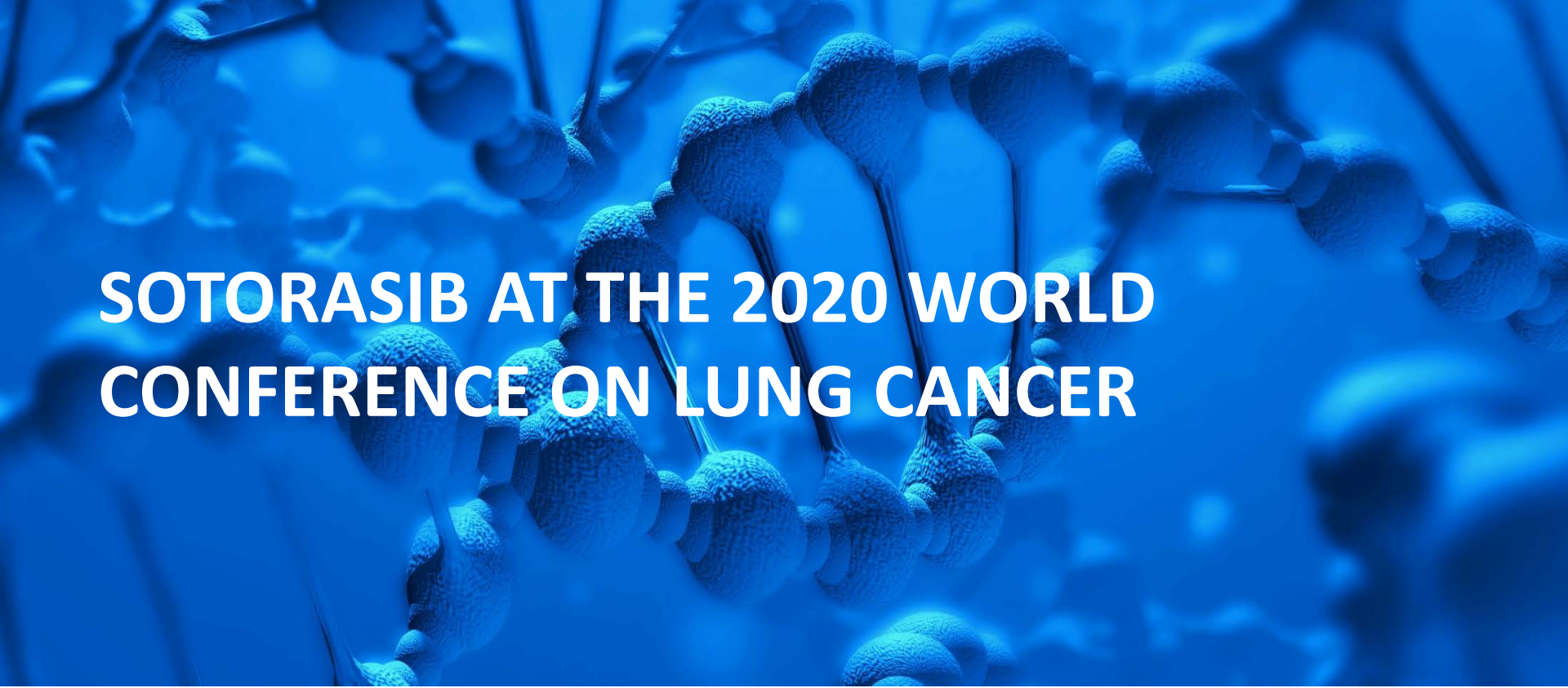

SOTORASIB AT THE 2020 WORLD CONFERENCE ON LUNG CANCER

JANUARY 29, 2021

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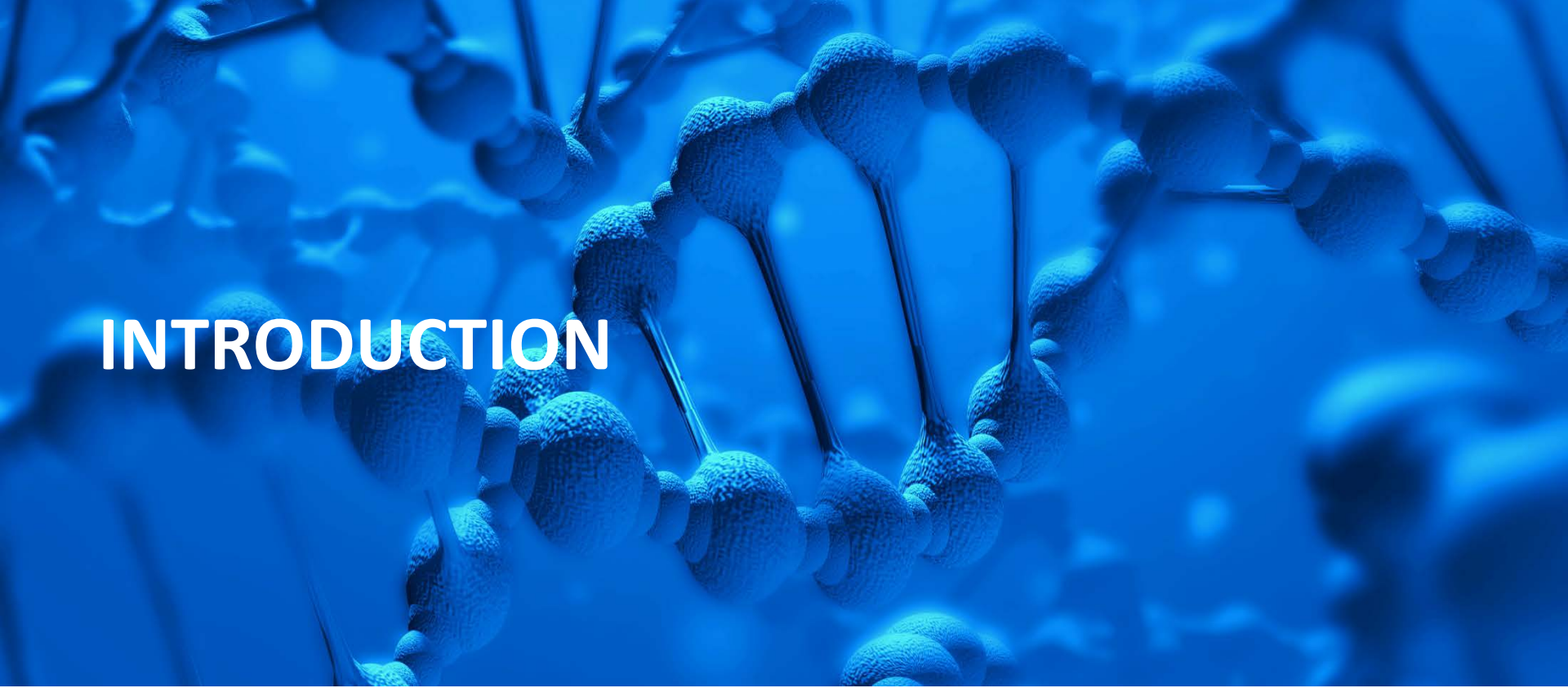

INTRODUCTION

DAVID REESE, M.D.

EXECUTIVE VICE PRESIDENT, RESEARCH AND DEVELOPMENT

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AGENDA

Introduction	**David Reese, M.D.—Executive Vice President, Research and Development**
Sotorasib Phase 2 NSCLC Update	**Gregory Friberg, M.D.—Vice President, Global Development and Oncology Therapeutic Area Head**
Q&A	**David Reese** **Gregory Friberg** **Hossein Borghaei, D.O., M.S.—Professor and Chief, Division of Thoracic Medical Oncology, Fox Chase Cancer Center, Philadelphia, PA** **Jurgen Wolf, M.D.—Professor and Medical Director, Center for Integrated Oncology, University Hospital of Cologne, Germany**

NSCLC = non-small cell lung cancer

Provided January 29, 2021, as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; Amgen disclaims any duty to update.

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SOTORASIB:
A DIFFERENTIATED FIRST-IN-CLASS KRAS^{G12C} INHIBITOR

- First in the clinic
- First completed pivotal study
- First robust PFS and DOR benefits
- First global regulatory submissions
