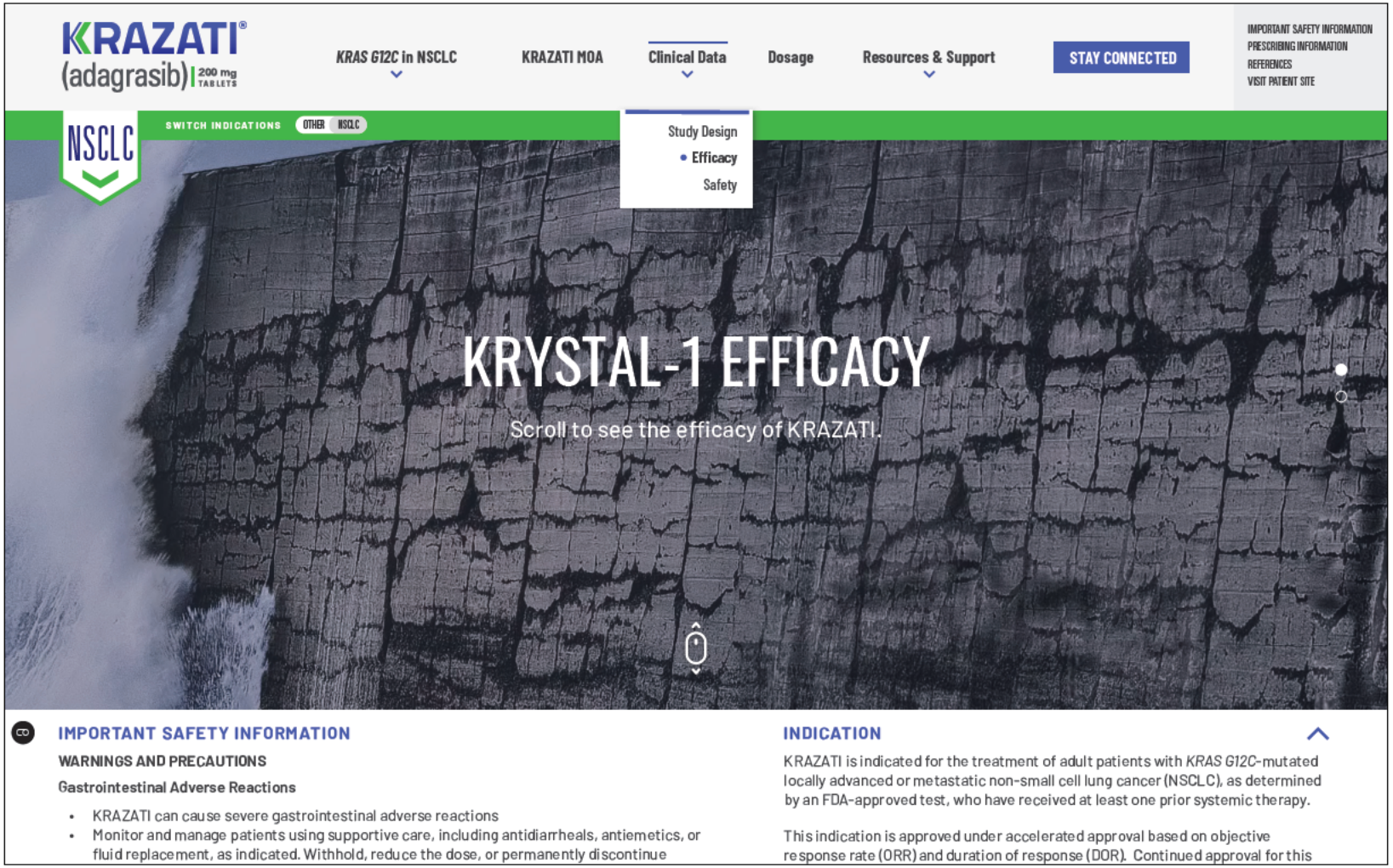
KRAZATI®
(adagrasib) 200 mg TABLETS
KRAS G12C in NSCLC
KRAZATI MOA
Clinical Data
Dosage
Resources & Support
STAY CONNECTED
IMPORTANT SAFETY INFORMATION
PRESCRIBING INFORMATION
REFERENCES
VISIT PATIENT SITE
NSCLC
SWITCH INDICATIONS
OTHER
NSCLC
Study Design
Efficacy
Safety
KRYSTAL-1 EFFICACY
Scroll to see the efficacy of KRAZATI.
IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS
Gastrointestinal Adverse Reactions
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REGISTRATIONAL PHASE 2 COHORT

