Efficacy and Safety of Erdafitinib in Patients with Advanced or Metastatic Cholangiocarcinoma and *FGFR* Alterations: Pooled Analysis of RAGNAR and LUC2001 Studies

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KEY TAKEAWAY

Data from a pooled analysis of the RAGNAR and LUC2001 studies confirm robust efficacy of erdafitinib in a diverse population of patients with advanced or metastatic CCA and prespecified *FGFR* fusions or mutations

CCA, cholangiocarcinoma; *FGFR*, fibroblast growth factor receptor

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CONCLUSIONS

- Erdafitinib demonstrated a high ORR (55.1%), DCR (98.7%) and durable responses (mDOR: 6.9 months) per IRC in patients with advanced or metastatic CCA harboring susceptible *FGFR* alterations
- Safety data were consistent with the known safety profile of erdafitinib

CCA, cholangiocarcinoma; DCR, disease control rate; *FGFR*, fibroblast growth factor receptor; IRC, Independent Review Committee; mDOR, median duration of response; ORR, objective response rate

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INTRODUCTION

- Patients with advanced CCA have a median survival of <12 months and 5-year survival rates of ≤10%[1,2]
- Up to 15% of patients with CCA harbor *FGFR* gene aberrations, and selective FGFR inhibitors have been shown to improve outcomes in *FGFR*-altered CCA[3]
- Erdafitinib is an oral selective pan-*FGFR* inhibitor approved in the US for the treatment of adults with locally advanced or metastatic urothelial carcinoma with susceptible *FGFR3* alterations who have progressed on or after ≥1 line of prior systemic therapy[4]
  - Primary analyses from the RAGNAR (in various solid tumors) and LUC2001 studies have shown efficacy and manageable safety of erdafitinib in patients with advanced CCA and *FGFR* alterations[5,6]
- **Here we report a pooled analysis of patients with CCA treated in the RAGNAR and LUC2001 studies**

1. Ramírez-Merino N, et al. *World J Gastrointest Oncol*. 2013;5:171-176. 2. Yu TH, et al. *Sci Rep*. 2021;11:3990. 3. Goyal L, et al. *Cancer Treat Rev*. 2021;95:102170. 4. FDA approves erdafitinib for locally advanced or metastatic urothelial carcinoma. 2024; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-erdafitinib-locally-advanced-or-metastatic-urothelial-carcinoma. 5. Pant S, et al. *Lancet Oncol*. 2023;24:925-935. 6. Feng YH, et al. Poster #430 presented at the ASCO Gastrointestinal Cancers Symposium 2022; San Francisco, CA, USA.
CCA, cholangiocarcinoma; *FGFR*, fibroblast growth factor receptor; US, United States

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METHODS

RAGNAR study design (NCT04083976)[1]

- A single-arm, multicenter, phase 2 study in 15 countries
- Patients: ages ≥12 years with advanced or metastatic tumors of any histology (except urothelial cancer) with predefined *FGFR1–4* alterations and disease progression on ≥1 previous line of systemic therapy, who exhausted all standard therapies
  - Treatment: erdafitinib 8 mg QD (with pharmacodynamically guided up-titration to 9 mg/day) on continuous 21-day cycles

LUC2001 study design (NCT02699606)

- An open-label, multicenter, phase 2a study in Asian patients (China, Taiwan, and South Korea)
- Patients: adults with advanced non-small cell lung cancer, urothelial cancer, esophageal cancer, or CCA with predefined *FGFR1–4* alterations and disease progression on ≥1 prior line of systemic therapy
  - Treatment: erdafitinib 8 mg QD (with pharmacodynamically guided up-titration to 9 mg/day) on 28-day treatment cycles

1. Pant S, et al. *Lancet Oncol*. 2023;24:925-935

CCA, cholangiocarcinoma; *FGFR*, fibroblast growth factor receptor; QD, once daily

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METHODS

Outcomes

- Efficacy
  - objective response rate (ORR, complete response [CR] + partial response [PR]) per RECIST 1.1 criteria by an Independent Review Committee (IRC)
  - duration of response (DOR)
  - disease control rate (DCR; i.e., CR+PR+stable disease [SD])
  - progression free survival (PFS)
  - overall survival (OS)

- Safety: treatment-emergent adverse events (TEAEs)

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RESULTS

Baseline demographics (treated patients)

- At data cutoff (RAGNAR: December 4, 2023; LUC2001: November 19, 2021)
  - 78 patients with CCA received erdafitinib (RAGNAR: n=66; LUC2001: n=12)
  - Median efficacy follow-up was 14.7 months
- Patients had a median age of 56 years; 60.3% were female; 47.4% were white, and 38.5% were Asian

Characteristics	N=78
Age, median (range), years	56.0 (24; 77)
Sex, women, n (%)	47 (60.3)
Race, n (%)	
White	37 (47.4)
Asian	30 (38.5)
Black or African American	2 (2.6)
Native Hawaiian or other Pacific Islander	1 (1.3)
Not Reported	8 (10.3)

