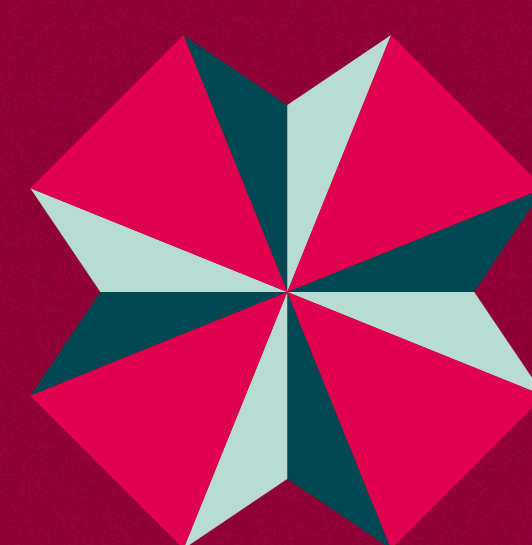
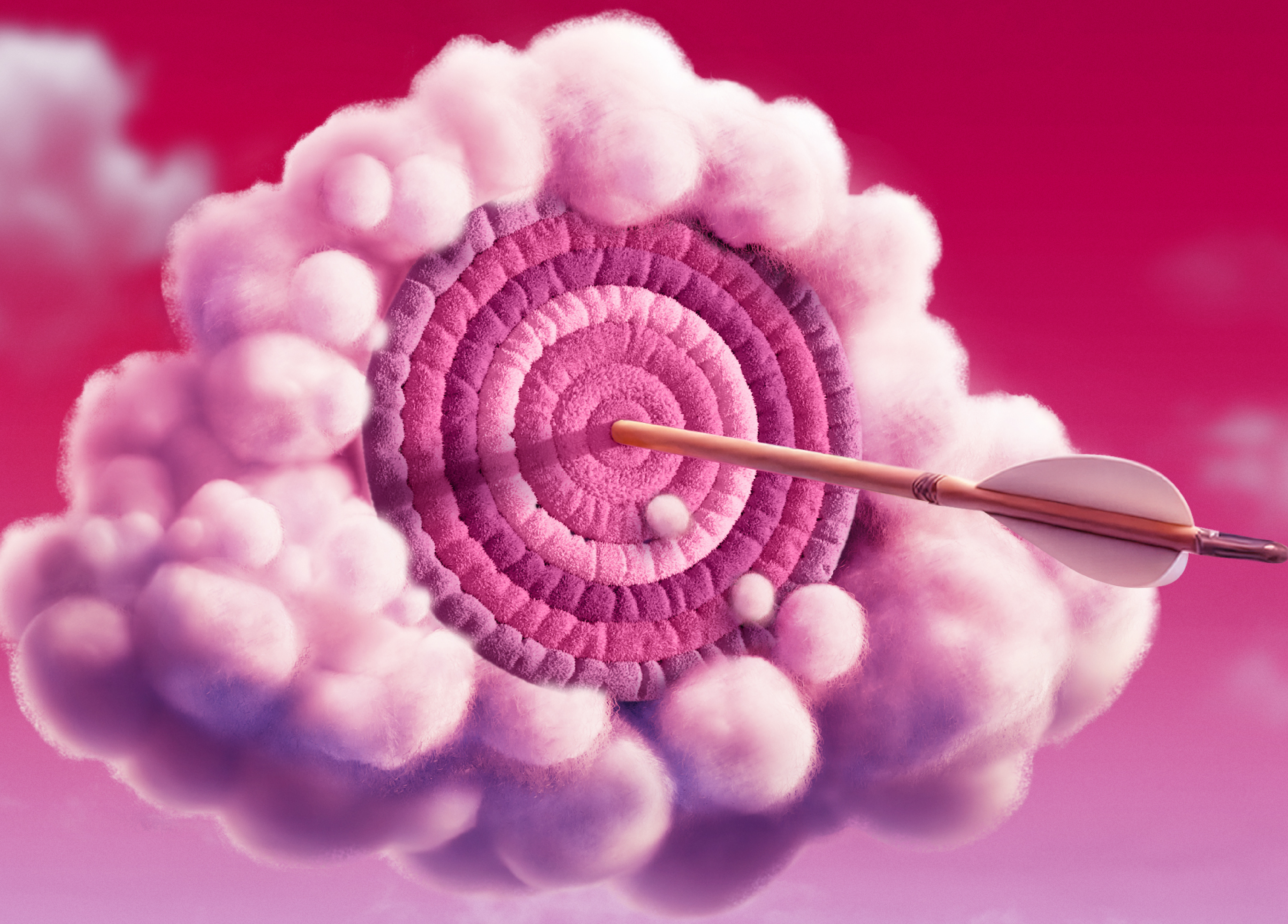


