LYTGOBI
(futibatinib) tablets

LYTGOBI® (futibatinib): key findings from FOENIX-CCA2

TAIHO ONCOLOGY

LYT-PM-UK-0016 | June 2026
Marketing Authorization Holder: Taiho Pharma Netherlands B.V., Netherlands.
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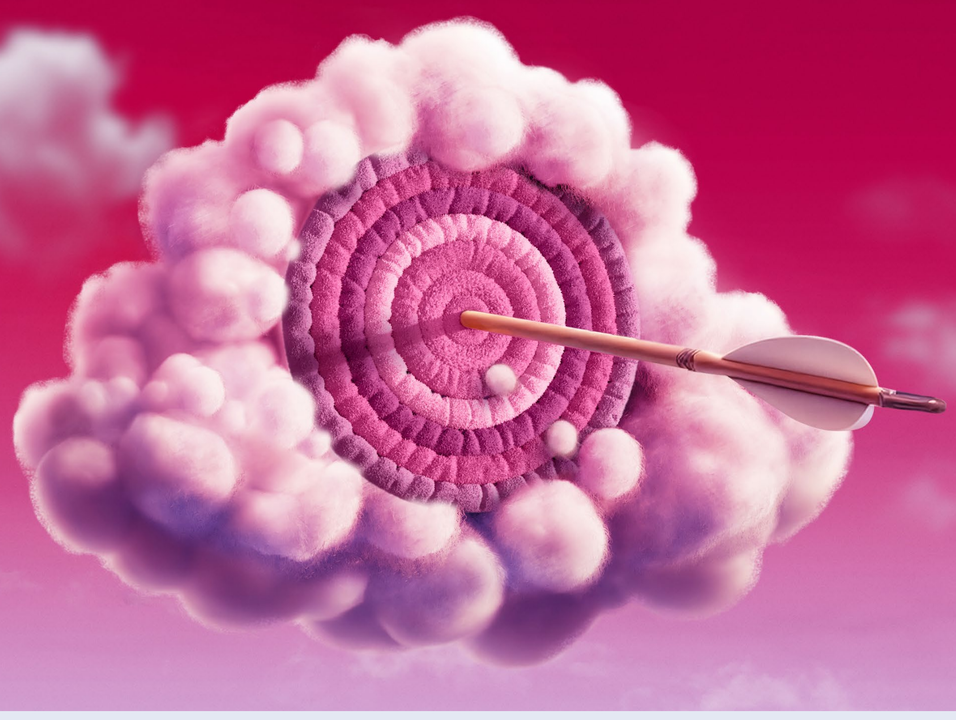

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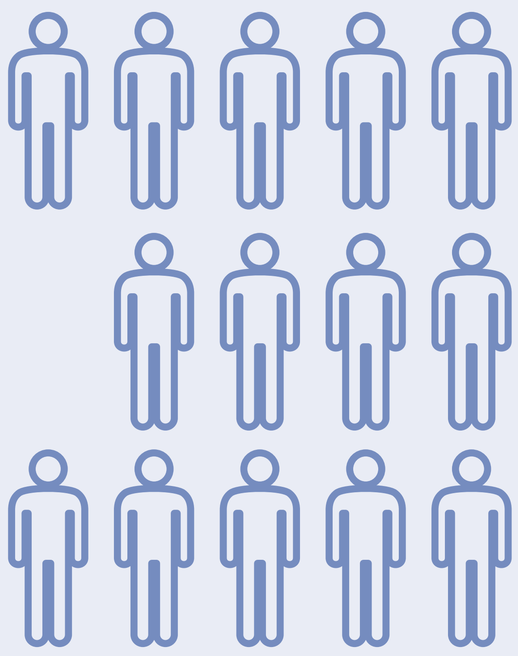
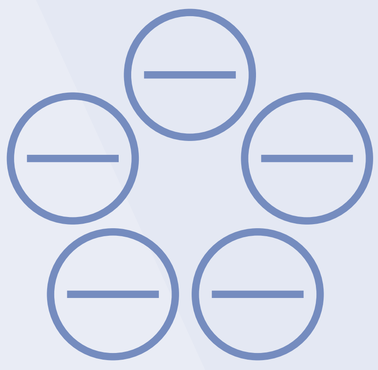
The efficacy and safety of LYTGOBI were reported in the FOENIX-CCA2 study[1]

- LYTGOBI is an irreversible FGFR inhibitor that binds covalently to a distinct site within the FGFR kinase domain, differentiating it from reversible ATP-competitive inhibitors and reducing susceptibility to on-target resistance mutations[1,2]
- FGFR-altered signalling plays an important role in oncogenesis, making it a key target for therapy in CCA[3]
- FOENIX-CCA2 was a multinational, open-label, single-arm, Phase 2 study in adult patients with previously treated, unresectable, locally advanced or metastatic iCCA harbouring an *FGFR2* fusion or rearrangement[1]

