1L ALECENSA
FOR THE TREATMENT OF PATIENTS WITH *ALK+* ADVANCED NSCLC

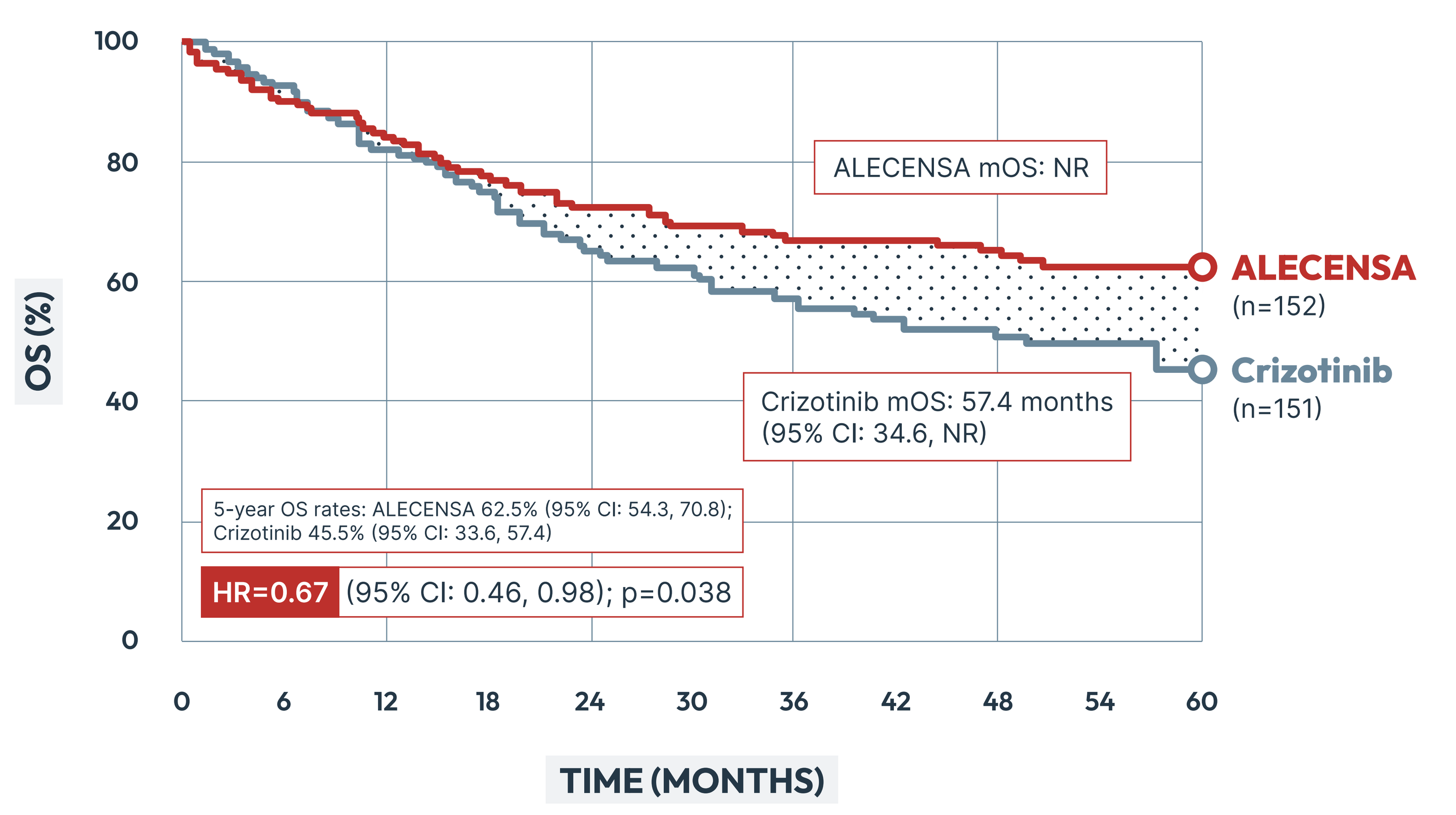
ALECENSA has **transformed outcomes** for patients with ***ALK+* advanced NSCLC**, demonstrating **overall and intracranial efficacy** across three Phase III trials.[1–3]