- Broadest and largest global program
  - > 700 patients with 13 tumor types enrolled across five continents
  - 10 Phase 1b combination cohorts—initial data expected in H1 ’21
- Differentiated safety profile with no treatment-related fatalities—most AEs mild to moderate
- Only once-daily oral dosing option

KRAS G12C = Kirsten rat sarcoma viral oncogene homolog with G12C mutation; PFS = progression-free survival; DOR = duration of response; AE = adverse event

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SOTORASIB:
ADVANCING RAPIDLY THROUGH GLOBAL CLINICAL DEVELOPMENT

- **Regulatory submissions completed**
  - **U.S.**
  - **EU**
  - **Canada**
  - **U.K.**
  - **Brazil**
  - **Australia**
- **U.S. Real-Time Oncology Review and Breakthrough Therapy Designation in U.S. and China**
- **Phase 2 first-line NSCLC study planned for H1 ’21 in patients at highest unmet need (i.e., STK11 mutations)**
- **Safety hurdle cleared for 960mg dose in combination with MEK inhibitor**
  - **Expansion cohort enrolled to assess efficacy**
  - **Sotorasib + MEK inhibitor + EGFR antibody triplet cohort initiated**

CRC = colorectal cancer; STK11 = serine threonine kinase 11; NSCLC = non-small cell lung cancer; MEK = mitogen-activated protein kinase kinase; EGFR = epidermal growth factor receptor

