

ONCOLOGY

Business Update

Lilly



Agenda

Introduction

Anne White, President, Lilly Oncology

RET Inhibitor Update

Dr. S. Michael Rothenberg, Vice President of
Research and Development, Loxo Oncology

Jacob Van Naarden, COO, Loxo Oncology

Closing Remarks

Dr. Dan Skovronsky, Chief Scientific Officer

Q&A

SAFE HARBOR PROVISION



This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.

For additional information about the factors that affect the company's business, please see the company's latest Forms 10-K and 10-Q filed with the Securities and Exchange Commission.

The company undertakes no duty to update forward-looking statements

The background of the slide is a solid red color. Overlaid on this background is a complex network diagram. It consists of numerous circular nodes of varying sizes, connected by thin, light-colored lines. The nodes are distributed across the entire frame, creating a sense of interconnectedness and complexity. The word "INTRODUCTION" is centered in the middle of the slide, written in a bold, white, sans-serif font.

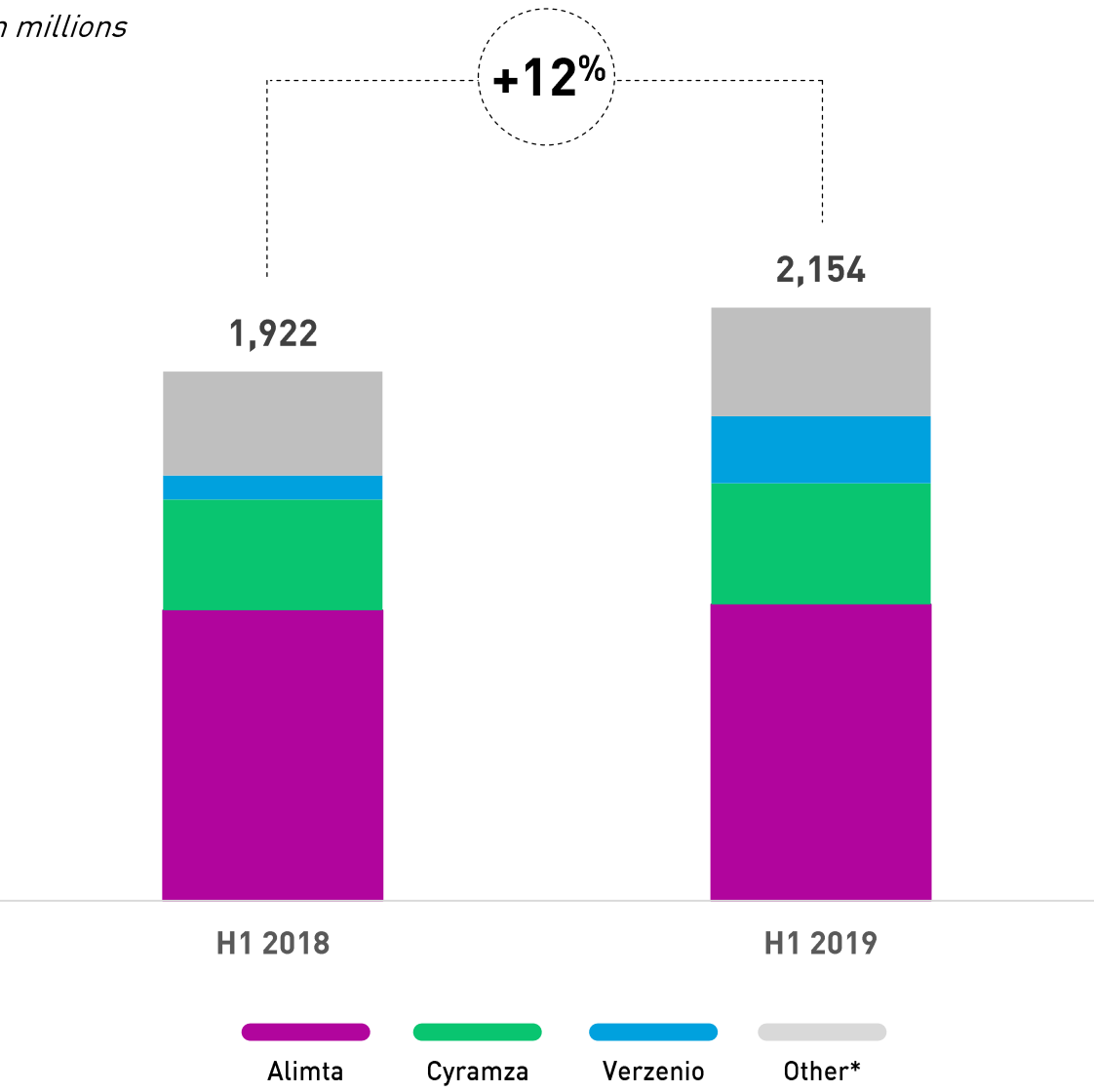
INTRODUCTION

LILLY ONCOLOGY PERFORMANCE



REVENUE GROWTH

USD in millions



* Excludes Lartruvo

KEY GROWTH DRIVERS

ALIMTA®

23% U.S. SOM in 1L non-squamous non-small cell lung cancer

CYRAMZA®

U.S. SOM in 2L non-small cell lung cancer doubled YoY from Q2 2018

Verzenio®

Eleven regulatory approvals around the world in 2019

达伯舒® ELUNATE®
信达利单抗注射液

Launched Tyvyt®¹ and Elunate®² expanding our presence in China

¹ In collaboration with Innovent Biologics, Inc.
² In collaboration with Hutchison China MediTech Limited

LILLY ONCOLOGY KEY EVENTS



COMMERCIAL



BUSINESS DEVELOPMENT



AurKaPharmaInc.