103
patients enrolled*[1]





20 mg
once daily

(five 4 mg tablets)

Key eligibility criteria[1]

- Unresectable or metastatic iCCA
- *FGFR2* fusion or rearrangements†
- Radiologically measurable disease per RECIST v1.1
- Progression after systemic therapy (incl. ≥1 previous regimen of gemcitabine + platinum-based chemotherapy)
- ECOG PS 0 or 1
- No prior treatment with an FGFR inhibitor

Dosing regimen[1]

- Continued until disease progression, drug intolerance or if any other discontinuation criteria was met
- Two dose reductions (to 16 mg and then to 12 mg) were permitted to manage TEAEs
- Treatment was discontinued if treatment-emergent ADRs did not resolve after two dose modifications or if the next cycle of treatment was delayed by >21 days

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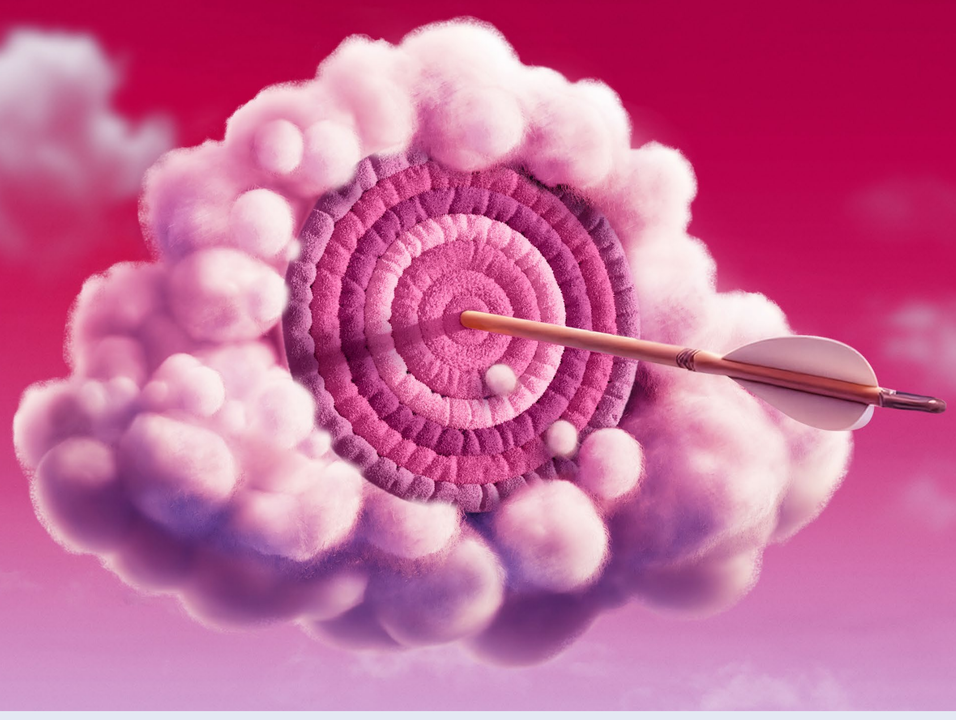