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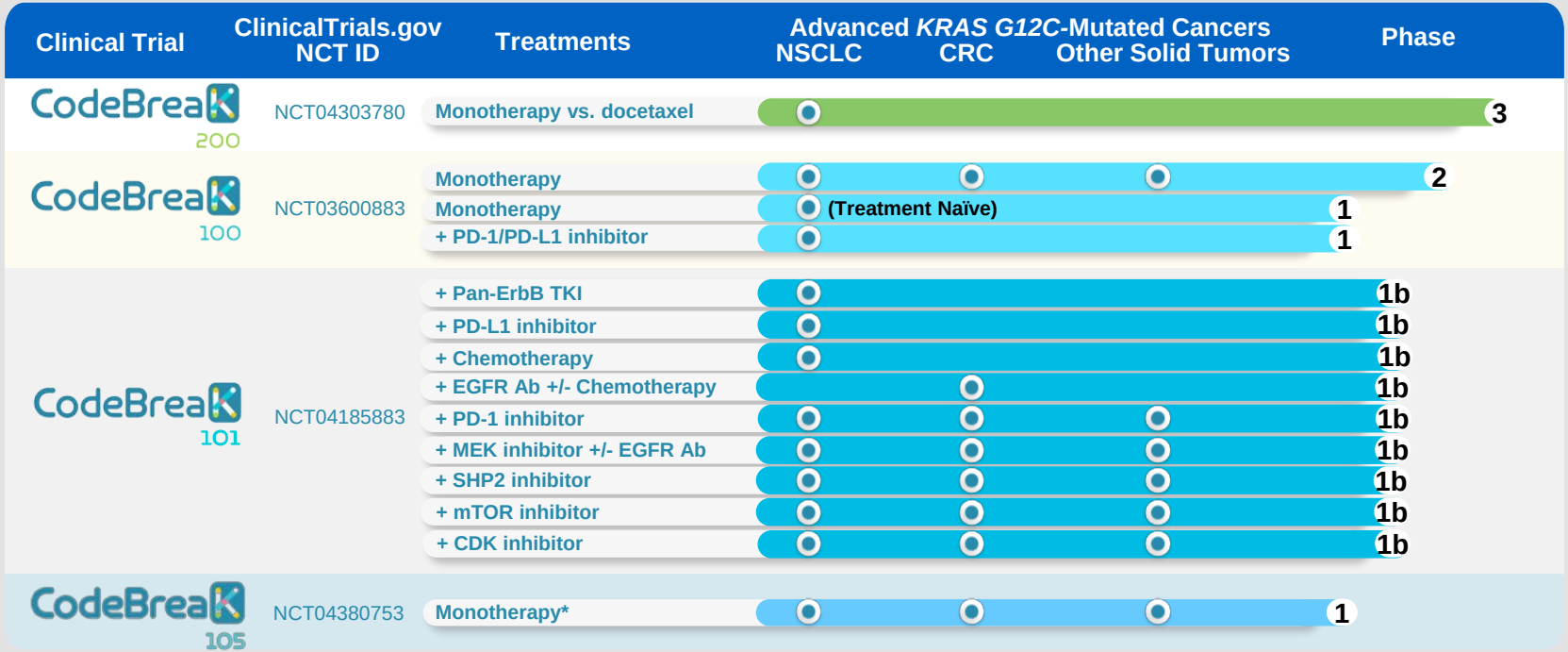
SOTORASIB:
THE BROADEST, MOST ADVANCED, GLOBAL KRAS^{G12C} CLINICAL PROGRAM



NCT = National Clinical Trial number; NSCLC = non-small cell lung cancer; CRC = colorectal cancer; PD-1 = programmed death-1; PD-L1 = programmed death ligand-1; ErbB = erythroblastic leukemia viral oncogene homolog; TKI = tyrosine kinase inhibitor; EGFR Ab = epidermal growth factor receptor antibody; MEK = mitogen-activated protein kinase kinase; SHP2 = Src homology region 2-containing protein tyrosine phosphatase 2; mTOR = mammalian target of rapamycin; CDK = cyclin-dependent kinase; *In subjects of Chinese descent

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SOTORASIB PHASE 2 DATA IN NSCLC

GREGORY FRIBERG, M.D.

VICE PRESIDENT, GLOBAL DEVELOPMENT AND ONCOLOGY THERAPEUTIC AREA HEAD

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CodeBreaK 100: Registrational Phase 2 Trial of Sotorasib in *KRAS* p.G12C Mutated Non-small Cell Lung Cancer

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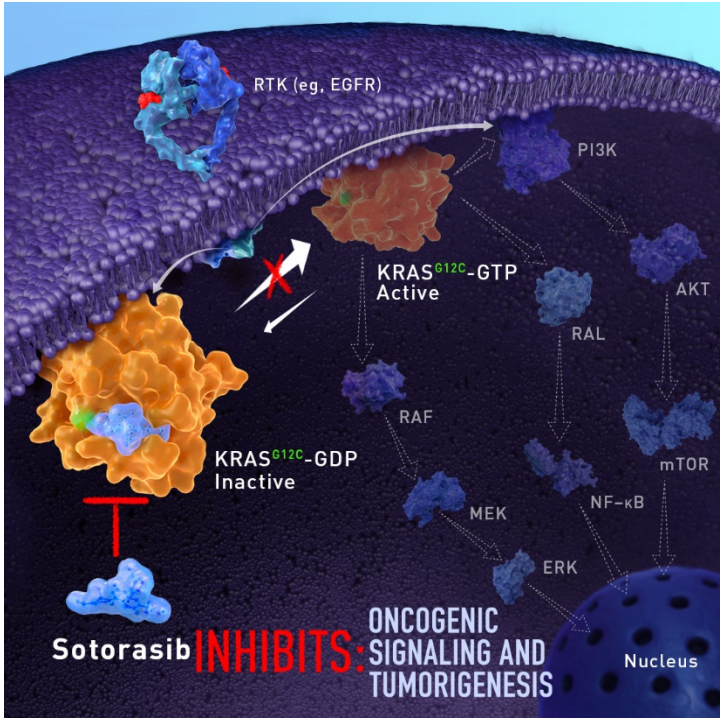
IASLC 2020 World Conference on Lung Cancer Singapore
JANUARY 28-31, 2021 | WORLDWIDE VIRTUAL EVENT