CLINICAL

Verzenio

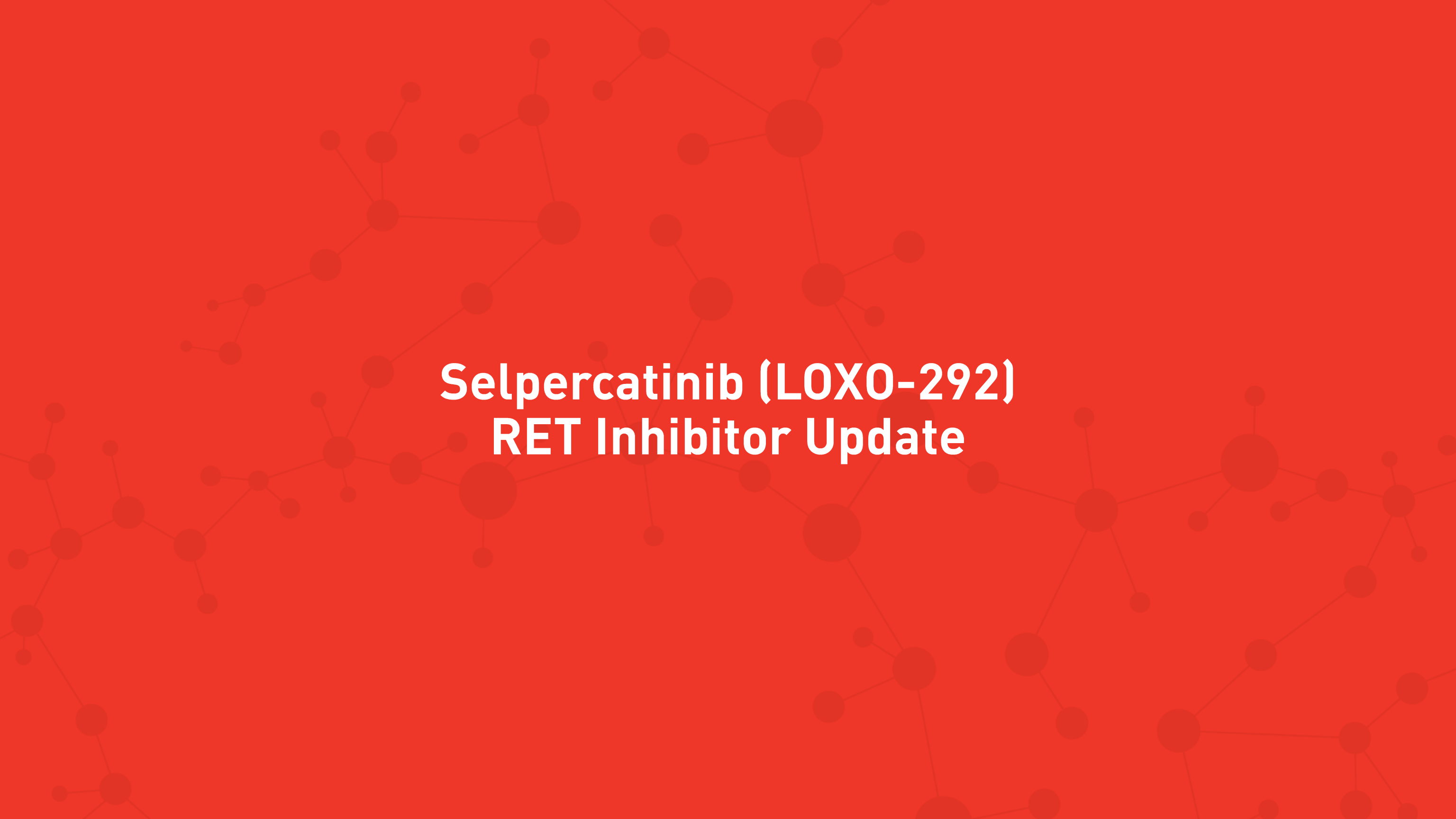
- ✓ Phase 3 MONARCH 2 overall survival
- ✓ Phase 2 HER2+
- ✓ Phase 3 China registration study

Cyramza

- ✓ AFP-high hepatocellular carcinoma
- ✓ EGFR-mutated non-small cell lung cancer

Selpercatinib

- ✓ RET fusion-positive non-small cell lung cancer

The background is a solid red color with a faint, abstract pattern of interconnected circles and lines, resembling a molecular or network structure. The circles vary in size, and the lines are thin and light red.

Selpercatinib (LOXO-292) RET Inhibitor Update

RET BACKGROUND



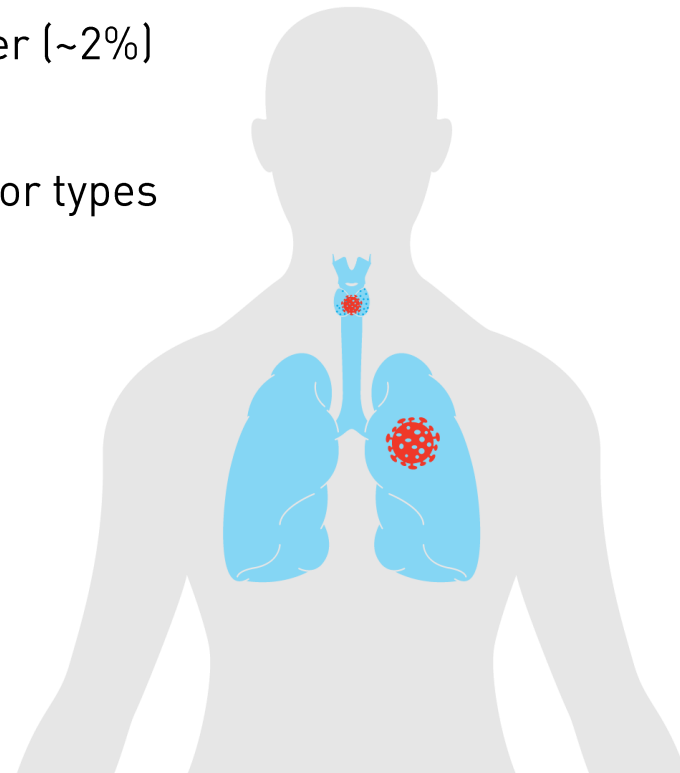
RET LANDSCAPE

RET fusions

- Non-small cell lung cancer (~2%)
- Thyroid cancer (10-20%)
- Many additional solid tumor types with lower incidence