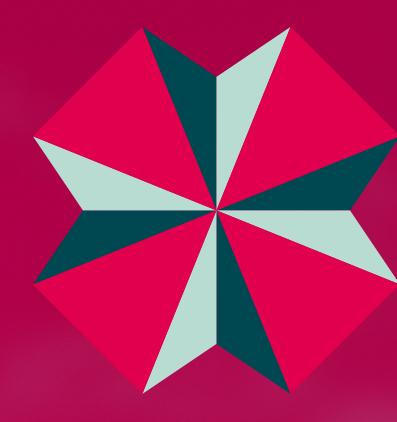
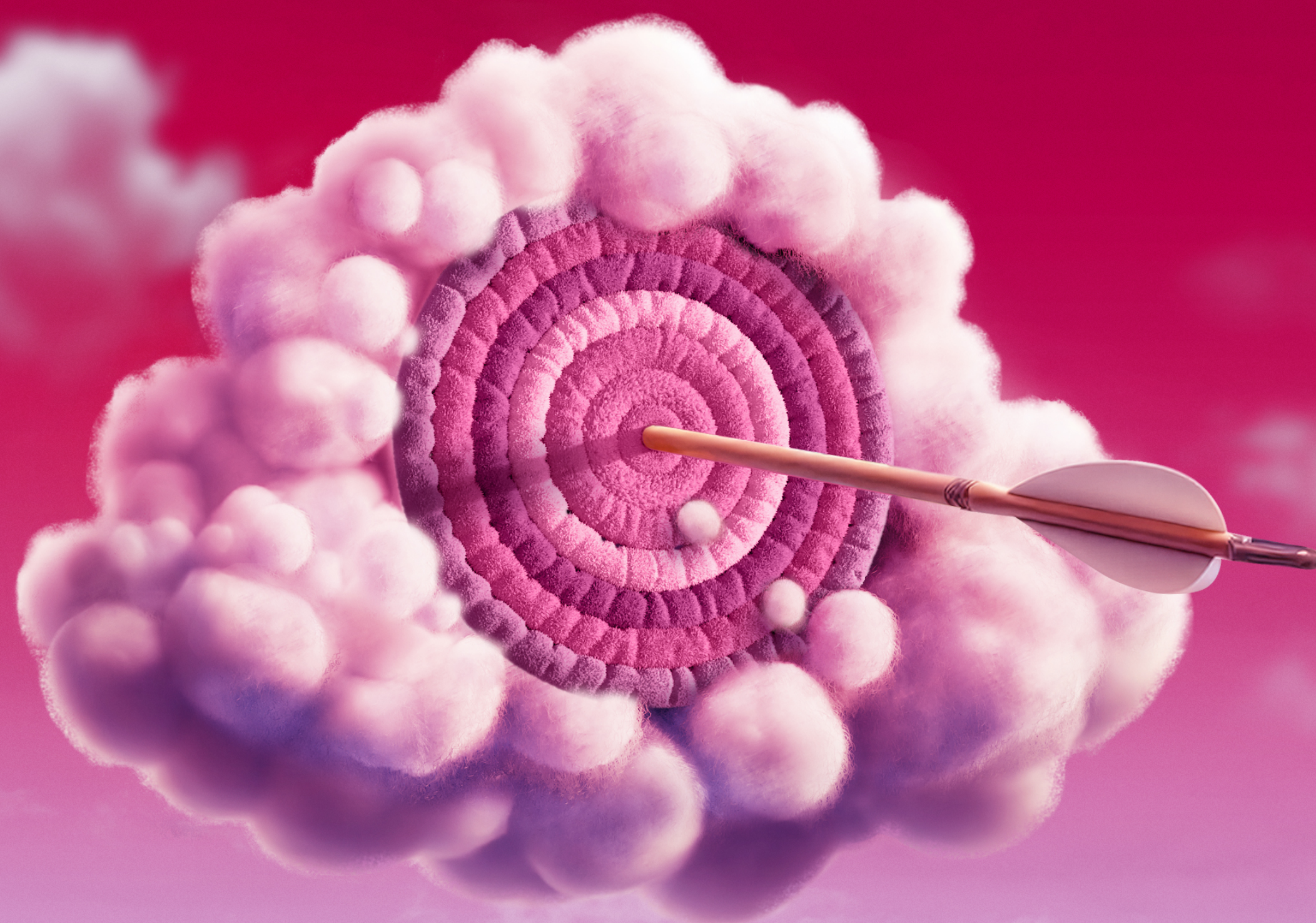


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(futibatinib) tablets

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



LYT-PM-ES-0019 | June 2025
Marketing Authorization Holder: Taiho Pharma Netherlands B.V., Netherlands.
Intended for Healthcare Professionals only.