CCA, cholangiocarcinoma

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RESULTS

Baseline disease characteristics (treated patients)

- Patients had a median of 2 prior lines of therapy; 92.0% patients had visceral metastases, and 16.7% of patients responded to their last line of therapy
- Overall, 93.6% of patients had *FGFR2* alterations, and 91.0% had *FGFR* fusions
- The most frequently co-altered genes among CCA patients (n=31) assessed for *FGFR* co-alterations in RAGNAR were *BAP1* (19%), *CDKN2A, CDKN2B* (13% each), *PIK3CA* (10%), *MTAP* (6%), and *TP53* (3%)

Characteristics	N=78
ECOG performance status, n (%)	
0	34 (43.6)
1	44 (56.4)
Visceral metastases, n (%)[a]	69 (92.0)
Time from progression/relapse on the last line of treatment to 1st dose, median (range), months[b]	0.95 (0.1-67.1)
Number of prior lines of anti-cancer therapies, n (%)	
Median (range)	2.0 (1.0; 6.0)
1	31 (39.7)
2	33 (42.3)
≥3	14 (17.9)
Prior systemic therapy in advanced/metastatic setting, n (%)	
Chemotherapy	78 (100)
Immunotherapy	11 (14.1)
Other systemic therapy	69 (88.5)
Best response to last line of prior systemic therapy	
ORR, n (%) [95% CI]	13 (16.7) [9.2-26.8]
FGFR altered gene, n (%)	
FGFR2	73 (93.6)
FGFR3	5 (6.4)
FGFR alteration type, n (%)	
Fusion	71 (91.0)
Mutation	7 (9.0)

[a]n=75, applicable only to patients with metastatic disease; [b]n=75, applicable only to patients with non missing values for progression/relapse date of last line of treatment.
CCA, cholangiocarcinoma; CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; *FGFR*, fibroblast growth factor receptor; ORR, objective response rate

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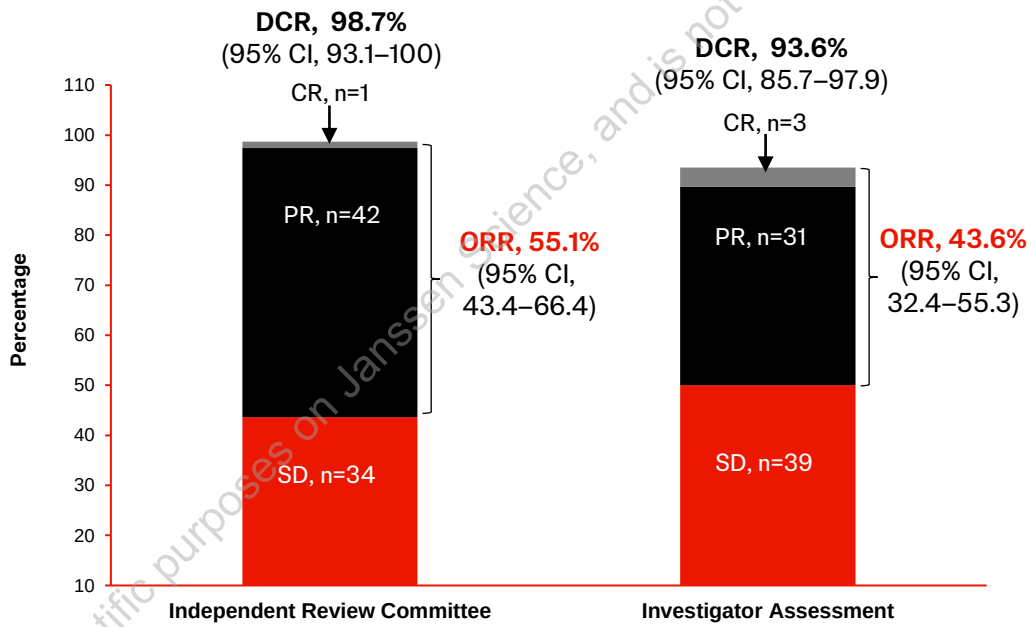
RESULTS

Efficacy outcomes (treated patients)

- ORR per IRC was 55.1% (95% CI, 43.4–66.4), and the DCR was 98.7% (95% CI, 93.1–100; Figure 1)
- The median time to response was 1.7 months (range, 1.4–2.8), and the median DOR was 6.9 months (95% CI, 4.37–8.61) per IRC
- The clinical benefit rate (CR+PR+SD ≥4 months) per IRC was 70.5% (95% CI, 59.1–80.3)
- The median PFS was 8.5 (95% CI, 6.83–9.72) months, and the median OS was 18.1 (95% CI, 13.40–24.28) months



Median (95% CI), months	N=78
DOR (per IRC)	6.9 (4.37–8.61)
PFS (per IRC)	8.5 (6.83–9.72)
OS	18.1 (13.40–24.28)

CI, confidence interval; CR; complete response; DCR, disease control rate; DOR, duration of response; IRC, Independent Review Committee; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; SD, stable disease