RET mutations

- Medullary thyroid cancer (60% sporadic, >90% hereditary)



SELPERCATINIB

Highly selective, oral RET inhibitor

Properties of a potential best in class asset

- Highly potent
- Highly selective
- CNS activity
- Anticipates acquired resistance

Breakthrough Therapy designations

- RET fusion-positive non-small cell lung cancer
- RET fusion-positive thyroid cancer
- RET mutant medullary thyroid cancer

SELPERCATINIB LIBRETTO-001 STUDY



KEY TRIAL ASPECTS

- RET fusion-positive NSCLC
 - Primary analysis set (PAS) of first 105 patients with prior platinum chemotherapy
 - Additional analysis set of 39 treatment-naïve patients
- Primary endpoint: objective response rate (RECIST 1.1)
- Secondary endpoints:
 - Duration of response
 - Progression-free survival
 - Safety

BASELINE CHARACTERISTICS

Characteristic	PAS (n=105)	Treatment-naïve (n=39)
Female / Male, n (%)	62 (59) / 43 (41)	22 (56) / 17 (44)
Median age (range), years	61 (23 - 81)	61 (23 - 86)
ECOG performance status, n (%)		
0	31 (30)	19 (49)
1	72 (69)	20 (51)
2	2 (2)	0 (0)
Median prior systemic regimens (range)	3 (1-15)	0
Prior platinum-based chemotherapy, n (%)	105 (100)	-
Prior PD1/PD-L1, n (%)	58 (55)	-
Concurrent with platinum-based chemotherapy	9 (9)	-
Sequential to platinum-based chemotherapy	49 (47)	-
Prior multikinase inhibitor (MKI), n (%)	50 (48)	-
1	37 (35)	-
≥ 2	13 (12)	-
Brain metastases, n (%) [‡]	37 (35)	7 (18)
Measurable disease	104 (99)	39 (100)

Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.
Data cut-off: June 17th, 2019. Total % may be different than the sum of the individual components due to rounding. [‡] Includes patients with non-target CNS metastases.