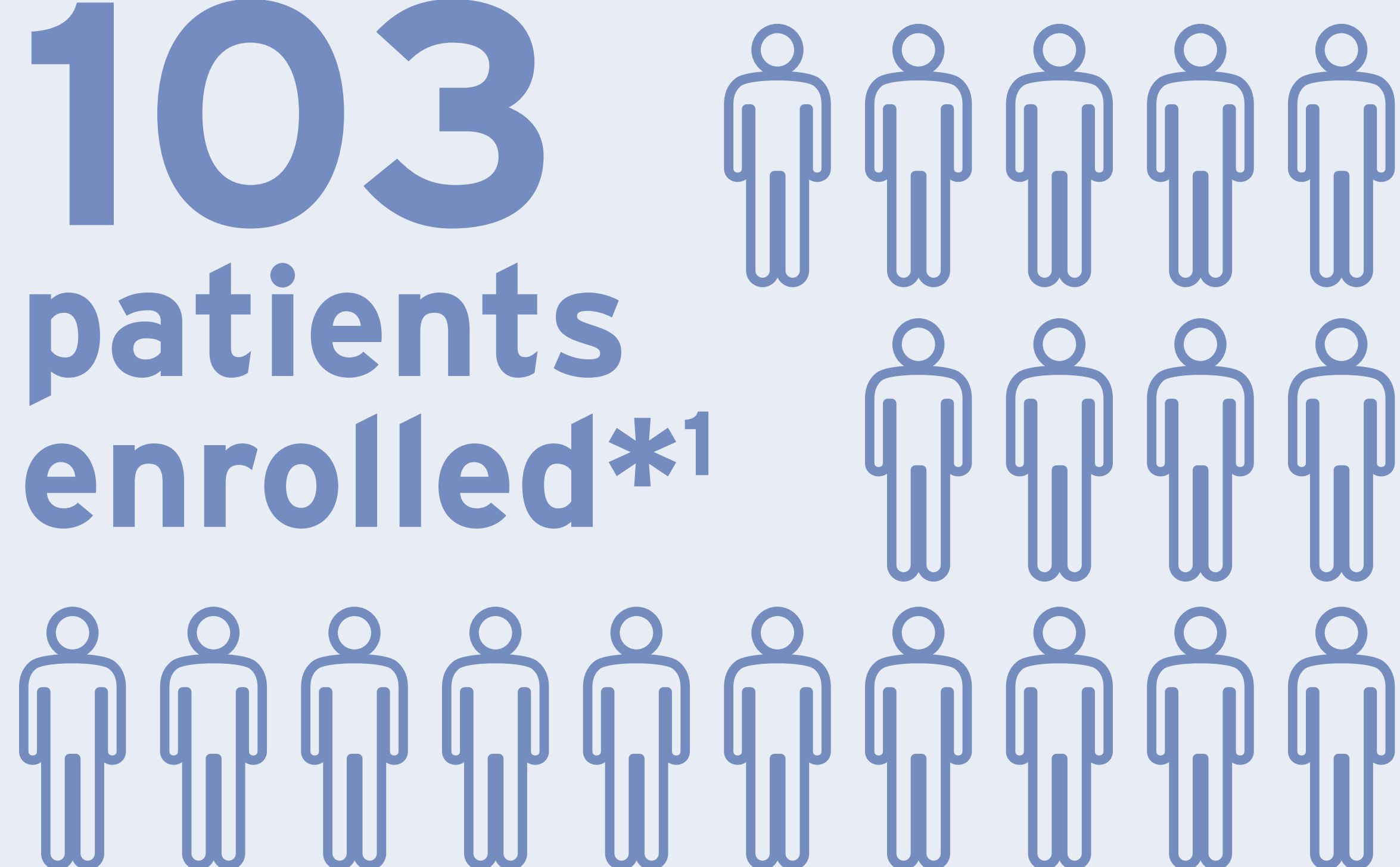


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The efficacy and safety of LYTGOBI were reported from FOENIX-CCA2¹

- 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 CCA³
- 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 rearrangement¹