Introduction

- *KRAS* p.G12C mutation is a key oncogenic driver occurring in ~13% of lung adenocarcinomas[1]
- Sotorasib is a first-in-class, highly selective and irreversible $KRAS^{G12C}$ inhibitor[2]
- Sotorasib has shown durable clinical benefit in heavily pretreated patients with non-small cell lung cancer (NSCLC) from the phase 1 CodeBreaK 100 trial[3]
  - Objective response rate was 32.2% across all doses tested, with the median duration of response of 10.9 months
  - Median progression-free survival was 6.3 months
- Here, we present results from the NSCLC cohort of the registrational phase 2 CodeBreaK 100 trial



1, Biernacka A, et al. *Cancer Genet* 2016; 209:195-8.
2, Canon J, et al. *Nature*. 2019; 575: 217-223.
3, Hong DS, et al. *N Engl J Med.* 2020; 383:1207-1217.

Trial Design

clinicaltrials.gov identifier: NCT03600883

Screening / Enrollment

Key Eligibility:

- Locally advanced or metastatic NSCLC
- *KRAS* p.G12C mutation as assessed by central testing of tumor biopsies
- Progressed on prior standard therapies[a]
- No active brain metastases

Sotorasib was orally administered at 960 mg once daily until disease progression[b]

Radiographic scan every 6 weeks up to week 48 and once every 12 weeks thereafter

Primary endpoint: ORR (RECIST 1.1) by blinded independent central review

Key secondary endpoints: DoR; disease control rate; TTR; PFS; OS; safety

Exploratory endpoints: Evaluation of biomarkers (PD-L1, co-occurring mutations)

Safety and Long-term Follow-up[c]

a: no more than 3 prior lines of therapies were allowed; b: treatment beyond disease progression was allowed if certain criteria were met; c: safety follow-up occurs 30 (+7) days after the last dose of sotorasib; long-term follow-up occurs every 12 (±2) weeks for up to 3 years.
NSCLC: non-small cell lung cancer; ORR: objective response rate; DoR: duration of response; TTR: time to response; PFS: progression-free survival; OS: overall survival; PD-L1: programmed death-ligand 1; RECIST: Response Evaluation Criteria in Solid Tumors.

Patients

Baseline Characteristics	Sotorasib 960mg, N = 126
Median age – years (range)	63.5 (37–80)
Smoking history – n (%)[a]	
Never	6 (4.8)
Current or former	117 (92.9)
ECOG performance status – n (%)	
0	38 (30.2)
1	88 (69.8)
Prior lines of systemic anticancer therapy – n (%)	
1	54 (42.9)
2	44 (34.9)
3	28 (22.2)
Types of prior systemic anticancer therapy[b] – n (%)	
Platinum-based chemotherapy	113 (89.7)
PD-1 or PD-L1 inhibitors	115 (91.3)
Platinum-based chemotherapy and PD1/L1 inhibitors	102 (81.0)

- A total of **126** patients were enrolled from **11 countries**
- **81%** of patients had progressed on prior **platinum-based chemotherapy** and **PD1/L1 inhibitors**
- Data cutoff was **December 1, 2020;** median follow-up time was **12.2 months**

a: smoking status was missing for 3 patients; b: prior systemic anticancer therapy also included targeted biologics (23.8%), targeted small molecules (7.1%), and other (0.8%).
ECOG: Eastern Cooperative Oncology Group; PD-1: Programmed cell death protein 1; PD-L1: Programmed death-ligand 1.