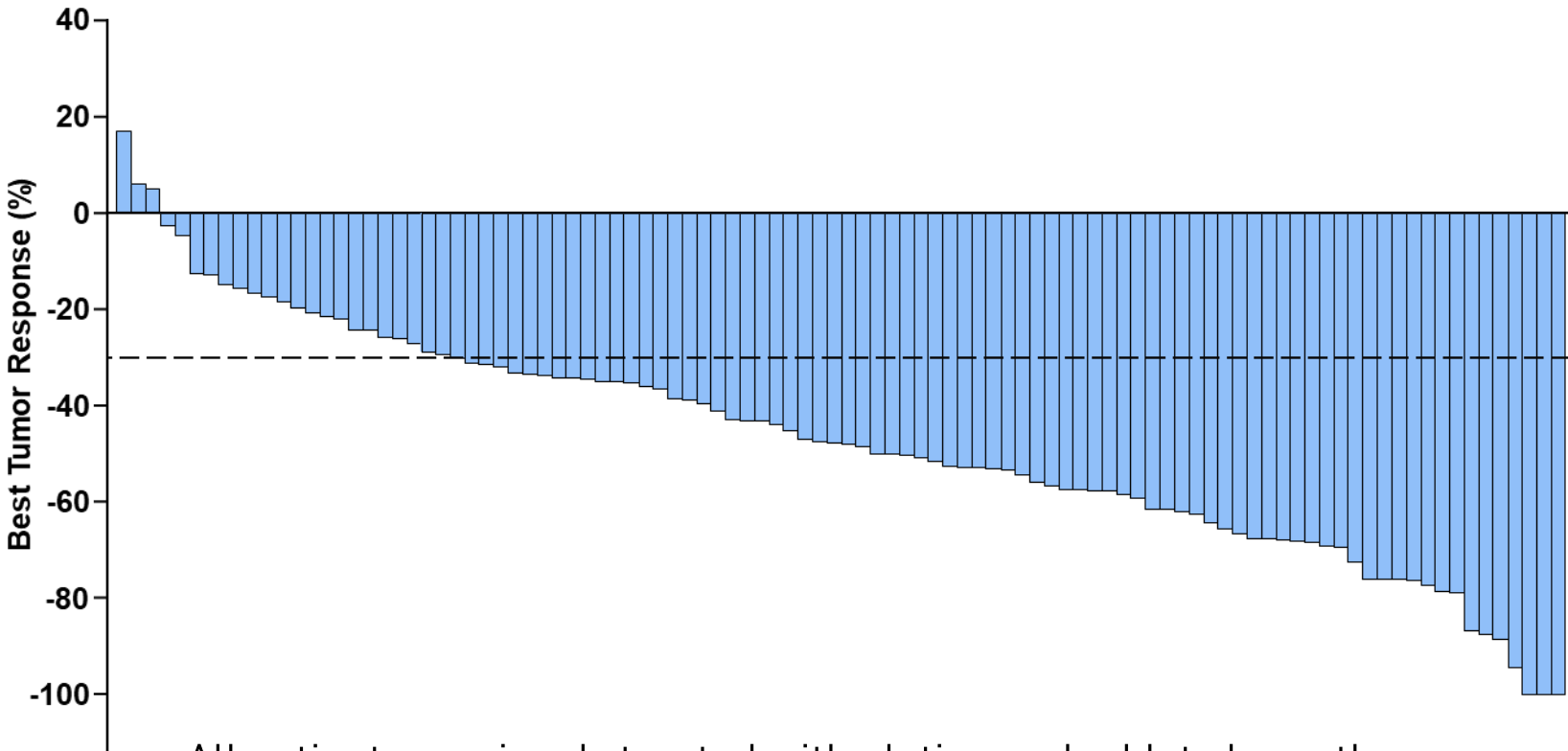
SELPERCATINIB LIBRETTO-001 STUDY



PRIMARY ANALYSIS SET n=105

ORR (95% CI)	Overall (n=105)	CNS** (n=11)
	68% (58%-76%)*	91% (59%-100%)
CR	2%	18%
PR	66%	73%
SD	26%	9%
PD	2%	-
NE	5%	-

- 68% ORR in heavily pretreated¹ RET fusion-positive NSCLC
- 91% intracranial CNS ORR
- Largest cohort of RET fusion-positive NSCLC patients treated with a RET inhibitor



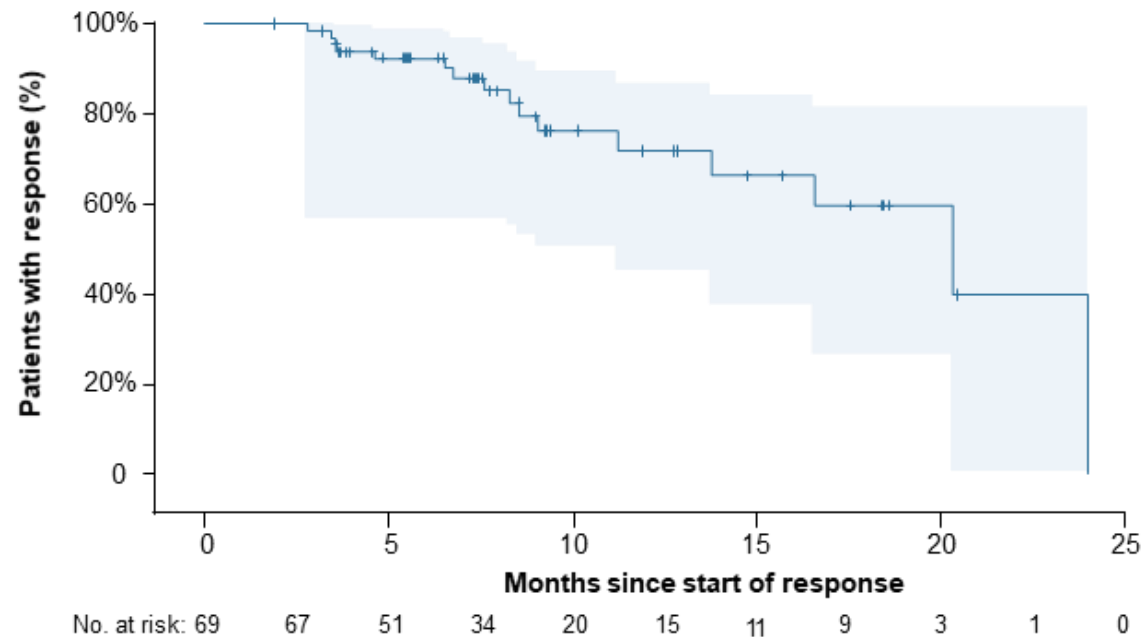
- All patients previously treated with platinum-doublet chemotherapy
- 55% previously treated with an anti-PD-1/PD-L1 antibody
- 48% previously treated with at least one multikinase inhibitor
- ORR similar regardless of prior therapy

¹ Median of 3 prior systemic regimens, range 1-15 prior systemic regimens
Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.
Investigator response assessments as of June 17th, 2019. 5 patients not shown in waterfall plot: 3 discontinued prior to any post-baseline imaging assessments, 1 did not have measurable disease at baseline, and 1 deemed not evaluable on study by the Investigator. NE—Not evaluable, n=5 patients: 3 discontinued prior to any post-baseline imaging assessments, 1 deemed not evaluable on study by the Investigator, and 1 discontinued after a single post-baseline imaging assessment showing SD, less than 6 weeks after starting treatment. Total % may be different than the sum of the individual due to rounding. *N=105 dataset includes 2 unconfirmed PRs awaiting confirmatory response assessments. **Patients with CNS target lesions at baseline.