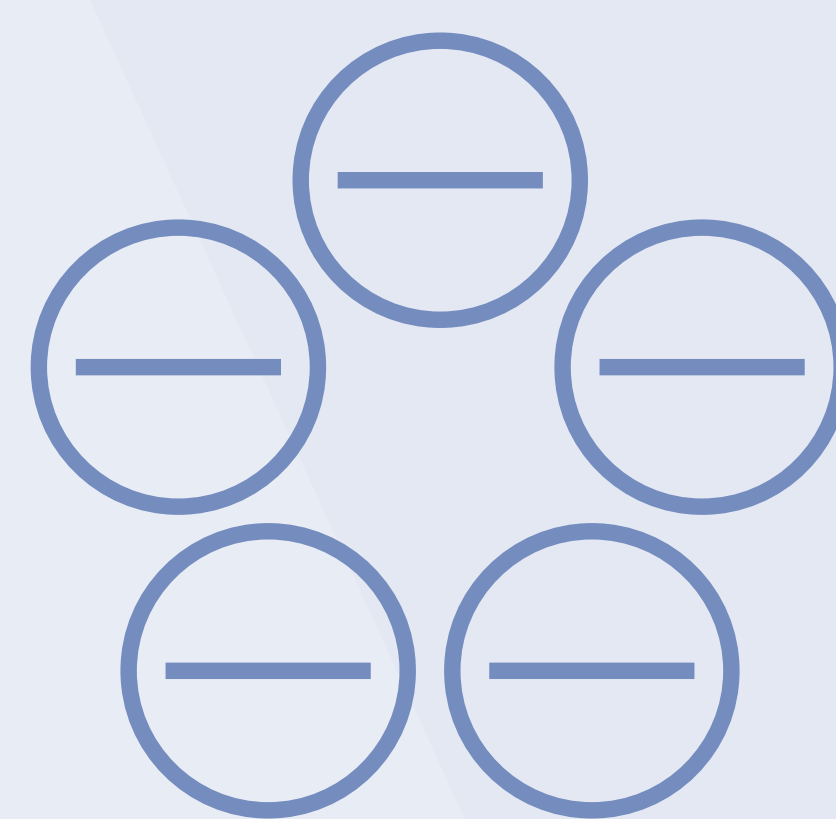
103
patients
enrolled*¹



Key eligibility criteria¹

- 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

20 mg
once daily



(five 4 mg tablets) in a
continuous regimen¹

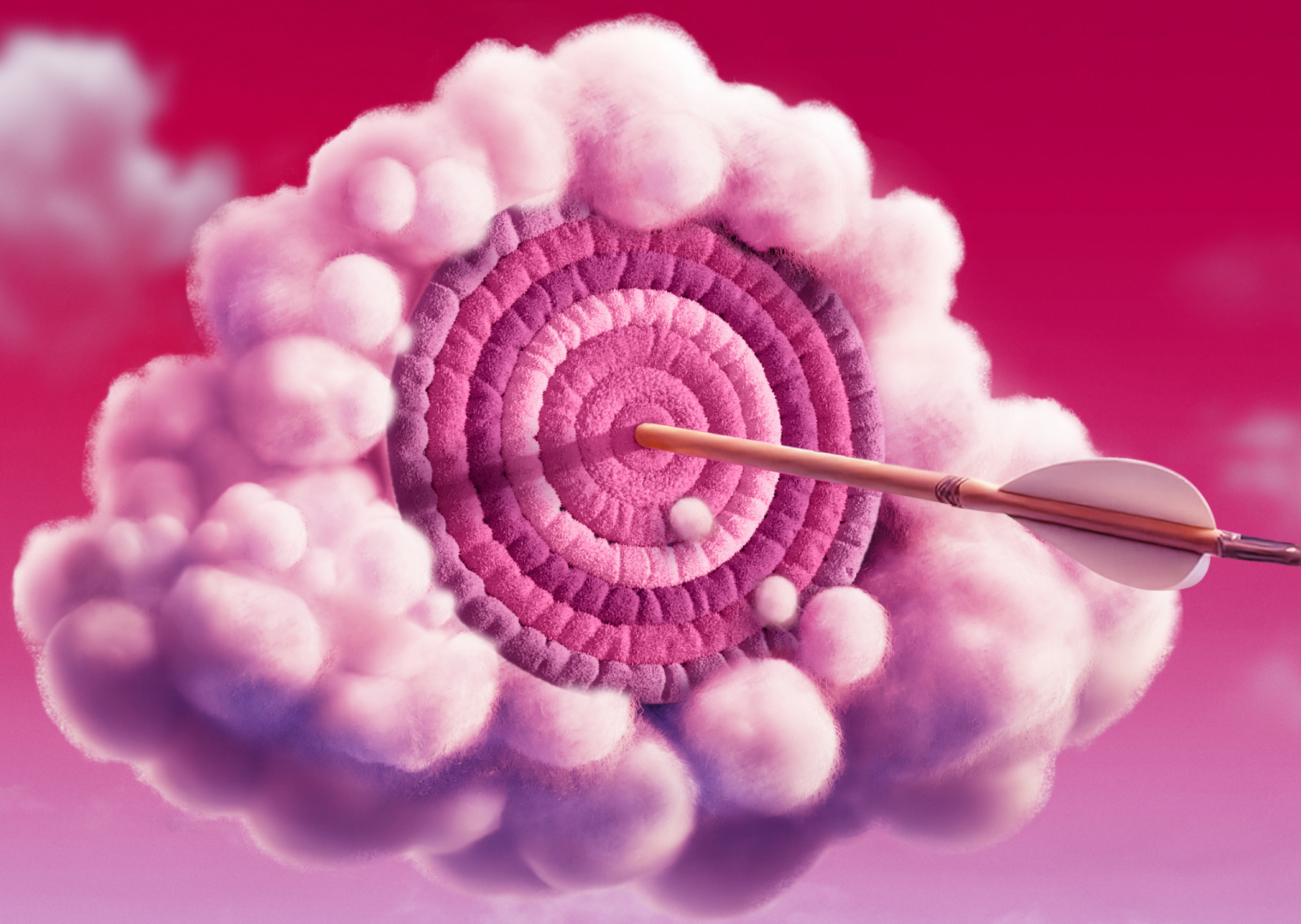
Dosing regimen¹

- 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 treatment-emergent adverse events (AEs)
- 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