43% ORR: A ROBUST RESPONSE TO A RELENTLESS DISEASE[30]

43% ORR*†
(n=112; 95% CI: 34-53)

58% HAD A RESPONSE DURATION OF ≥6 MONTHS[30]

- Median time to response was 1.4 months (range: 0.9-7.2)[31]
- At data cutoff, treatment was ongoing in 50% (24/48) of patients who experienced a response[33]
- Median DOR: 8.5 months (95% CI: 6.2-13.8)[30]
- Median OS: 12.6 months (95% CI: 9.2-19.2)[31]
- Median PFS: 6.5 months (95% CI: 4.7-8.4)[31]

CATEGORY 2A
NCCN
RECOMMENDED
NSCLC
NCCN Guidelines recommend adagrasib (KRAZATI) as a subsequent therapy option for patients with *KRAS G12C*-mutated advanced or metastatic NSCLC after progression (Category 2A).[1]

Single-arm trials do not adequately characterize time-to-event endpoints such as OS and PFS. Thus, these data from KRYSTAL-1 cannot be interpreted as having OS and PFS benefit.

*Tumor response was assessed by BICR. Phase 2 data cutoff: October 15, 2021 (median follow-up: 12.9 months). Data cutoff for OS: January 15, 2022 (median follow-up: 15.8 months). Additional follow-up planned.
†Included in this analysis were patients lost to follow-up (15%) who were not evaluated.[31]

BICR=blinded independent central review; CI=confidence interval; DCR=disease control rate; DOR=duration of response; NCCN=National Comprehensive Cancer Network; NSCLC=non-small cell lung cancer; ORR=objective response rate; OS=overall survival; PFS=progression-free survival.

SAFETY →

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ORR | DCR | Intracranial ORR | OS | PFS | DOR

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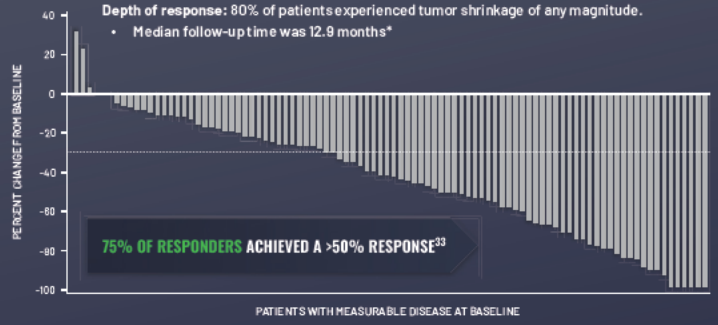

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- Stable Disease
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- Complete Response
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ORR | DCR | Intracranial ORR | OS | PFS | DOR

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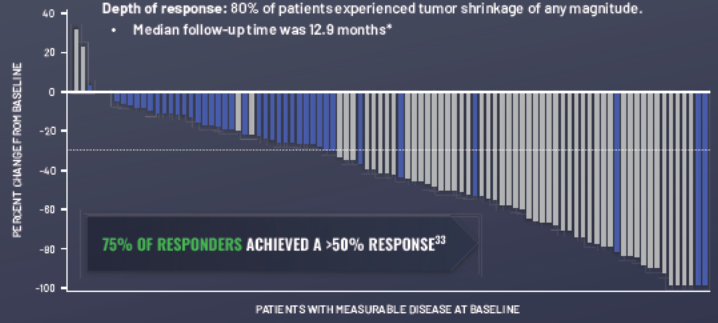