SELPERCATINIB LIBRETTO-001 STUDY PRIMARY ANALYSIS SET

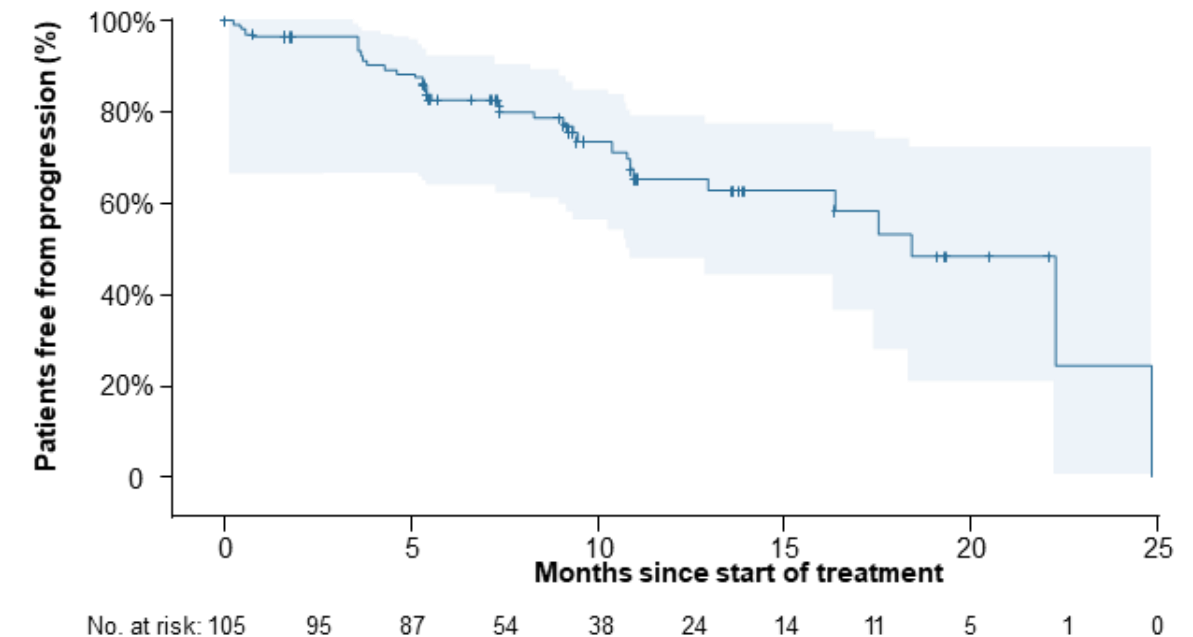


DURATION OF RESPONSE



- Number of events: 16/69
- Median follow-up: 8.0 months
- Median duration of response: 20.3 months* (95% CI: 13.8, 24.0)

PROGRESSION-FREE SURVIVAL



- Number of events: 33/105
- Median follow-up: 9.6 months
- Median PFS: 18.4 months* (95% CI: 12.9, 24.9)

- Majority of NSCLC patients remain in response or progression-free
- Consistent DOR and PFS regardless of prior therapy

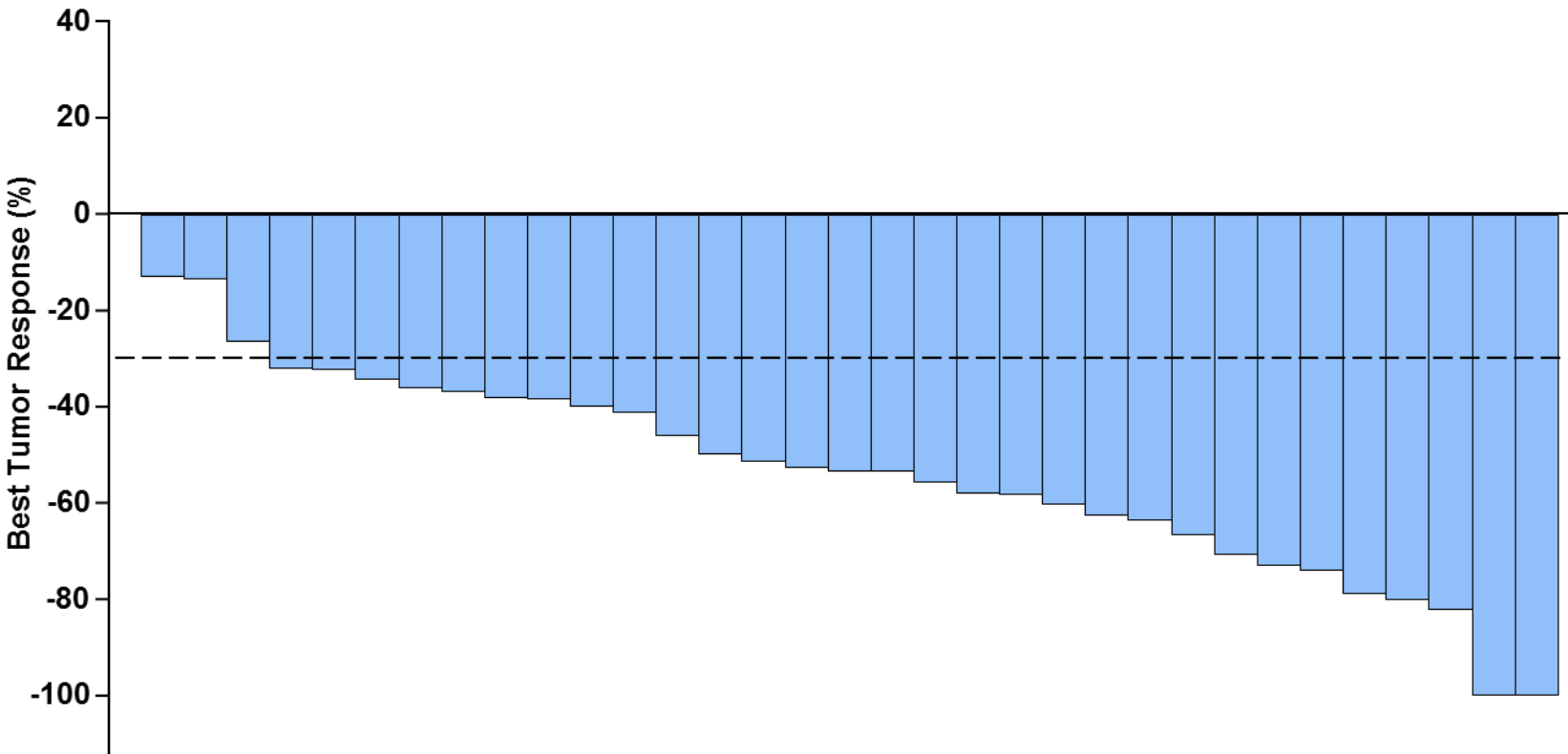
Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain. Data cut-off: June 17th, 2019. Shading in PAS Kaplan-Meier curves indicates the 95% confidence interval. *Medians are not statistically stable due to a low number of events.