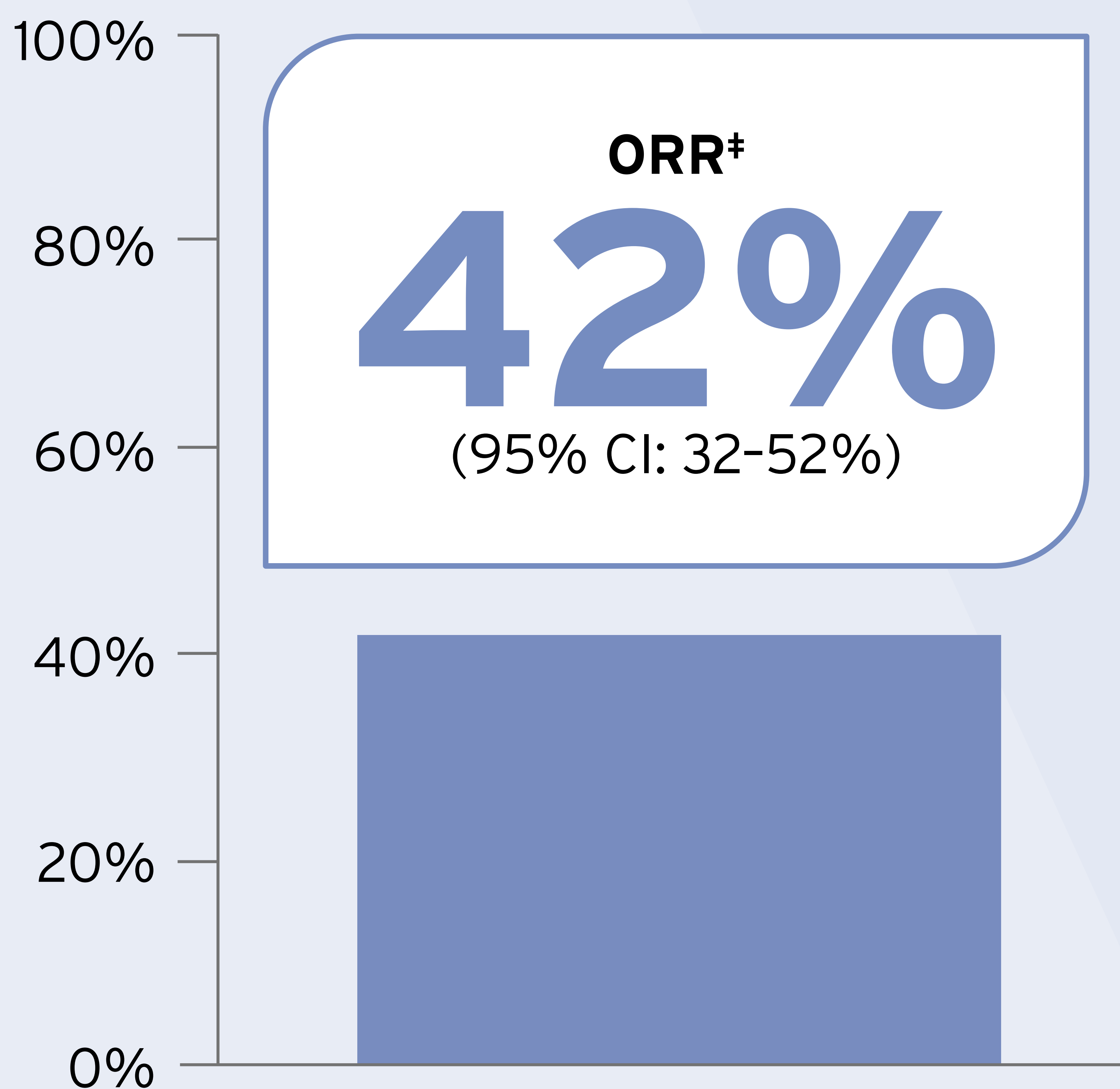


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