	79 (17.3)	3 (0.7)	42 (18.3)	2 (0.9)
Proteinuria	79 (17.3)	8 (1.8)	12 (5.2)	2 (0.9)
Constipation	78 (17.1)	2 (0.4)	22 (9.6)	0
Dysphonia	74 (16.2)	0	12 (5.2)	0

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Conclusions

- FRESCO-2 met the primary endpoint of OS
  - mOS improvement of 2.6 months with fruquintinib vs placebo (7.4 m vs 4.8 m; HR=0.66 [95% CI, 0.55-0.80]; $p < 0.001$)
  - OS improvement was consistent across all pre-specified subgroups
- FRESCO-2 met the key secondary endpoint of PFS
  - mPFS improvement of 1.9 months with fruquintinib vs placebo (3.7 m vs 1.8 m; HR=0.32 [95% CI, 0.27-0.39]; $p < 0.001$)
  - PFS improvement was consistent across all pre-specified subgroups
- Fruquintinib was well tolerated with a safety profile consistent with the previously established monotherapy profile
- The FRESCO-2 results are consistent with those of FRESCO and support a new global oral treatment option for patients with refractory mCRC, which enriches the continuum of care for these patients

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