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SAFETY →

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NSCLC

SWITCH INDICATIONS: OTHER NSCLC

ORR | DCR | Intracranial ORR | OS | PFS | DOR

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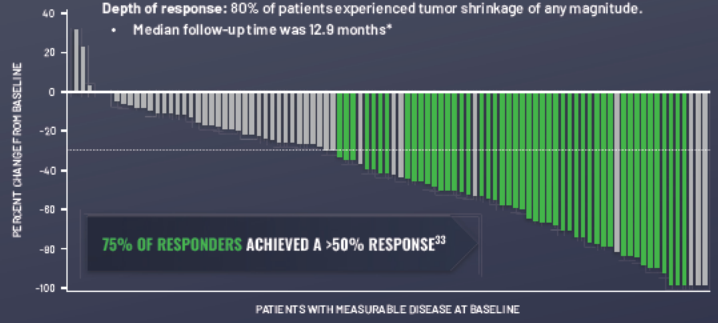

Click a button to see the best tumor response

- Stable Disease
- Partial Response 42%
- Complete Response
- Progressive Disease

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ORR | DCR | Intracranial ORR | OS | PFS | DOR

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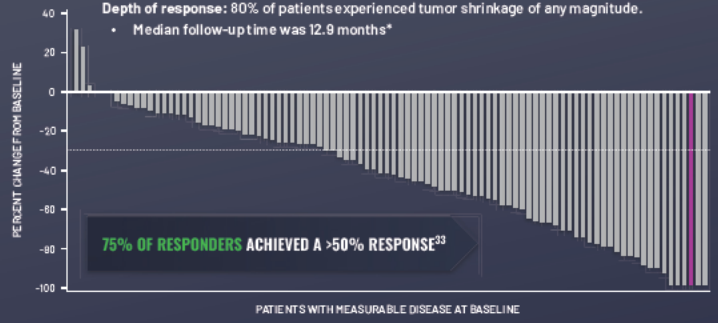

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- Complete Response 1%
- Progressive Disease

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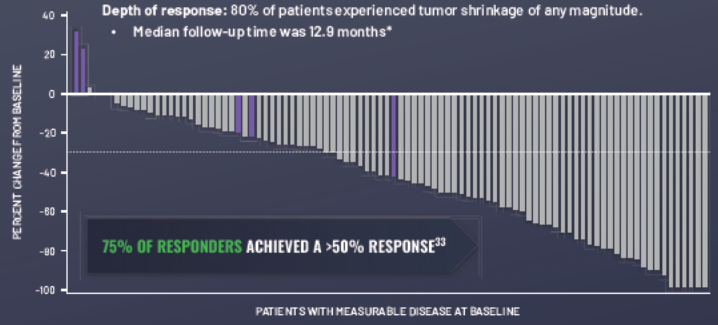

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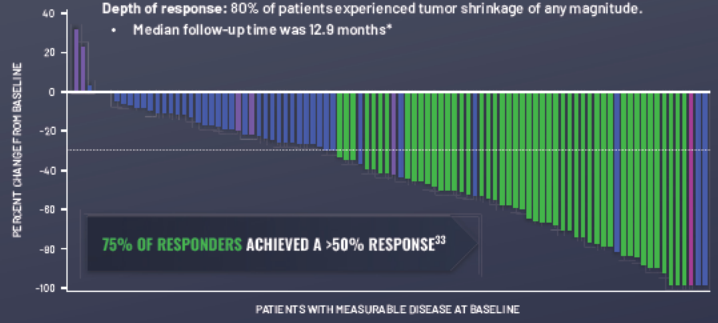

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USE IN SPECIFIC POPULATIONS

Females and Males of Reproductive Potential

- Infertility: Based on findings from animal studies, KRAZATI may impair fertility in females and males of reproductive potential

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INDICATION

KRAZATI is indicated for the treatment of adult patients with *KRAS G12C*-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.