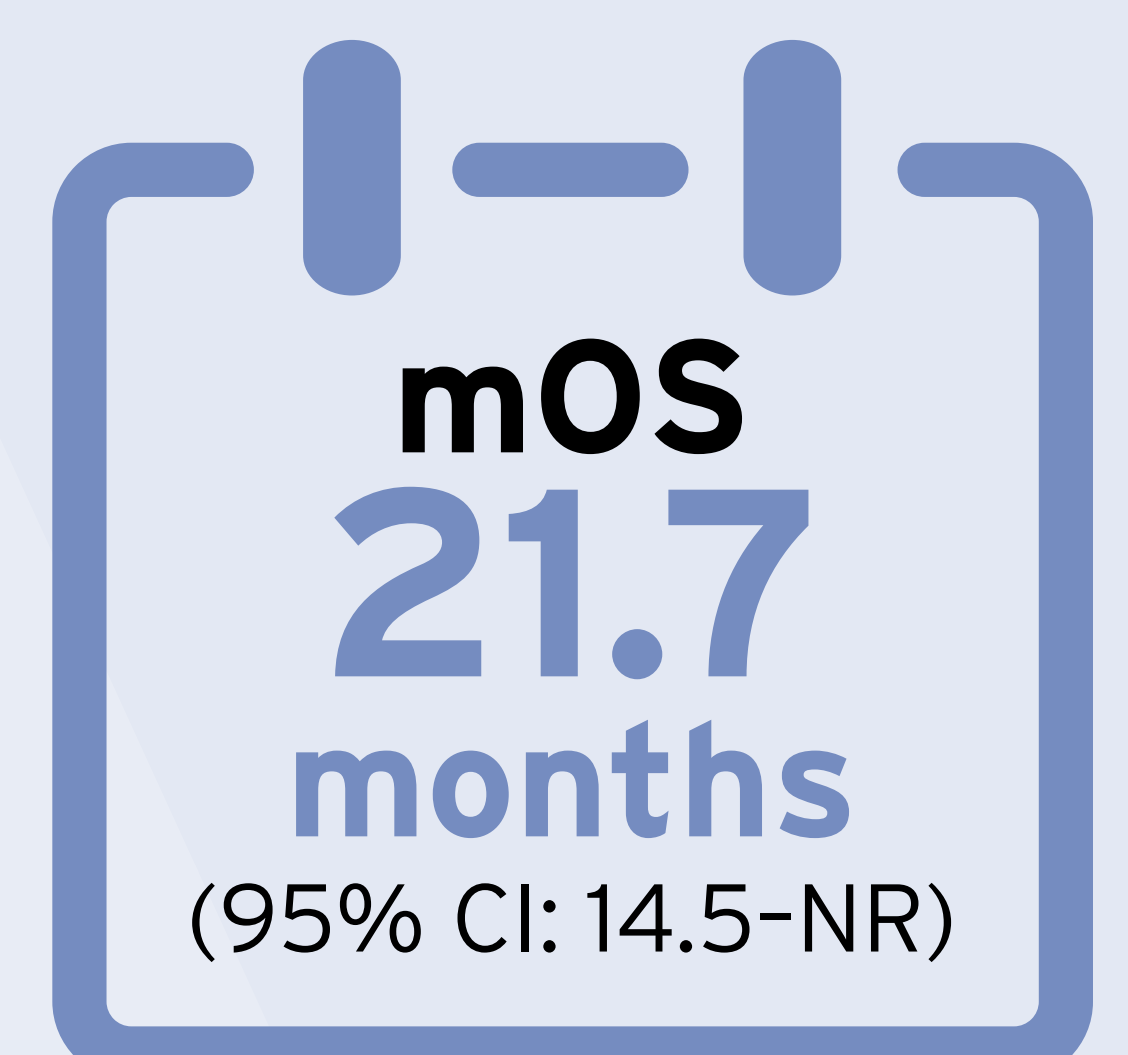
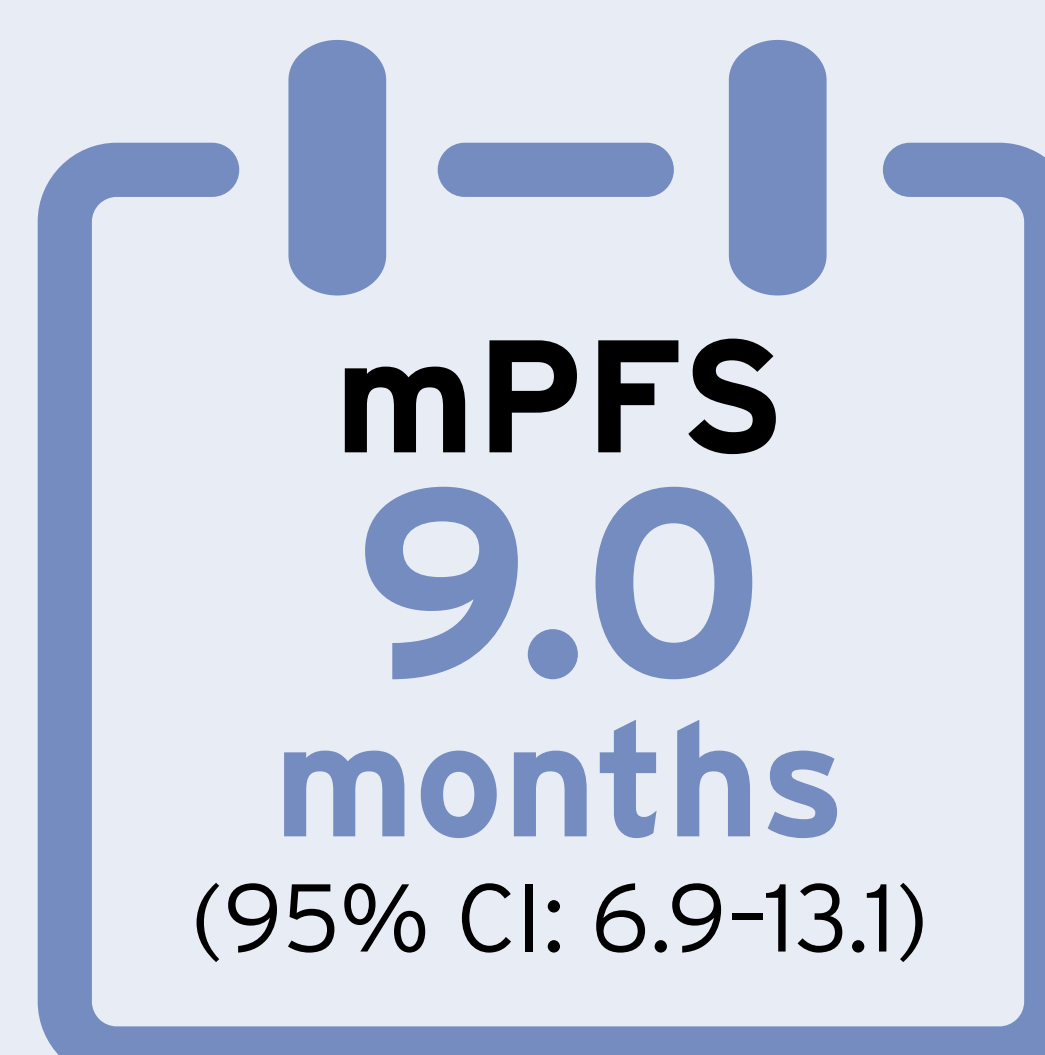
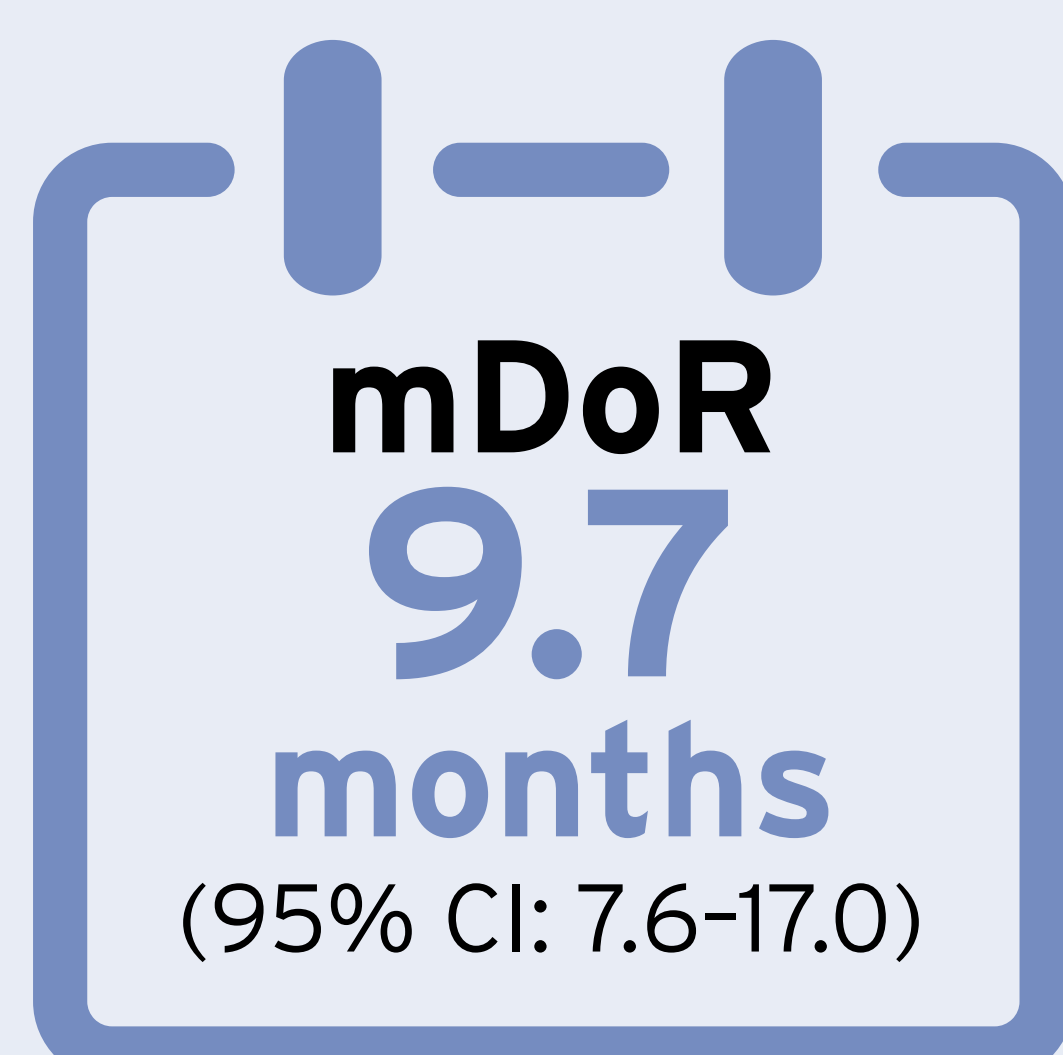