SELPERCATINIB LIBRETTO-001 STUDY



TREATMENT-NAIVE NSCLC PATIENTS n=34

ORR (95% CI)	n=34
	85% (69%-95%)*
CR	3%
PR	82%
SD	9%
PD	3%
NE	3%



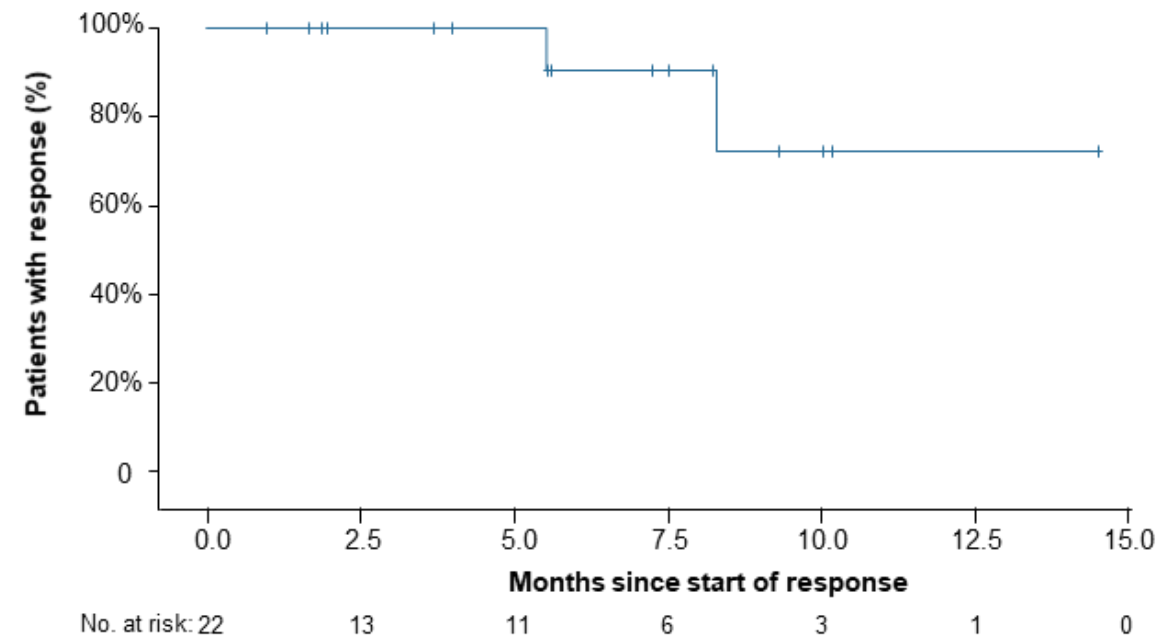
○ ORR 85% in treatment naïve patients

Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain. Investigator response assessments as of June 17th, 2019. Data include patients with at least one evaluable post-baseline imaging assessment and those who discontinued therapy prior to any post-baseline imaging assessment. 1 patient discontinued prior to any post-baseline imaging assessment and is not shown in the waterfall plot. NE—not evaluable, n=1 patient who discontinued prior to any post-baseline imaging assessment. Total % may be different than the sum of the individual due to rounding. *N=34 dataset includes 7 unconfirmed PRs awaiting confirmatory response assessments.