Tumor Response with Sotorasib

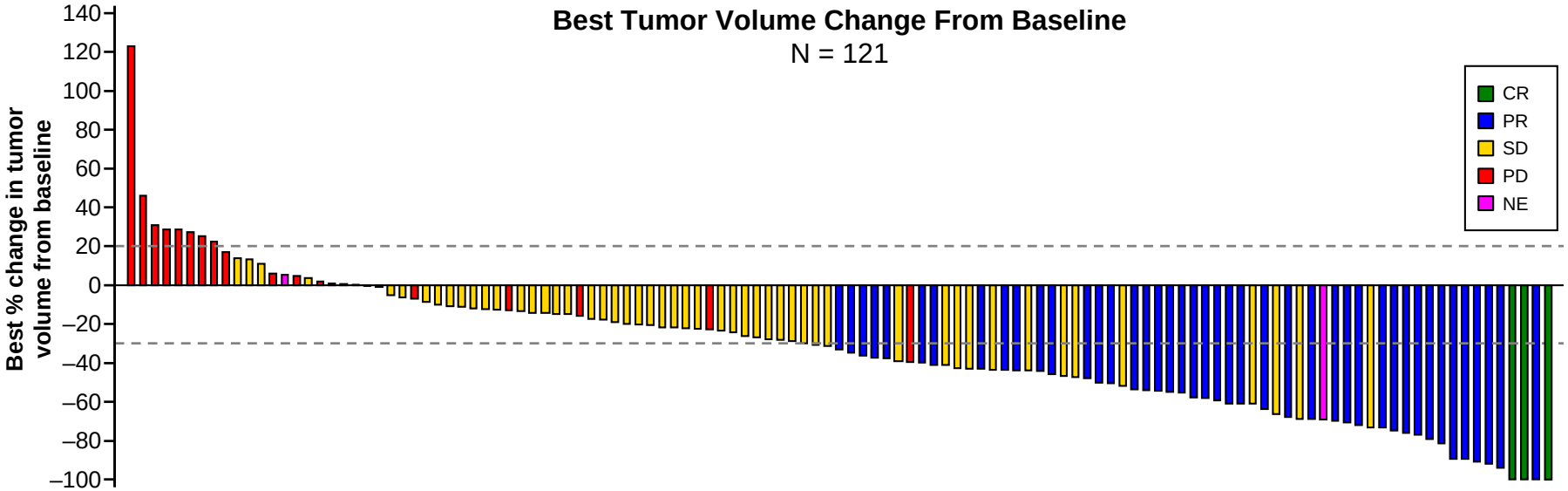
Over 80% of patients achieved disease control, including 3 CRs and 43 PRs

Response assessed by central review	Sotorasib 960mg, N = 124[a]
Confirmed objective response rate – % (95% CI)	**37.1 (28.6, 46.2)**
Best overall response – n (%)	
Complete response	3 (2.4)
Partial response	43 (34.7)
Stable disease	54 (43.5)
Progressive disease	20 (16.1)
"Not evaluable" or "Missing scan"[b]	4 (3.2)
Disease control rate – % (95% CI)	**80.6 (72.6, 87.2)**

a: according to central review, 2 patients did not have measurable lesions at baseline per RECIST 1.1 and were excluded from response assessment; b: 2 patients stopped treatment without post-baseline scans and were deemed as "missing scan"; 2 patients had 1 post-baseline scan and were assessed as "not evaluable" by central review.
CR: complete response; PR: partial response.

Depth of Tumor Response

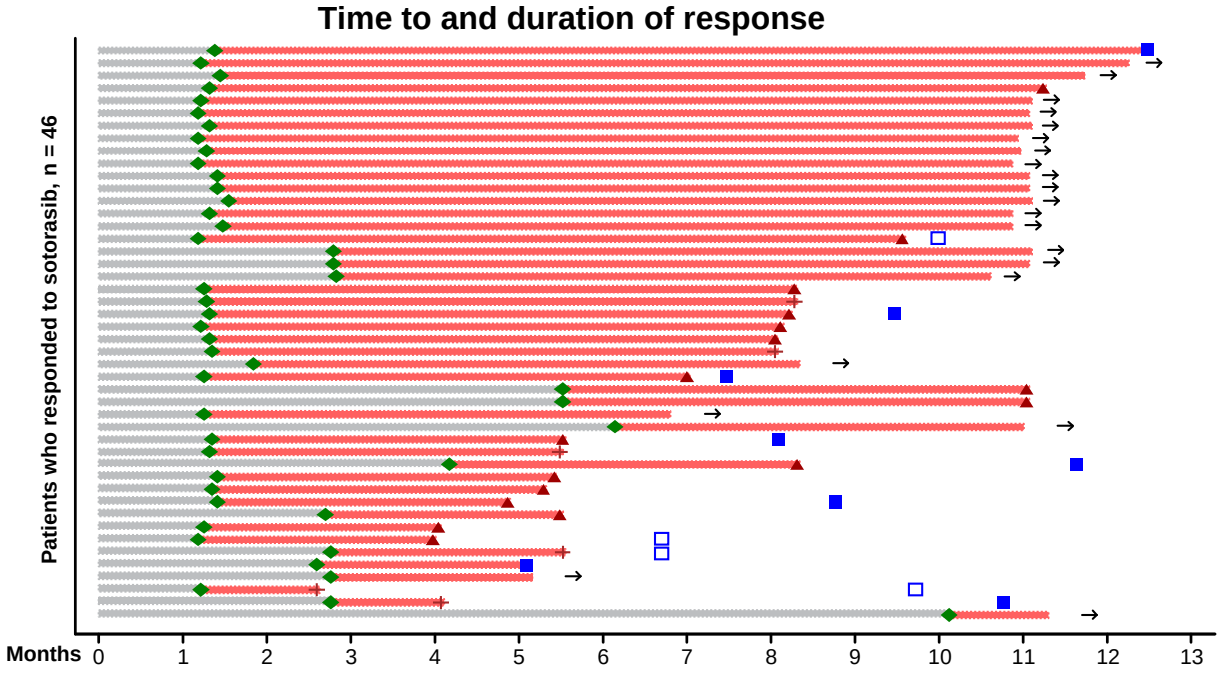
Tumor shrinkage of any magnitude was observed in 81% of patients (101/124)
Median percentage of best tumor shrinkage among all responders was 60%



Graph excluded 3 patients without post-baseline measurement in target lesions.
CR: complete response; PR: partial response; SD: stable disease; PD: progressive disease; NE: not evaluable.