Additionally, ALECENSA has a **well-established** and **well-tolerated safety profile** in ***ALK+* advanced NSCLC** as shown by a wealth of data.[4–6]

6 OUT OF 10 PATIENTS WHO STARTED 1L ALECENSA ARE STILL ALIVE AFTER 5 YEARS[1]

ALECENSA is the **first *ALK* inhibitor** to demonstrate a **clinically meaningful improvement in 5-year OS rate** vs crizotinib[1,*]

ALEX Phase III clinical trial:[†] 5-year OS (ITT population)[1]



No. of patients at risk

	0	6	12	18	24	30	36	42	48	54	60
ALECENSA	152	131	120	103	94	88	81	81	77	46	8
Crizotinib	151	128	104	93	73	67	60	55	48	18	3

SUPERIOR CNS BENEFIT WITH ALECENSA VERSUS CRIZOTINIB REGARDLESS OF BASELINE CNS METASTASES[5]

ALECENSA reduces risk of **CNS progression** (as the first progression event)[5]

84% REDUCTION in the risk of CNS progression with **ALECENSA** vs **crizotinib**

HR=0.16 (95% CI: 0.10, 0.28); p<0.001

ALECENSA protects against the **development of new CNS metastases**[5]

4X LESS 12-month CIR for CNS progression with **ALECENSA** vs **crizotinib**

ALECENSA is effective in patients with **CNS metastases at baseline**[5]

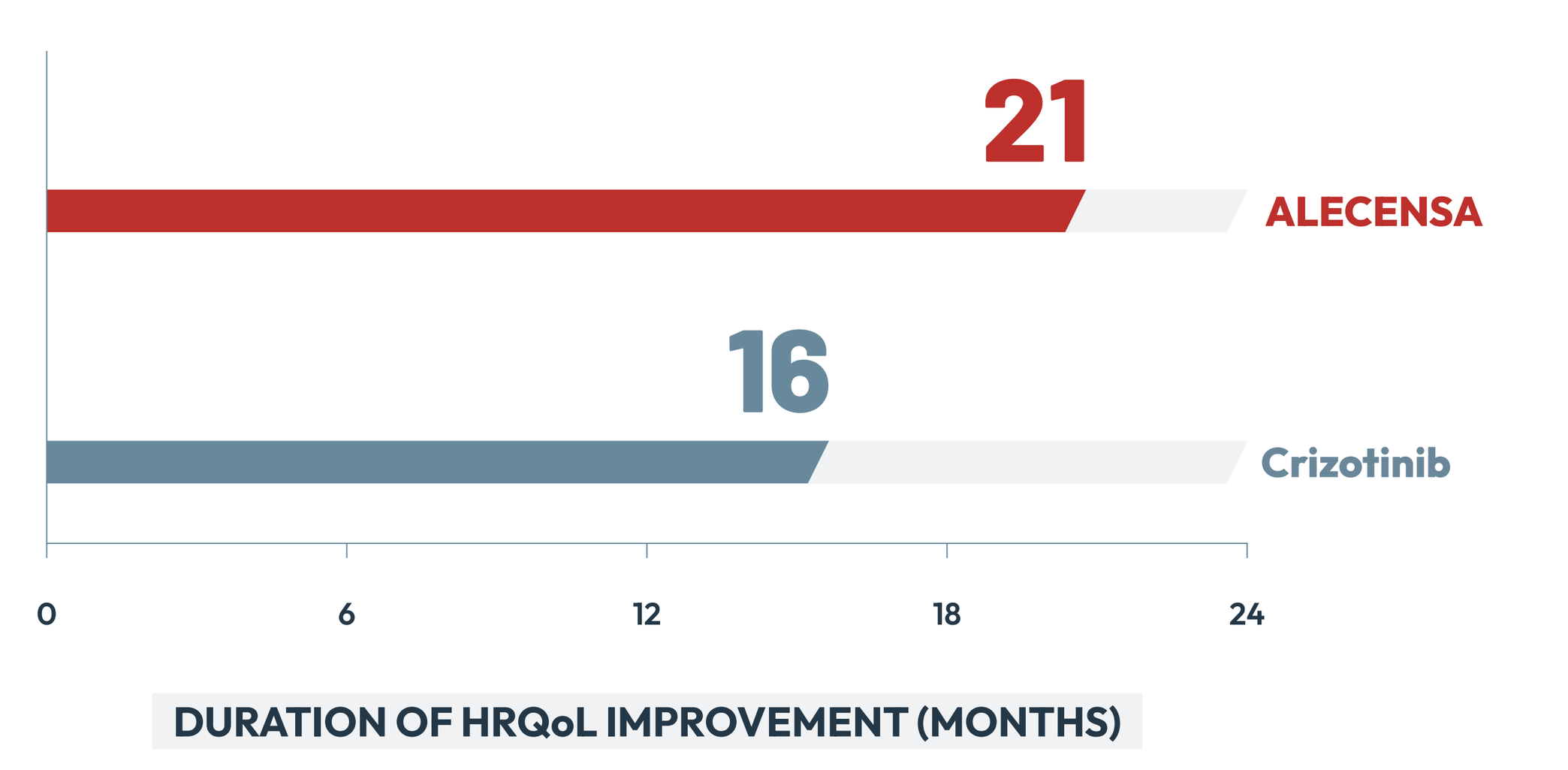
CNS ORR[5]: **81%** ALECENSA vs **50%** crizotinib

