Cullinan Pearl

2021 ASCO Update on CLN-081

June 4, 2021

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Owen Hughes
Chief Executive Officer

Intarcia

BainCapital

Jeff Trigilio
Chief Financial Officer

BlueRock Therapeutics

ALEXION

Jon Wigginton, MD
Senior Adviser &
Chairman of SAB

MacroGenics

MERCK

Bristol-Myers Squibb

Leigh Zawel, PhD
Chief Scientific Officer,
Small Molecules

Pfizer

MERCK

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Cullinan Pearl (CLN-081)

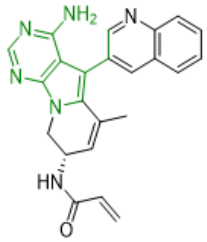
Selective EGFR inhibitor targeting Exon 20 insertion mutant NSCLC

Hypothesis

- EGFR is a therapeutically validated oncogenic driver in NSCLC
- CLN-081 is highly selective for exon 20 and exhibits weaker inhibitory effects on WT EGFR relative to mutants, thereby creating the potential for an enhanced therapeutic window relative to other compounds in development

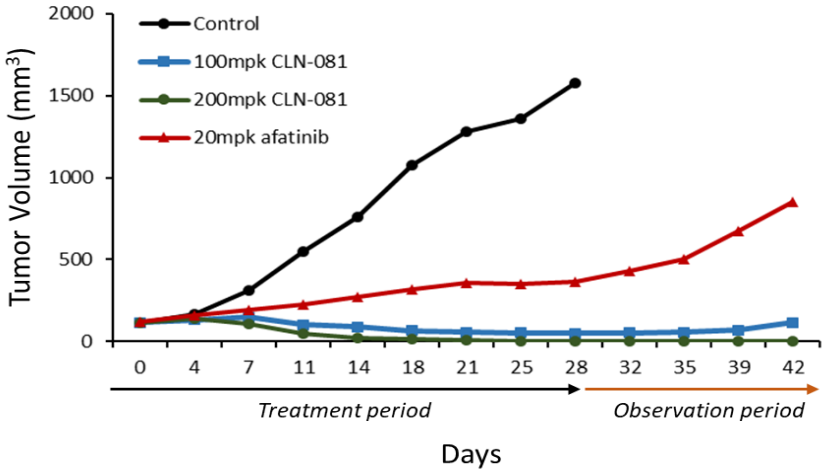
Design

- Unique scaffold (pyrrolopyrimidine) relative to all other TKIs targeting Exon 20 NSCLC
- Selective for EGFR activating mutations only; limited activity against HER2 WT and Exon 20
- Potential to differentiate on tolerability and clinical activity

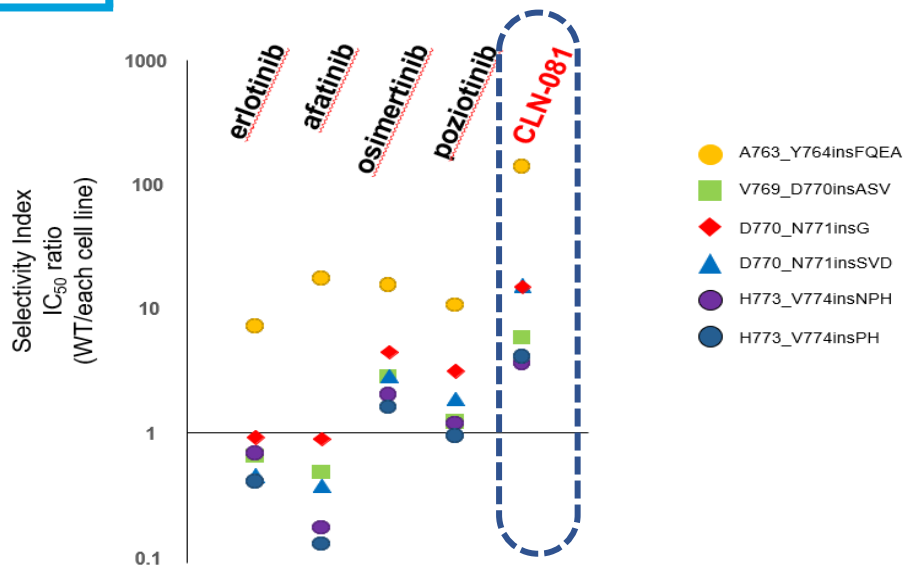


Key PC Data

Antitumor activity in LXF2478 (PDX model for lung cancer harboring EGFR V769_D770INSASV)



Selectivity for CLN-081 vs. other EGFR inhibitors in Exon20 insertion mutations



As of April 1, 2021

Cullinan Pearl Enrollment Progress

Patient Enrollment

Dose (BID)	Accelerated Titration	Rolling 6	Phase 1 Expansion	Phase 2a Expansion
30 mg	N = 2 →	N = 6		
45 mg	N = 1			
65 mg	N = 1 →	N = 6 →	N = 7	
100 mg	N = 1 →	N = 6 →	N = 6 →	N = up to 23
150 mg		N = 7	*Expansion under consideration*	

Geographic Footprint

Location	US	Netherlands	Singapore	Hong Kong	Taiwan	China
# of Sites	9	1	2	1	1	IND approved

Zai Lab has licensed CLN-081 for Greater China.