Durability of Tumor Response

Responses to sotorasib were durable; 72% were seen at the first assessment

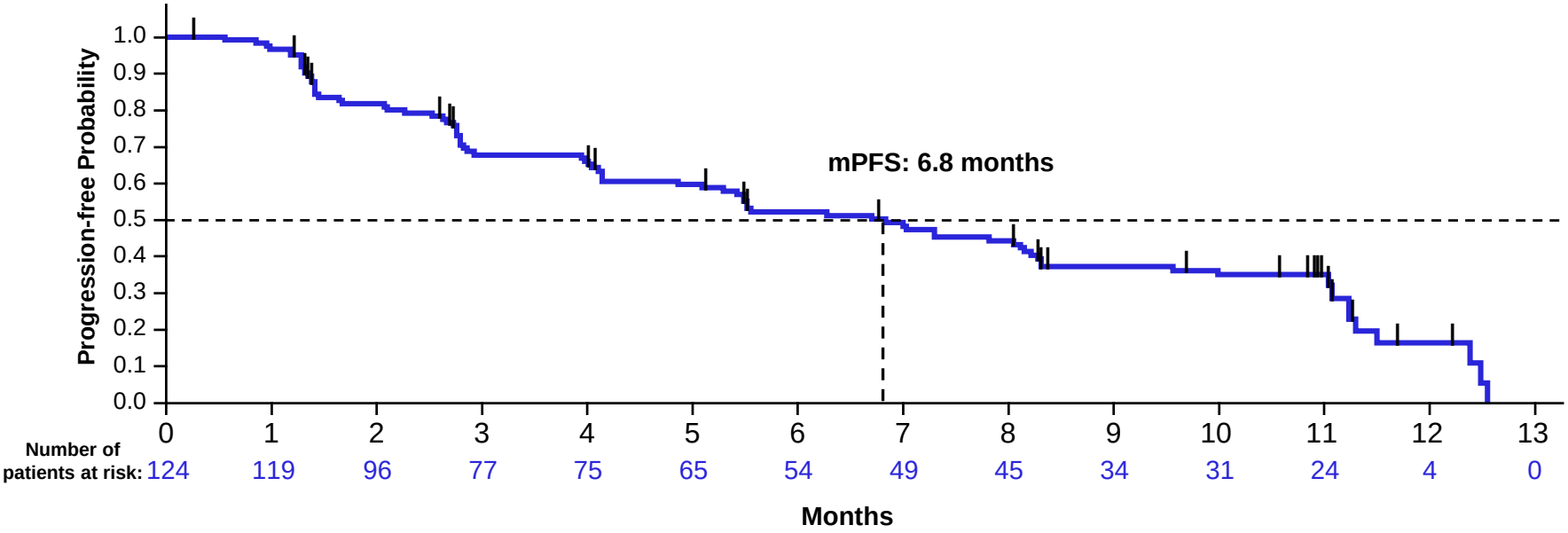


- Median duration of response: **10.0 months** (95% CI: 6.9, 11.1)
- Median time to objective response: **1.4 months**
- **43%** (20/46) of responders remained on treatment without progression as of the data cutoff

PFS: progression-free survival; OS: overall survival.

Progression-Free Survival

Median progression-free survival was 6.8 months (95% CI: 5.1, 8.2)



Treatment-Related Adverse Events

Treatment-related adverse events were generally mild and manageable

Treatment-related adverse events (TRAEs) occurring in >5%, n (%)	Any Grade N = 126	Grade 3 N = 126
Any event	**88 (69.8)**	**25 (19.8)**
Diarrhea	39 (31.0)	5 (4.0)
Nausea	24 (19.0)	0
ALT increase	19 (15.1)	8 (6.3)
AST increase	19 (15.1)	7 (5.6)
Fatigue	14 (11.1)	0
Vomiting	10 (7.9)	0
Blood alkaline phosphatase increase	9 (7.1)	1 (0.8)
Maculopapular rash	7 (5.6)	0

1 patient (0.8%) reported grade 4 TRAEs (pneumonitis and dyspnea)

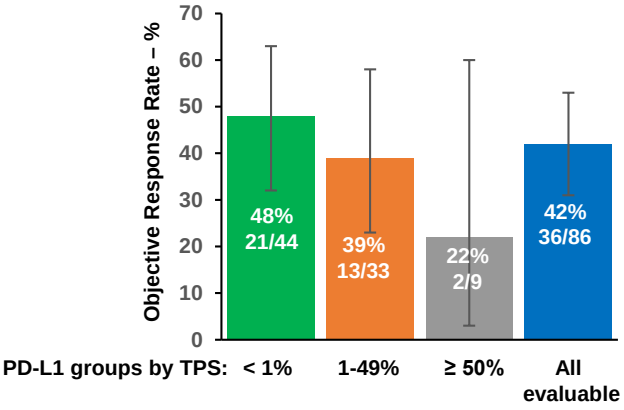
- Most TRAEs were grade 1 or 2
- No fatal TRAEs occurred
- TRAEs led to treatment discontinuation in 7.1% of patients
- TRAEs led to dose modification in 22.2% of patients

ALT: alanine aminotransferase; AST: aspartate aminotransferase.