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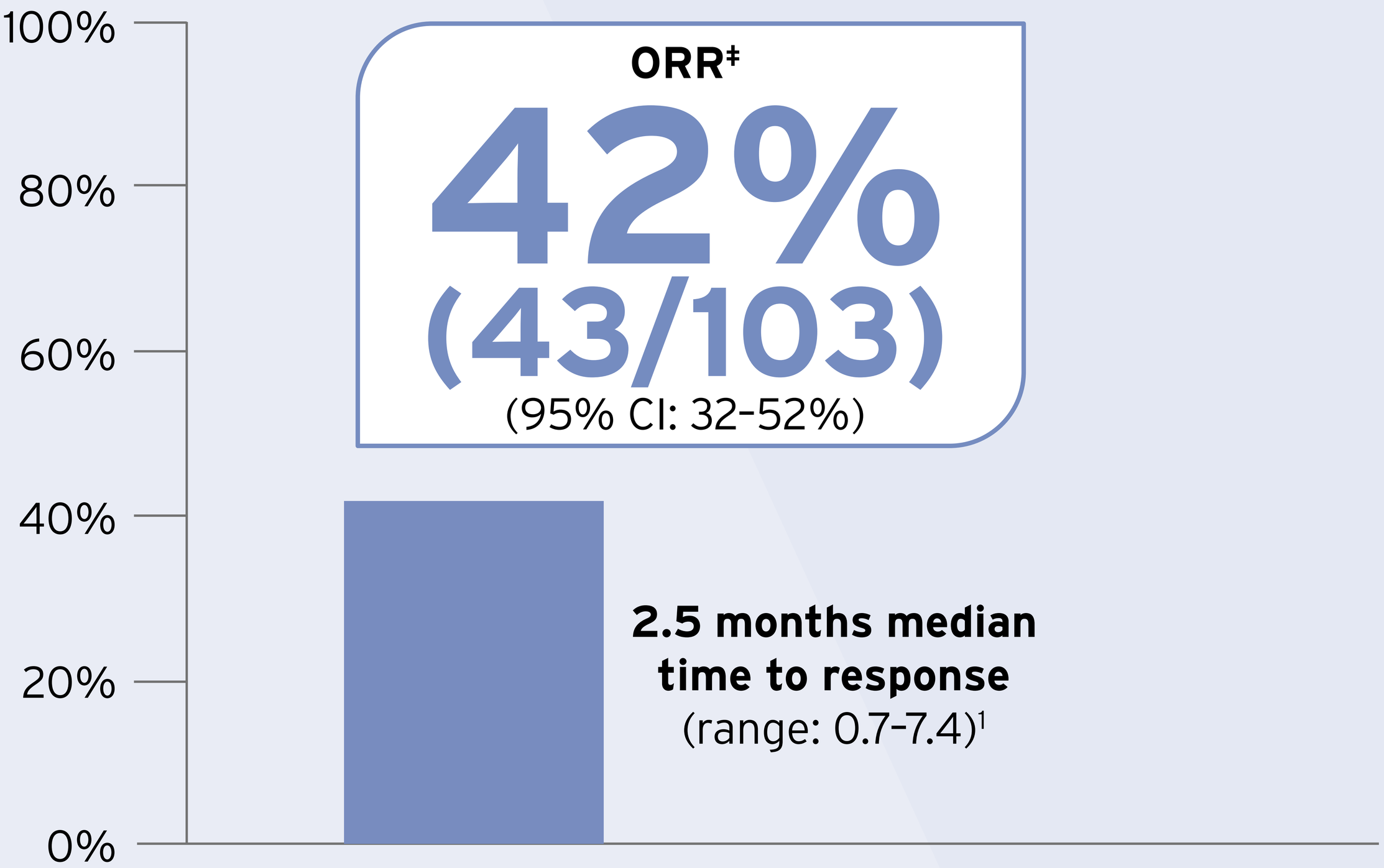
N=103 | Median follow-up: 17.1 months[1]

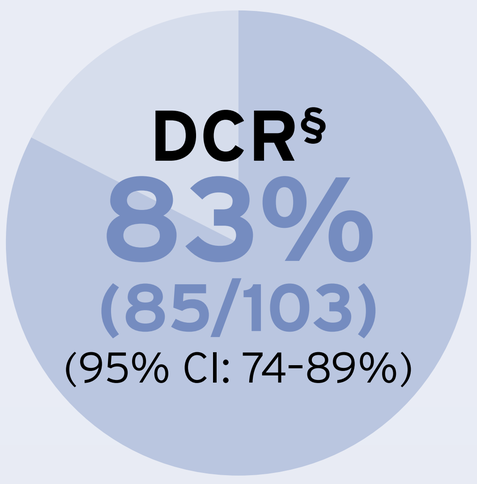
Primary endpoint[1]



ORR‡
42%
(43/103)
(95% CI: 32-52%)

2.5 months median time to response
(range: 0.7-7.4)[1]

Secondary endpoints[1]



DCR§
83%
(85/103)
(95% CI: 74-89%)

mDoR
9.7
months
(95% CI: 7.6-17.0)

mPFS
9.0
months
(95% CI: 6.9-13.1)

mOS
21.7
months
(95% CI: 14.5-NR)

Extended follow-up (25.0 months median): treatment response and survival outcomes were maintained in the overall study population[1,4]