CNS CR[5]: **38%** ALECENSA vs **5%** crizotinib

ALECENSA EFFICACY TRANSLATES INTO SUSTAINED QUALITY OF LIFE IMPROVEMENTS[7]

The duration of **clinically meaningful improvement in HRQoL** (defined as ≥10 point increase) was **longer with ALECENSA** compared with crizotinib[7,‡,§]

Clinically meaningful improvement in HRQoL[7,‡]



5 MONTH EXTENSION IN HRQoL IMPROVEMENT WITH ALECENSA VS CRIZOTINIB[7]

ALECENSA HAS A FAVOURABLE SAFETY AND TOLERABILITY PROFILE WITH NEARLY 3X LONGER MEDIAN DURATION OF TREATMENT COMPARED WITH CRIZOTINIB[1]

ALEX Phase III clinical trial: overview of adverse events[1]

Event	ALECENSA (n=152)	Crizotinib (n=151)
Any-grade adverse event (%)	97	97
Grade 3–5 adverse event (%)	52	56
Serious adverse event (%)	39	32
Adverse event leading to treatment discontinuation (%)	15	15
Adverse event leading to dose reduction (%)	20	20
Adverse event leading to dose interruption (%)	26	27

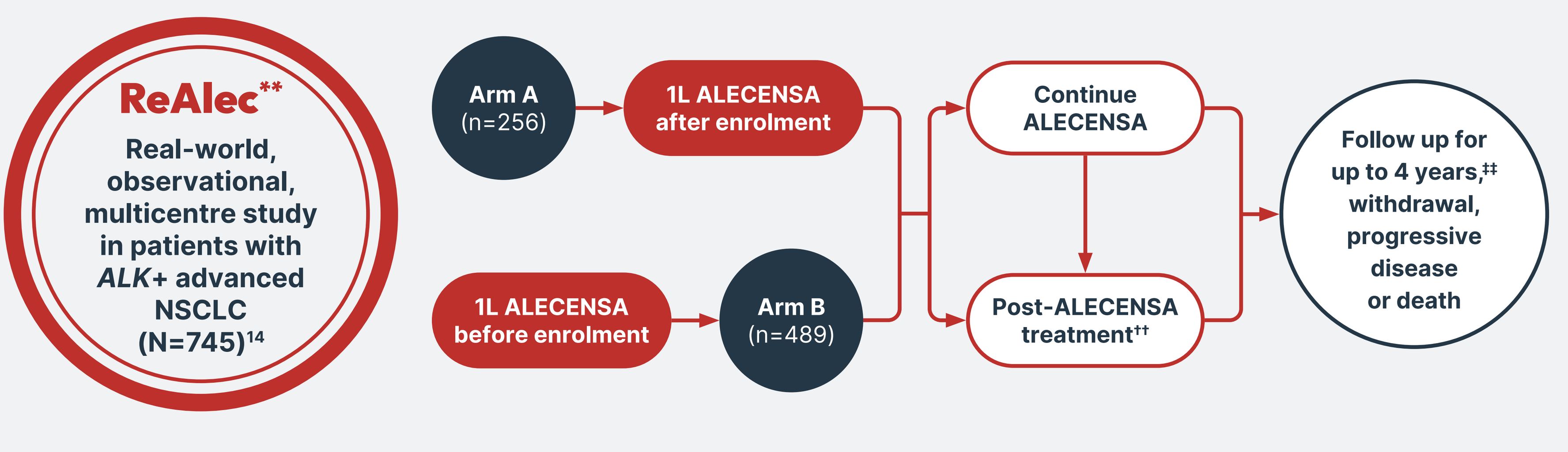
- Data cut-off: 19 November 2019[1]
- Median duration of treatment was 28.1 months with ALECENSA and 10.8 months with crizotinib[1]

5 YEARS NO NEW SAFETY SIGNALS OBSERVED WITH ALECENSA[1]

REAL-WORLD OUTCOMES WITH ALECENSA CONFIRM THOSE REPORTED IN CLINICAL TRIALS[8–10]

More than **92,000 patients treated in clinical practice** and **seven years of clinical experience** solidify **trust in 1L ALECENSA** for the management of patients with *ALK+* advanced NSCLC[11–13]

THE SAFETY PROFILE OF ALECENSA IN CLINICAL PRACTICE IS CONSISTENT WITH THAT REPORTED IN A CLINICAL TRIAL SETTING[14,¶]