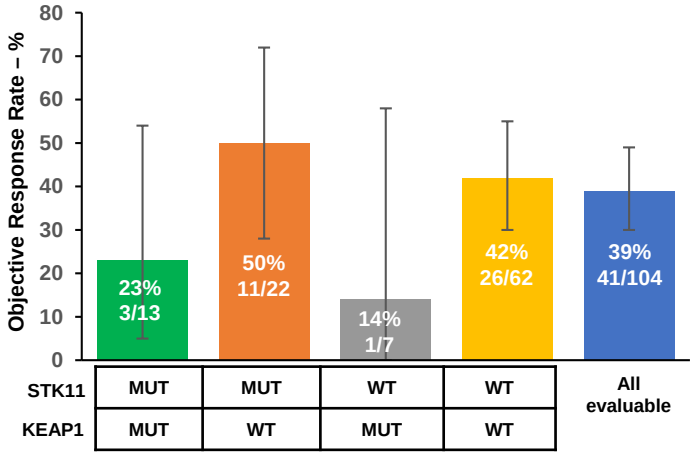
Tumor Response by PD-L1 Levels and STK11/KEAP1 Co-Occurring Mutations

In the exploratory biomarker analyses, responses to sotorasib were observed across the range of PD-L1 expression levels and STK11/KEAP1 co-occurring mutations

Response by PD-L1 Levels
n = 86



Response by STK11/KEAP1 Co-Occurring Mutations
n = 104



Both analyses were conducted retrospectively in the patient population (N=124) evaluable for efficacy per central review, who had available biomarker data. Tissue-based PD-L1 analysis was analyzed centrally using PD-L1 IHC 22C3 pharmDx. STK11/KEAP1 co-occurring mutation status was analyzed using tissue and/or plasma samples.
PD-L1: Programmed death-ligand 1; TPS: Tumor proportion score; MUT: mutant; WT: wild type.

Conclusions

- Sotorasib, the first-in-class KRAS^{G12C} inhibitor administered as once daily oral therapy, demonstrated early, deep, and durable responses in the advanced NSCLC cohort from the phase 2 CodeBreaK 100 trial
  - ORR was 37.1%, with median DoR of 10.0 months and median PFS of 6.8 months, validating the phase 1 results
- Sotorasib was well tolerated with no deaths attributed to treatment and low incidence of grade 3 or 4 treatment-related adverse events, treatment discontinuation, and dose modification
- Tumor response to sotorasib was observed across a range of biomarker subgroups, including patients with negative or low PD-L1 expression level and those with mutant STK11
- Breakthrough therapy designation was granted by FDA; regulatory filings based on current data are underway
- Confirmatory phase 3 CodeBreaK 200 trial is currently enrolling (clincaltrials.gov identifier: NCT04303780)

NSCLC: non-small cell lung cancer; ORR: objective response rate; DoR: duration of response; PFS: progression-free survival; PD-L1: Programmed death-ligand 1; FDA: U.S. Food & Drug Administration