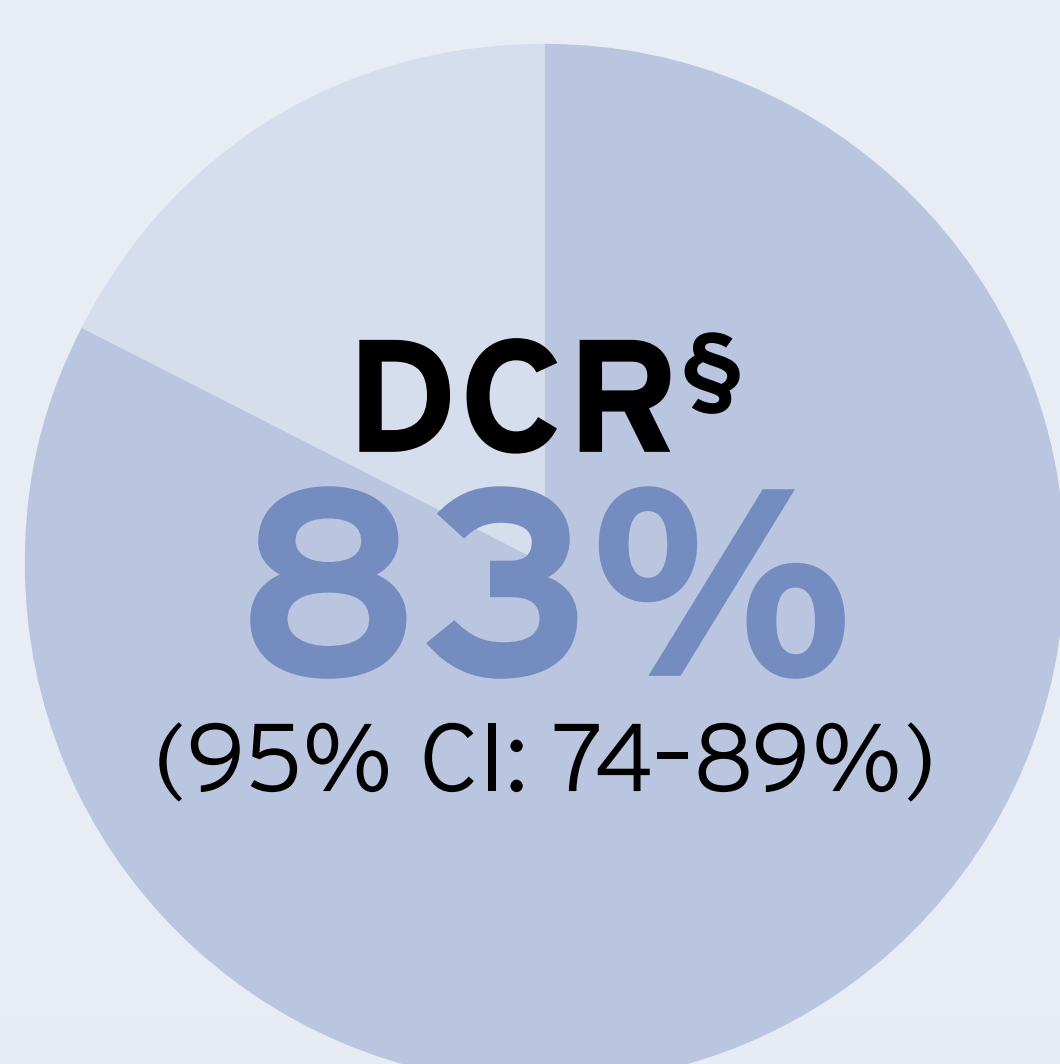
N=103 | Median follow-up: 17.1 months¹