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POST HOC ANALYSIS

33% INTRACRANIAL ORR IN PATIENTS WITH STABLE, ADEQUATELY TREATED BRAIN METASTASES[31]

INTRACRANIAL 33% ORR*†
(n=33; 95% CI: 18.0-51.8)

Post hoc subgroup analysis of *KRAS G12C*–mutated NSCLC patients with stable, adequately treated brain metastases (n=42).*

- Median follow-up time was 15.4 months.
  Data cutoff: December 31, 2021

INTRACRANIAL DCR IN PATIENTS WITH BRAIN METASTASES: 85% (n=33; 95% CI: 68-95)[32]

CATEGORY 2A NCCN RECOMMENDED

CNS CANCERS
NCCN Guidelines for CNS cancers recommend adagrasib (KRAZATI) as a systemic therapy option for patients with *KRAS G12C*-mutated advanced NSCLC with brain metastases (Category 2A).[3]

Patients identified by BICR as having brain metastases at baseline were evaluated by mRANO-BM; 33 were considered radiographically evaluable (ie, with ≥1 on-study scan).†

INTRACRANIAL ORR AND DCR CANNOT BE ATTRIBUTED TO KRAZATI ALONE, GIVEN BRAIN METASTASES WERE PREVIOUSLY TREATED, SOME WITH RECENT PRIOR RADIATION. THESE RESULTS SHOULD BE INTERPRETED WITH CAUTION.

*Patients were eligible if brain metastases were adequately treated and patients were neurologically stable ≥2 weeks prior to enrollment without the use of corticosteroids or were on a stable or decreasing dose of ≤10 mg daily prednisone (or equivalent).
†Modifications to RANO-BM include ≥5 mm lesions, corticosteroid use monitored per concomitant medications, and ECOG PS (rather than Karnofsky Performance Scale).
BICR=blinded independent central review; CI=confidence interval; CNS=central nervous system; DCR=disease control rate; ECOG PS=Eastern Cooperative Oncology Group Performance Status; mRANO-BM=modified Response Assessment in Neuro-Oncology Brain Metastases; NCCN=National Comprehensive Cancer Network; NSCLC=non-small cell lung cancer; ORR=objective response rate.

SAFETY →

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Gastrointestinal Adverse Reactions

- KRAZATI can cause severe gastrointestinal adverse reactions
- Monitor and manage patients using supportive care, including antidiarrheals, antiemetics, or fluid replacement, as indicated. Withhold, reduce the dose, or permanently discontinue KRAZATI based on severity

QTc Interval Prolongation

- KRAZATI can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (eg, torsades de pointes) or sudden death
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Hepatotoxicity

- KRAZATI can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis
- Monitor liver laboratory tests (AST, ALT, alkaline phosphatase, and total bilirubin) prior to the start of KRAZATI, and monthly for 3 months or as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Reduce the dose, withhold, or permanently discontinue KRAZATI based on severity

Interstitial Lung Disease/Pneumonitis

- KRAZATI can cause interstitial lung disease (ILD)/pneumonitis, which can be fatal
- Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever) during treatment with KRAZATI
- Withhold KRAZATI in patients with suspected ILD/pneumonitis and permanently discontinue KRAZATI if no other potential causes of ILD/pneumonitis are identified

ADVERSE REACTIONS

- The most common adverse reactions in NSCLC patients (≥20%) are diarrhea, nausea, fatigue, vomiting, musculoskeletal pain, hepatotoxicity, renal impairment, dyspnea, edema, decreased appetite, cough, pneumonia, dizziness, constipation, abdominal pain, and QTc interval prolongation