Acknowledgement

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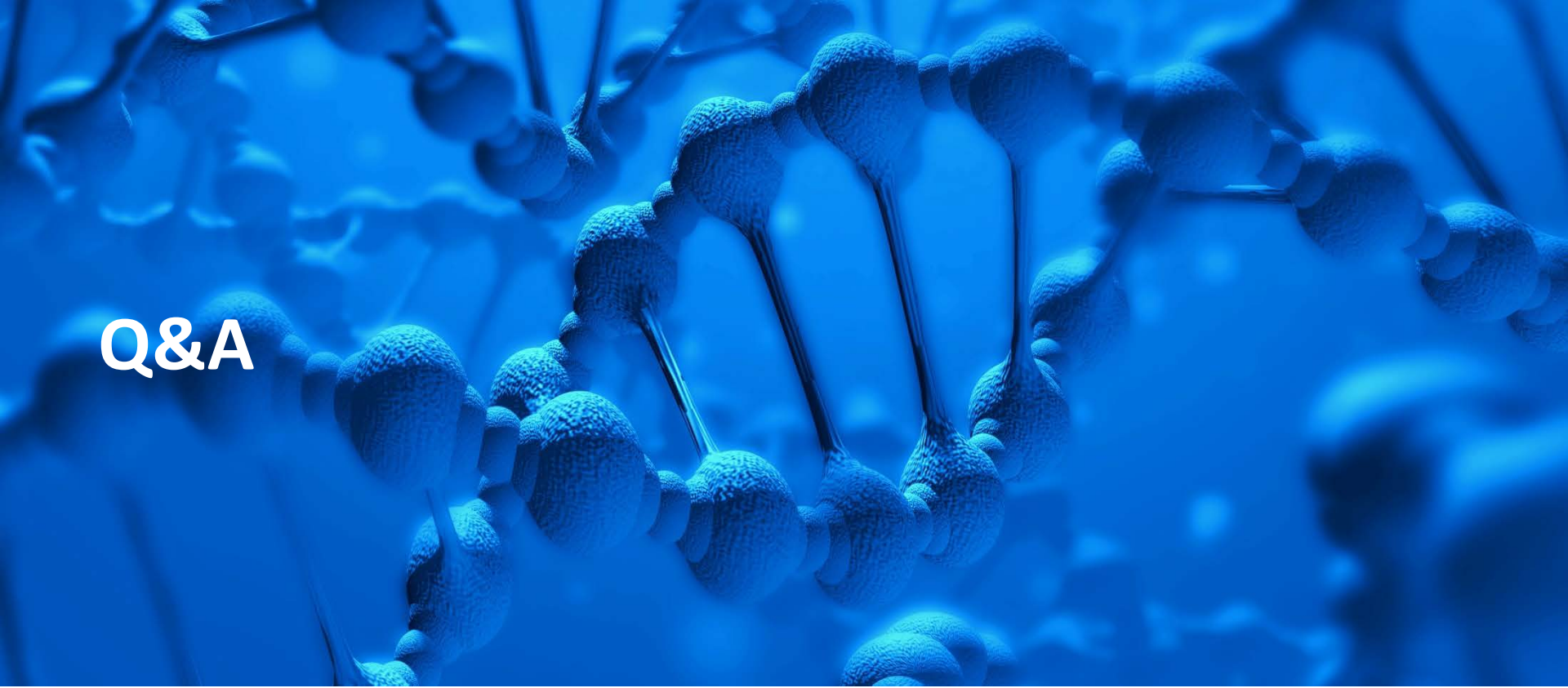
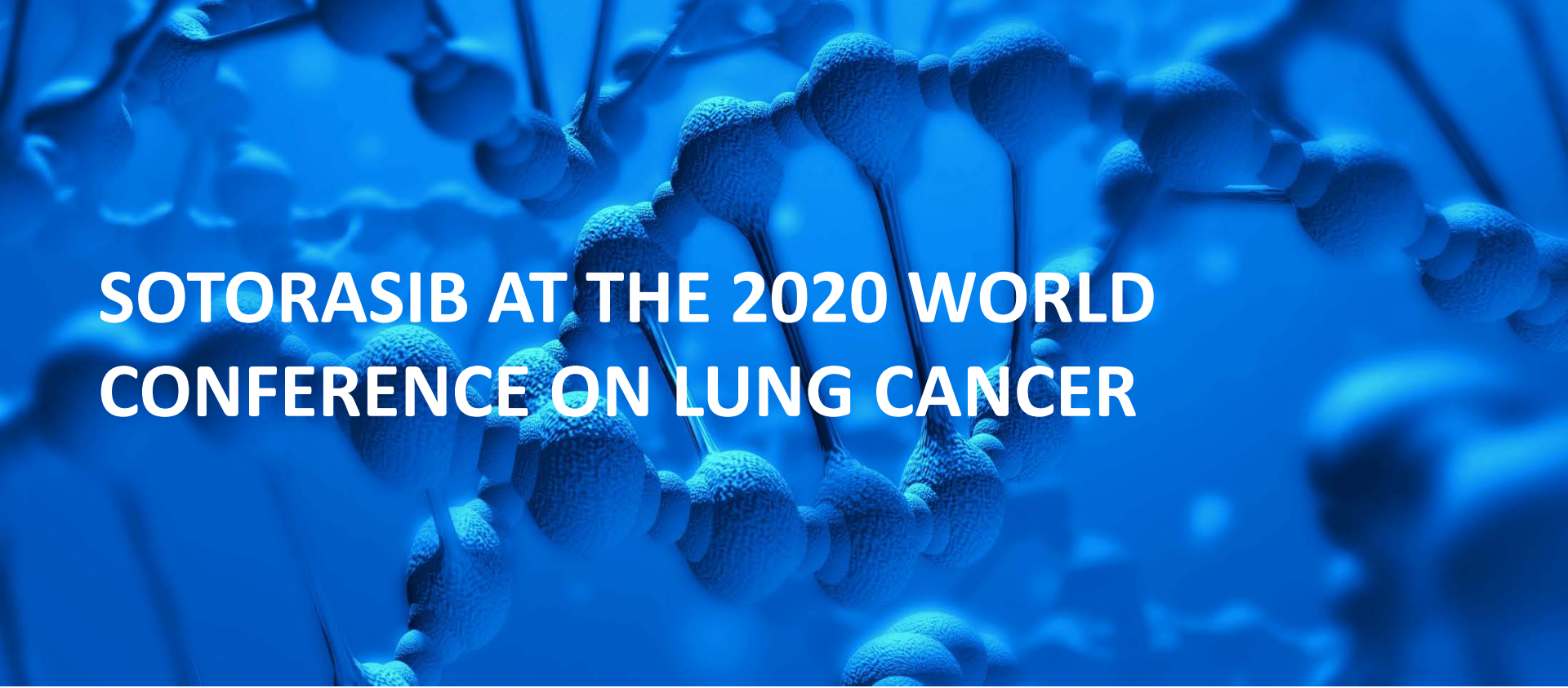
- Medical writing assistance was provided by Yang Li, PhD and Amy Foreman-Wykert, PhD (both of Amgen Inc.)


Q&A



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