SELPERCATINIB LIBRETTO-001 STUDY TREATMENT-NAÏVE

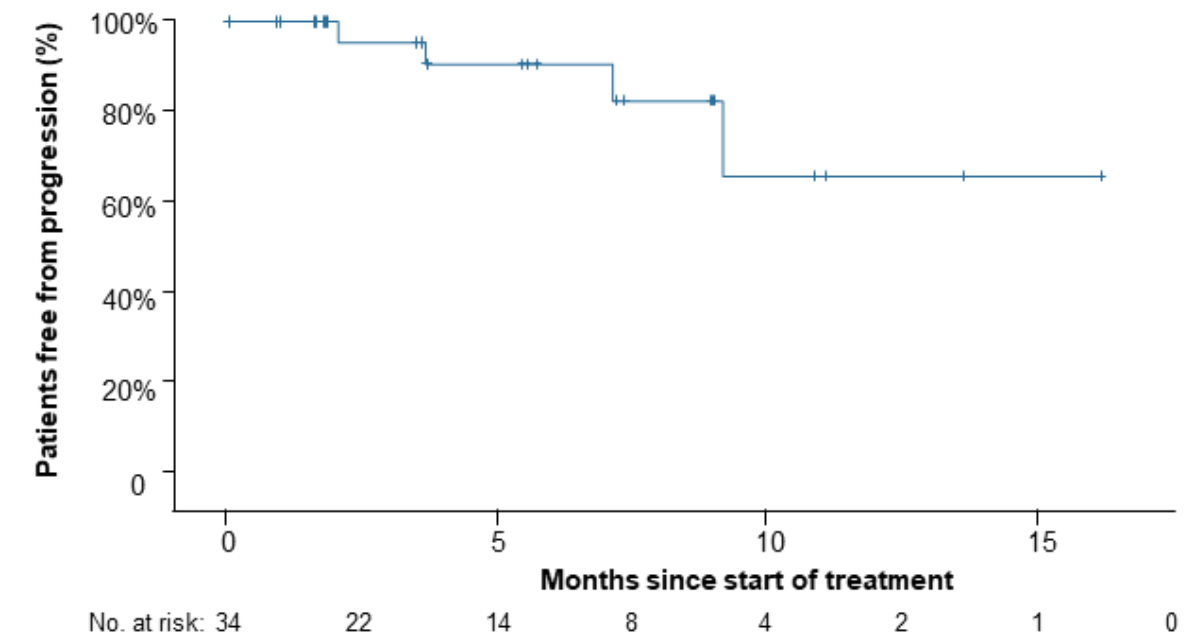


DURATION OF RESPONSE



- Number of events: 2/22
- Median follow-up: 4.8 months
- Median duration of response not reached (95% CI: 8.3, NE)

PROGRESSION-FREE SURVIVAL



- Number of events: 4/34
- Median follow-up: 3.7 months
- Median PFS not reached (95% CI: 9.2, NE)

Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.
Data cut-off: June 17th, 2019. No shading to show 95% confidence interval due to a very low number of events.

MEANINGFUL CNS RESPONSES



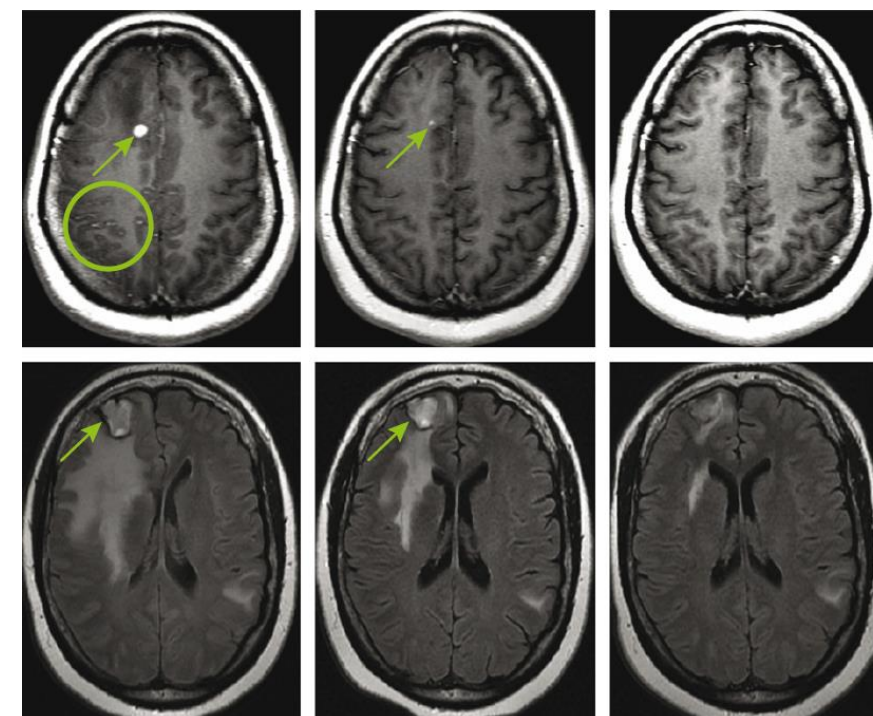
CNS ACTIVITY

Up to 50% of RET fusion-positive NSCLC will metastasize to the brain*

Only RET inhibitor to demonstrate robust CNS ORR

- ORR 91%, n=11**
- In RET fusion-positive NSCLC with CNS target lesions

LEPTOMENINGEAL DISEASE †



Demonstrated activity in leptomeningeal disease in a single patient protocol

Intracranial complete response with selpercatinib

*Drilon A, et al. Journal of Thoracic Oncology. 2018

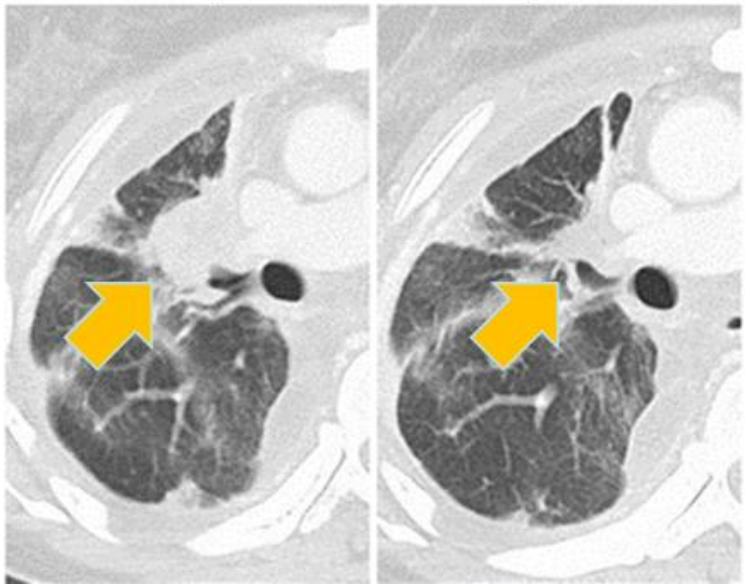
**Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.

† Guo et al. JCO Precision Oncology 2019.