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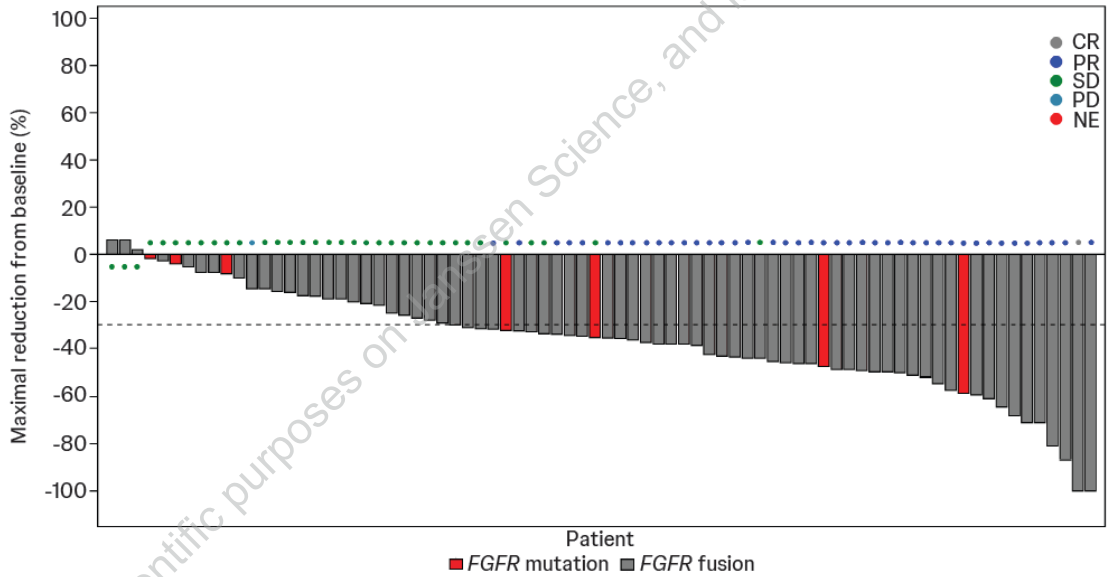
RESULTS

Efficacy by *FGFR* alterations (treated patients)

	ORR, n (%), [95% CI]	Median DOR (95% CI), months
FGFR2 alteration (n=73)	41 (56.2) [44.1–67.8]	6.93 (4.37–8.28)
FGFR3 alteration (n=5)	2 (40.0) [5.3–85.3	NE (2.83–NE)
FGFR mutation (n=7)	2 (28.6) (3.7–71.0)	NE (2.76–NE)
FGFR fusion (n=71)	41 (57.7) (45.4–69.4)	6.93 (4.37–8.28)



- Responses were observed in patients with altered *FGFR2* and *FGFR3* genes and across both *FGFR* mutations and fusions
- Objective response to erdafitinib in patients with *FGFR* co-alterations was similar to those without co-alterations (data not shown)

CI, confidence interval; CR, complete response; DOR, duration of response; *FGFR*, fibroblast growth factor receptor; IRC, Independent Review Committee; NE, non-estimable, ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease

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RESULTS

Safety summary

TEAEs, n (%)	N=78
Any TEAEs	78 (100)
Grade ≥3 TEAEs	50 (64.1)
Serious TEAEs	12 (15.4)
TEAEs leading to dose reduction	65 (83.3)
TEAEs leading to dose interruption	64 (82.1)
TEAEs leading to treatment discontinuation	6 (7.7)
TEAEs leading to death	0

Data are n (%). Adverse events are coded using MedDRA Version 24.1. Patients were counted only once for any given event, regardless of the number of times they actually experienced the event.
TEAEs, treatment-emergent adverse events

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RESULTS

TEAEs

- The most common drug-related TEAEs were hyperphosphatemia (82.1%), stomatitis (69.2%), palmar-plantar erythrodysesthesia (51.3%), diarrhea (50.0%), and dry mouth (48.7%)

TEAEs, n (%)	N=78	
TEAE by preferred term in ≥20% of patients	**Any grade**	**Grade ≥3**
Hyperphosphatemia	64 (82.1)	4 (5.1)
Stomatitis	54 (69.2)	14 (17.9)
Palmar-plantar erythrodysesthesia	40 (51.3)	5 (6.4)
Diarrhea	39 (50.0)	2 (2.6)
Dry mouth	38 (48.7)	2 (2.6)
Alopecia	25 (32.1)	0
Dry skin	25 (32.1)	2 (2.6)
Onycholysis	21 (26.9)	7 (9.0)
Dry eye	19 (24.4)	1 (1.3)
Nail discoloration	18 (23.1)	1 (1.3)
Epistaxis	18 (23.1)	0
Paronychia	17 (21.8)	4 (5.1)
Increased AST	17 (21.8)	0
Dysgeusia	17 (21.8)	0
Increased ALT	16 (20.5)	3 (3.8)

Data are n (%). Adverse events are coded using MedDRA Version 24.1. Patients were counted only once for any given event, regardless of the number of times they actually experienced the event.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; TEAEs, treatment-emergent adverse events

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