ReAlec**
Real-world, observational, multicentre study in patients with ALK+ advanced NSCLC (N=745)14
Arm A (n=256)
1L ALECENSA after enrolment
1L ALECENSA before enrolment
Arm B (n=489)
Continue ALECENSA
Post-ALECENSA treatment††
Follow up for up to 4 years,‡‡ withdrawal, progressive disease or death

CO-PRIMARY OBJECTIVES[14]

- Investigator-confirmed PFS (per RECIST criteria) and treatment sequencing patterns after treatment with 1L ALECENSA

KEY SECONDARY OBJECTIVES[14]

- Demographics and disease characteristics
- Safety[§§] and reasons for discontinuation
- OS

The **real-world demographics** and **disease characteristics** were **in line with clinical trial experience**[14,¶¶]

- Median treatment duration on the study was 8.3 months for arm A versus 13.8 months for arm B; most patients were still receiving ALECENSA at the data cut-off date[14]
- Overall, **TRAEs** occurred in **26.3% of patients**, and were **mostly Grade 1–2** and **non-serious**[14]
- The **three most common TRAEs** in arm A and B were, respectively:[14]

Increased blood bilirubin (7.0% and 5.5%)

Increased AST (5.9% and 3.5%)

Anaemia (4.7% and 3.5%)

- Overall, TRAEs leading to **dose modification/interruptions** and **treatment discontinuation** occurred in **6.4%** and **0.9%** of patients, respectively[14]
- Serious AEs in arms A and B included **pneumonia** (1.6% and 1.4%, respectively), **dyspnoea** (1.2% and 0.4%, respectively) and **pleural effusion** (0% and 0.8%, respectively)[14]

Please see the full EU Summary of Product Characteristics here.