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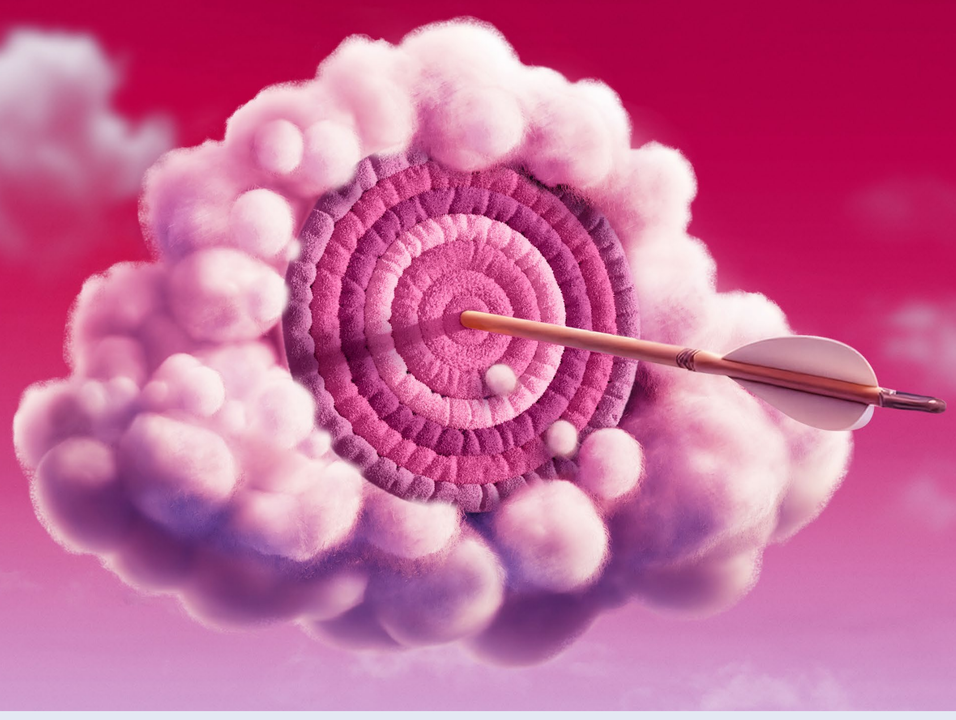

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Summary of the overall safety profile of LYTGOBI (safety population; N=145)[5]

The safety population is based on patients with CCA receiving LYTGOBI 20 mg orally once daily in the Phase 1 and Phase 2 studies[5]

Most common (≥20%) adverse reactions[5]	
Hyperphosphataemia	89.7%
Nail disorders	44.1%
Constipation	37.2%
Alopecia	35.2%
Diarrhoea	33.8%
Dry mouth	31%
Fatigue	31%
Nausea	28.3%
Dry skin	27.6%
Increased AST	26.9%
Abdominal pain	24.8%
Stomatitis	24.8%
Vomiting	23.4%
Palmar-plantar erythrodysaesthesia syndrome	22.8%
Arthralgia	21.4%
Decreased appetite	20.0%

- The most common serious adverse reactions were intestinal obstruction (1.4%) and migraine (1.4%)[5]
- Permanent discontinuation due to adverse reactions was reported in 7.6% of patients: the most common adverse reaction that led to dose discontinuation was stomatitis (1.4%); all other adverse reactions were single occurrences[5]

Gain a deeper understanding of the LYTGOBI data

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Please refer to the SmPC for full Prescribing Information:

LYTGOBI® (futibatinib) monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.[5]

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to 0800 04 89 461 or medicalinformation@taihoeurope.com.

This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. The Medicines and Healthcare products Regulatory Agency will review new information on this medicinal product at least every year and the Summary of Product Characteristics will be updated as necessary.[5]

References: 1. Goyal L, et al. *N Engl J Med*. 2023;388(3):228-239; **2.** Sootome H, et al. *Cancer Res*. 2020;80:4986-4997; **3.** Wang J, et al. *Ther Adv Med Oncol*. 2020;12:1758835920940948; **4.** Goyal L, et al. *N Engl J Med*. 2023;388(3):228-239. Supplementary appendix; **5.** LYTGOBI® (futibatinib) Summary of Product Characteristics.

Abbreviations
ADR, adverse reaction; AST, aspartate aminotransferase; ATP, adenosine triphosphate; CCA, cholangiocarcinoma; CI, confidence interval; ctNA, circulating tumour deoxyribonucleic acid; DCR, disease control rate; ECOG PS, Eastern Cooperative Oncology Group Performance Status; FGFR, fibroblast growth factor receptor; iCCA, intrahepatic cholangiocarcinoma; mDoR, median depth of response; mOS, median overall survival; mPFS, median progression-free survival; NR, not reached; ORR, objective response rate; RECIST, Response Evaluation Criteria in Solid Tumours; TEAE, treatment-emergent adverse event.

*Across 47 international sites between April 2018 and November 2019.[1] †Prospectively identified by local testing of tumour tissue or ctDNA, or by testing of tumour tissue at a central or local laboratory with the use of a 324-gene panel assay (FoundationOne CDx assay, Foundation Medicine).[1] ‡Per independent central review.[1] §DCR is the sum of complete response, partial response and stable disease.[1,4]

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