Primary endpoint¹



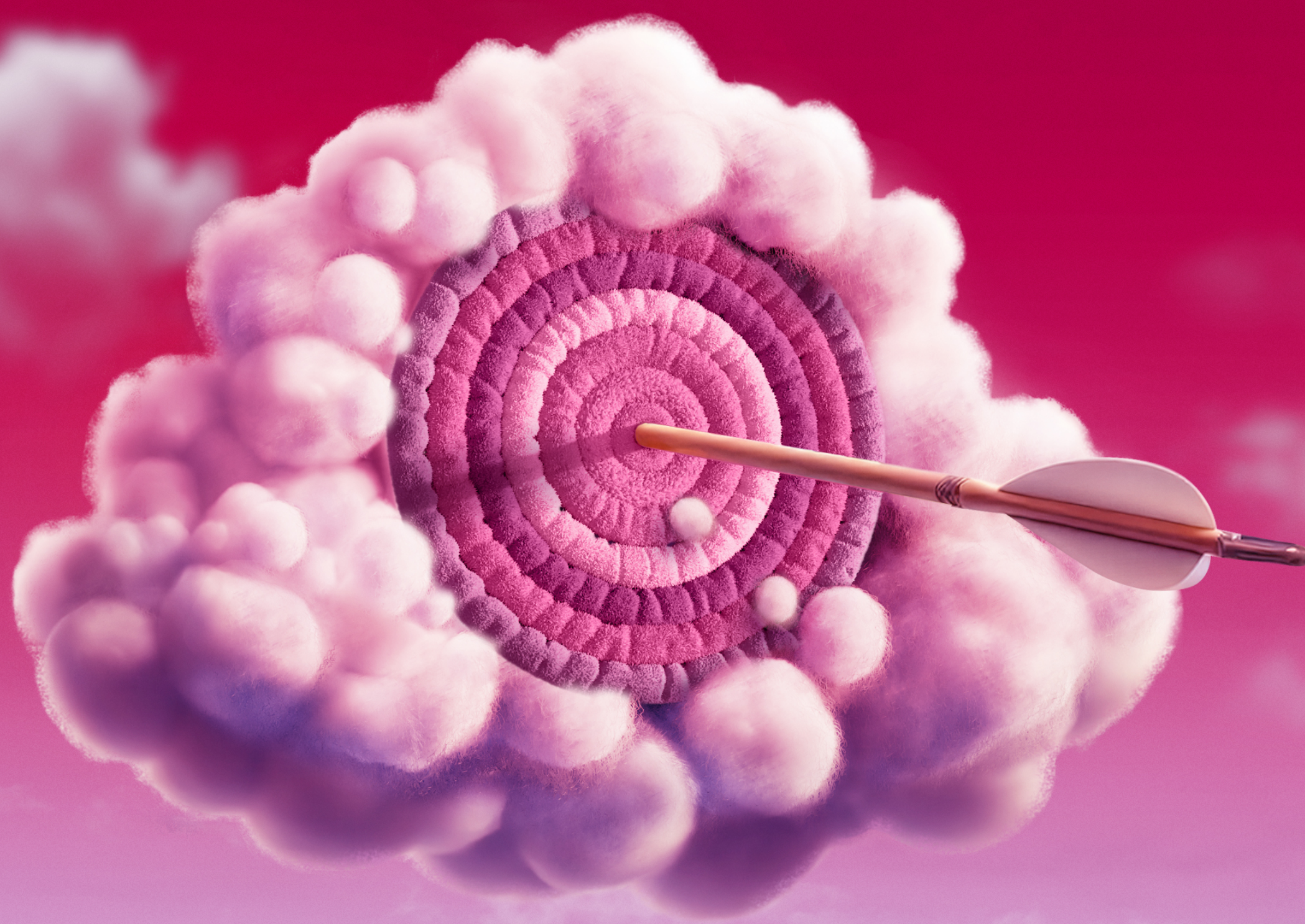
**2.5 months median
time to response**
(range: 0.7-7.4)¹

Secondary endpoints¹



**Extended follow-up (25.0 months median):
treatment response and survival outcomes were
maintained in the overall study population^{1,5}**





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Summary of the overall safety profile of LYTGOBI (safety population; N=145)⁴

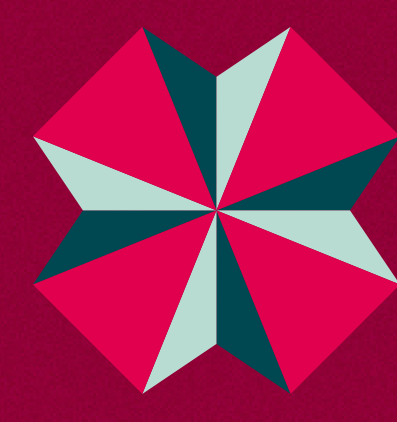
The safety population is based on patients with CCA receiving LYTGOBI 20 mg orally once daily in the Phase 1 and Phase 2 studies⁴

Most common (≥20%) adverse reactions ⁴	
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 erythrodysesthesia 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%)⁴
- 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 occurrences⁴

Gain a deeper understanding of the LYTGOBI data





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Please refer to the SmPC for full Prescribing Information:



EU



Spain (CIMA)

Prescribing Information is also available on the stand upon request. Registration conditions differ from country to country. Please refer to your local label.

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 who have progressed after at least one prior line of systemic therapy.⁴

Medicamento de uso hospitalario sujeto a seguimiento adicional.
El medicamento esta reembolsado por el SNS desde el 01/01/2024.
Precio de venta laboratorio notificado: 2.416 EUR.

▼ Este medicamento está sujeto a seguimiento adicional, es prioritaria la notificación de sospechas de reacciones adversas asociadas a este medicamento.

See section 4.8 of the LYTGOBI Summary of Product Characteristics for how to report adverse reactions.

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.** LYTGOBI® Summary of Product Characteristics; **5.** Goyal L, et al. *N Engl J Med*. 2023;388(3):228-239. Supplementary appendix.

Abbreviations

ADR, adverse reaction; AST, aspartate aminotransferase; ATP, adenosine triphosphate; CCA, cholangiocarcinoma; CI, confidence interval; CIMA, Centro de Información online de Medicamentos de la AEMPS; 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.

*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.^{1,5}