This document is based on the EU SmPC for ALECENSA. Regulatory approval and reimbursement status or indication statements may differ in your country. You are advised to consult the product label applicable in your location or to get in touch with the appropriate national health authority for up-to-date product information and prescribing guidance.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system or via medinfo.roche.com.

*OS data is still immature.[1] †NCT02075840. ‡Changes in HRQoL and functioning were assessed using EORTC questionnaires (QLQ-C30 and QLQ-LC13).[7] §One month equal to 4.3 weeks. ¶Data cut-off date: 10 May 2023.[14] **NCT04764188. ††Patients discontinue ALECENSA due to disease progression or other reasons and go onto next line of treatment.[14] ‡‡This includes an expected ALECENSA treatment period of approximately 3 years (observation period) and then up to a maximum of 1 year on the next line of treatment (post-ALECENSA follow-up period).[14] §§AEs were not collected prior to enrolment for patients in arm B.[14] ¶¶Rates of ALECENSA discontinuation were 21.9% (arm A) and 15.3% (arm B); 73.2% (arm A) and 86.7% (arm B) of these patients discontinued ALECENSA due to progressive disease.[14]

1L: first line; AE: adverse event; ALK: anaplastic lymphoma kinase; CI: confidence interval; CIR: cumulative incidence rate; CNS: central nervous system; CR: complete response; EMA: European Medicines Agency; EORTC: European Organisation for Research and Treatment of Cancer; EU: European Union; FDA: Food and Drug Administration; HR: hazard ratio; HRQoL: health-related quality of life; ITT: intention-to-treat; mOS: median overall survival; NR: not reached; NSCLC: non-small cell lung cancer; ORR: overall response rate; OS: overall survival; PBRER: periodic benefit-risk evaluation report; PFS: progression-free survival; PSUR: periodic safety update report; QLQ-C30: Quality of Life Questionnaire C30; QLQ-LC13: Quality of Life Questionnaire-lung cancer module 13; RECIST: Response Evaluation Criteria in Solid Tumours; SmPC: Summary of Product Characteristics; TRAE: treatment-related adverse event.

1. Mok T, et al. *Ann Oncol* 2020;31(8):1056–1064; 2. Nakagawa K, et al. *Lung Cancer* 2020;139:195–199; 3. Zhou C, et al. Presented at the European Society for Medical Oncology Asia Congress (abstract LBA11), 2–4 December 2022, Singapore; 4. Hida T, et al. *Lancet* 2017;390(10089):29–39; 5. Peters S, et al. *N Engl J Med* 2017;377(9):829–838; 6. Zhou C, et al. *Lancet Respir Med* 2019;7(5):437–446; 7. Pérol M, et al. *Lung Cancer* 2019;138:79–87; 8. Dziadziuszko R, et al. *ESMO Open* 2022;7(6):100612; 9. Krebs MG, et al. Presented at the European Society of Medical Oncology 2021 (abstract 1201P), 16–21 September, virtual meeting; 10. Zhang Q, et al. *JTO Clin Res Rep* 2023;4(4):100483; 11. ALECENSA PBRER/PSUR 2023 - Roche Data on File; 12. FDA Press release; 6 November 2017. Available here (accessed July 2024); 13. EMA. ALECENSA (EMA/376895/2018). Available here (accessed July 2024); 14. Bria E, et al. Presented at the European Lung Cancer Congress 2024, 20–23 March, Prague, Czech Republic; 15. Roche. ALECENSA (alectinib) Summary of Product Characteristics. 2024. Available here (accessed July 2024).