ILLUSTRATIVE EXAMPLES OF SELPERCATINIB ACTIVITY



GATEKEEPER RESISTANCE

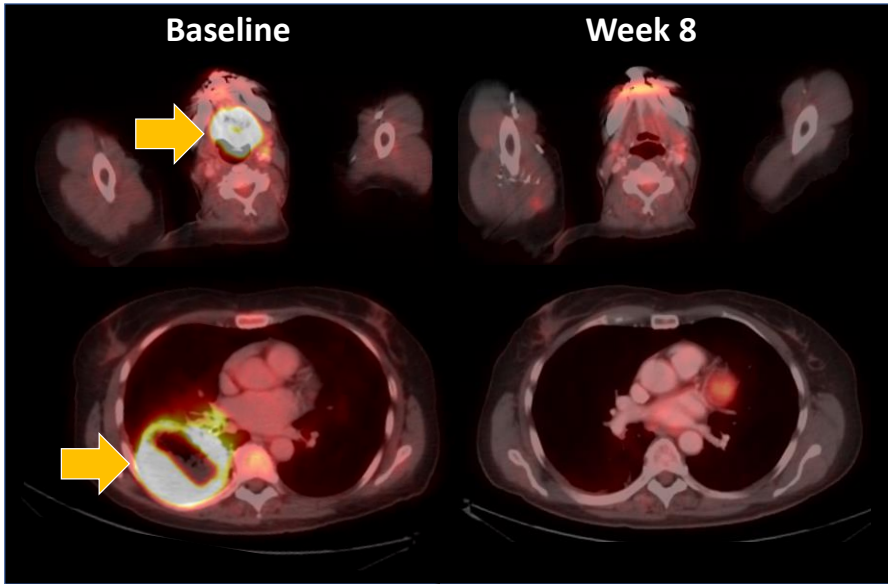


Pre-treatment

Partial response
after 8 weeks

- KIF5B-RET fusion-positive NSCLC patient previously treated with 15 prior regimens, and acquired RET V804L gatekeeper mutation after vandetanib treatment
- First reported case of a NSCLC patient with an acquired RET gatekeeper mutation successfully treated with a RET inhibitor
- Patient remains on treatment at 11 months

TREATMENT-NAÏVE SETTING



- KIF5B-RET fusion-positive NSCLC patient
- Remains on treatment at 10 months

Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.

SELPERCATINIB LIBRETTO-001 STUDY



SAFETY PROFILE (n=531)

	LIBRETTO-001 Safety Database, n=531								
	Treatment-emergent AEs (≥15% overall)						Treatment-related AEs		
	Grade 1	Grade 2	Grade 3	Grade 4	Total		Grade 3	Grade 4	Total
Dry mouth	29%	4%	–	–	32%		–	–	27%
Diarrhea	21%	8%	2%	–	31%		1%	–	16%
Hypertension	4%	11%	14%	<1%	29%		8%	<1%	18%
Increased AST	17%	5%	6%	1%	28%		4%	1%	22%
Increased ALT	13%	4%	7%	1%	26%		6%	1%	21%
Fatigue	15%	9%	1%	–	24%		<1%	–	14%
Constipation	19%	3%	<1%	–	22%		<1%	–	11%
Headache	15%	4%	1%	–	20%		<1%	–	7%
Nausea	15%	4%	<1%	–	19%		<1%	–	8%
Peripheral edema	16%	4%	<1%	–	19%		–	–	10%
Increased creatinine	14%	4%	–	<1%	18%		–	–	10%

Largest safety database of RET-altered patients treated with a RET inhibitor (n=531)

9 patients (1.7%) discontinued due to treatment-related adverse events

Abstract PL 02.08. Presented at the 20th meeting of the International Association for the Study of Lung Cancer at the World Conference on Lung Cancer; September 7-10, Barcelona, Spain.
Data cut-off: June 17th, 2019. AE – adverse event; total % for any given AE may be different than the sum of the individual grades, due to rounding.

Selpercatinib Summary



Striking and durable overall and CNS response rates

Consistent response rates with previously reported data, in a larger, more heavily pretreated patient population



Impressive durability

Early durability trends show potential opportunity for patients to have control of their disease for a long time



Meaningful results in a treatment-naïve population

Strong support for use as potential first-line treatment



Low treatment-related discontinuation rate

Supporting the potential for durable disease control

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Lilly Oncology Next Steps

LILLY ONCOLOGY: UPCOMING MILESTONES



LOXO NEXT STEPS

Selpercatinib

- Thyroid cancer data from the LIBRETTO-001 study to be presented at ESMO
- NDA to be submitted by year-end
- Two confirmatory Phase 3 studies in 1L settings
 - Selpercatinib vs. platinum doublet chemotherapy +/- pembrolizumab in treatment-naïve RET fusion-positive NSCLC
 - Selpercatinib vs. cabozantinib/vandetanib in treatment-naïve RET-mutant MTC

LOXO-305

- Highly selective, non-covalent BTK inhibitor being developed for B-cell leukemias and lymphomas
- Phase 1 clinical update at a medical meeting by year-end

ADDITIONAL DATA DISCLOSURES

Verzenio

- Data to be presented at ESMO:
 - Phase 3 MONARCH 2 overall survival
 - Phase 2 HER2+
 - Phase 3 China registration study
- Phase 3 adjuvant (2021)

Pegilodecakin

- Phase 3 Pancreatic (2019), Phase 2 NSCLC (1H 2020)

Summary



Transformative time in Lilly Oncology

Strong commercial portfolio with several catalysts to accelerate future growth



Promising results from Loxo Oncology acquisition

Selpercatinib poised to be first-in-class and best-in-class RET inhibitor following rapid development timeline



Additional value to be seen in precision medicine

Loxo Oncology acquisition has brought a highly talented team and leadership in precision medicine



QUESTIONS AND ANSWERS

**LILLY UNITES
CARING WITH DISCOVERY
TO CREATE MEDICINES THAT
MAKE LIFE BETTER
FOR PEOPLE
AROUND THE WORLD**

Lilly