USE IN SPECIFIC POPULATIONS

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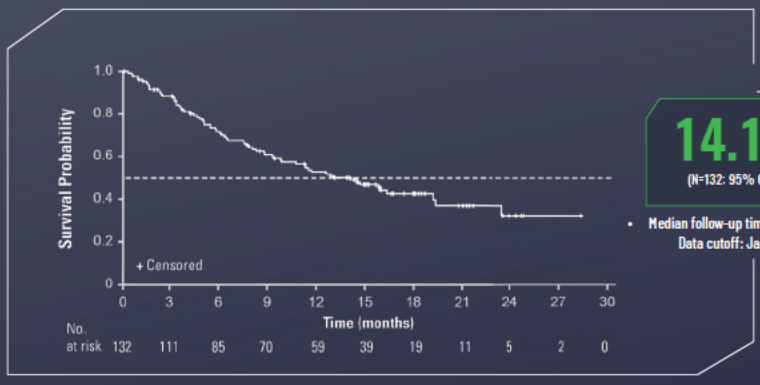
MEDIAN OS IN PATIENTS TAKING KRAZATI: 14.1 MONTHS[32]



14.1 MONTHS
(N=132; 95% CI: 9.2-19.2)

- Median follow-up time was 15.9 months.
  Data cutoff: January 15, 2022

Single-arm trials do not adequately characterize time-to-event endpoints such as OS. Thus, these data from KRYSTAL-1 cannot be interpreted as having OS benefit.
CI=confidence interval; OS=overall survival.

SAFETY →

IMPORTANT SAFETY INFORMATION

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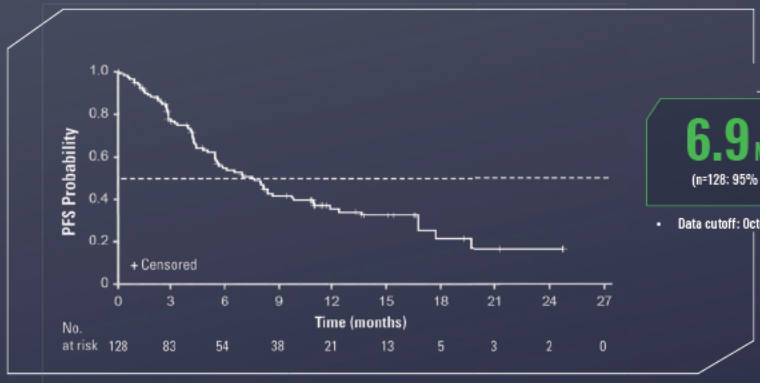
MEDIAN PFS IN PATIENTS TAKING KRAZATI: 6.9 MONTHS[32]



6.9 MONTHS
(n=128; 95% CI: 5.4-8.7)

- Data cutoff: October 15, 2021

Single-arm trials do not adequately characterize time-to-event endpoints such as PFS. Thus, these data from KRYSTAL-1 cannot be interpreted as having PFS benefit.
CI=confidence interval; PFS=progression-free survival.

SAFETY →

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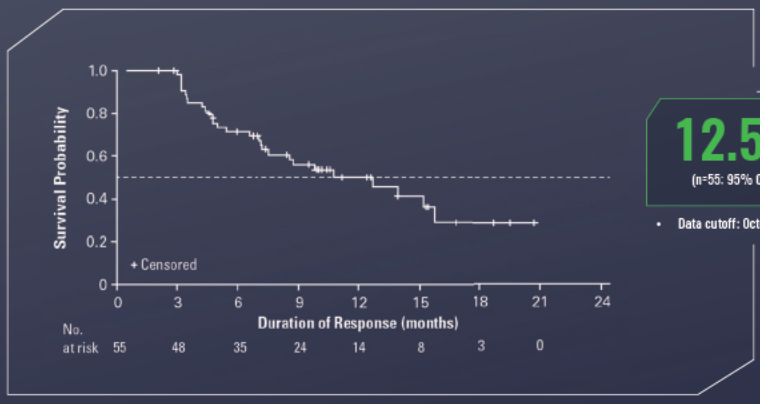
DESCRIPTIVE ANALYSIS

MEDIAN DOR IN PATIENTS TAKING KRAZATI: 12.5 MONTHS[32]



12.5 MONTHS
(n=55; 95% CI: 7.0-15.6)

- Data cutoff: October 15, 2021

CI=confidence interval; DOR=duration of response.

SAFETY →

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