As of April 1, 2021

Cullinan Pearl Baseline Demographics

Select Baseline Characteristics	
Characteristic	All patients (n=44[1])
Median age (range)	64 (44-82)
Number of prior systemic anticancer regimens	
1 (%)	12 (27%)
2 (%)	17 (39%)
≥3 (%)	15 (34%)
Median (range)	2 (1-9)
Prior EGFR TKI, including pozio / mobo (%)	18 (40%)
Prior checkpoint inhibitor therapy (%)	25 (56%)
Brain mets at baseline (%)	12 (27%)

- **Heavily pretreated patient population**
- **Greater than 70% of patients have had at least 2 prior lines of therapy**

1. Excludes 1 patient that does not have baseline demographic info.

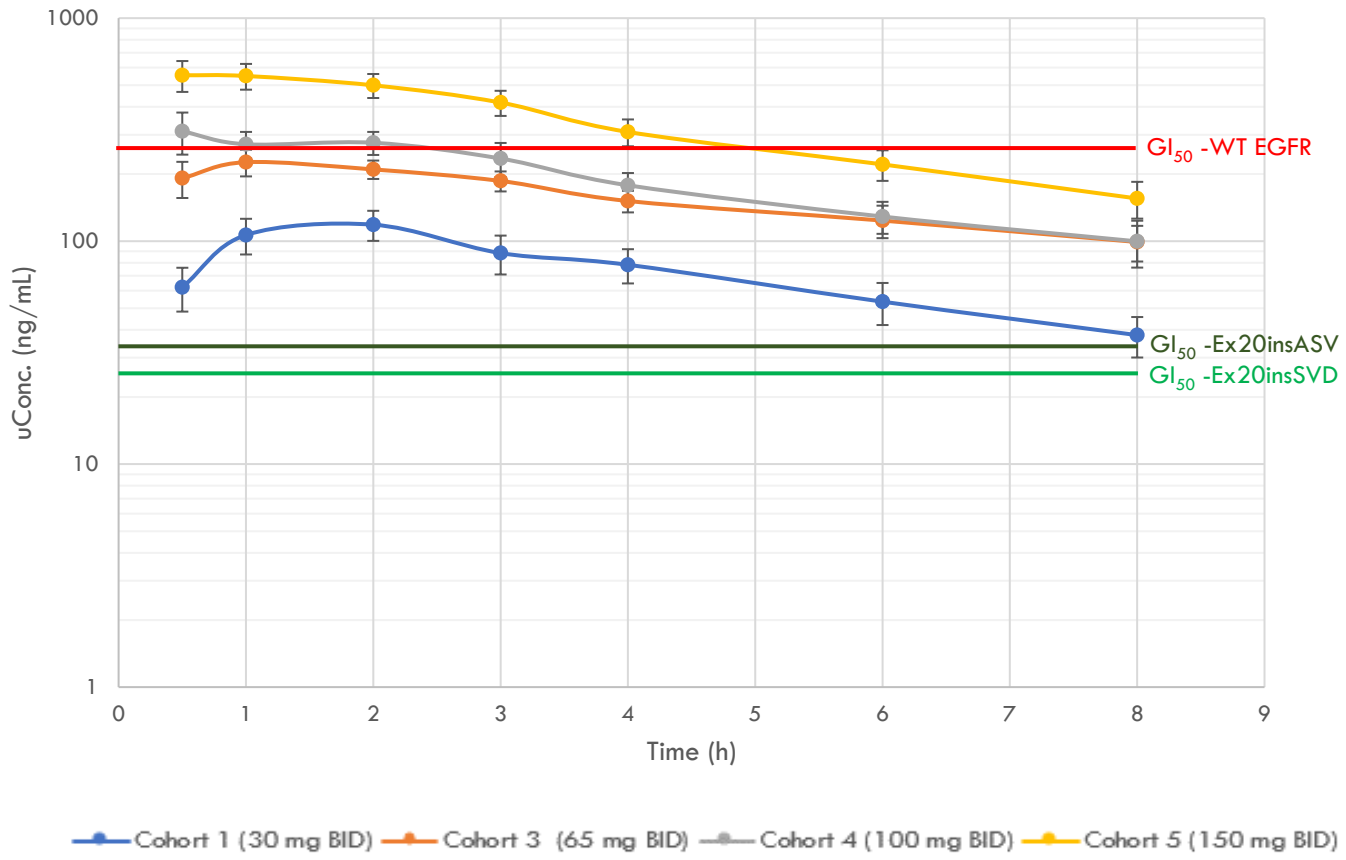
As of April 1, 2021

Preliminary Safety Overview

Dose (BID)	30 mg	45 mg	65 mg	100 mg	150 mg
Safety Population (n)	**8**	**1**	**14**	**15**	**7**
DLTs	--	--	--	--	1
Grade 1 TRAEs of interest					
Skin Rash	6	--	7	5	4
Diarrhea	2	--	1	3	1
Elevated ALT / AST	1	--	2	2	2
Anemia	--	--	1	2	--
Grade 2 TRAEs of interest					
Skin Rash	--	--	6	5	1
Diarrhea	--	--	--	1	1
Elevated ALT / AST	--	--	--	1	--
Anemia	--	--	--	1	--
Grade ≥3 TRAEs of interest					
Skin Rash	--	--	--	--	--
Diarrhea	--	--	--	--	1
Elevated ALT / AST	--	--	2	1	2
Anemia	1	--	2	--	1
Treatment Related Dose Reduction / Discontinuation	--	--	2 / 1	2 / --	1 / 2

Preliminary CLN-081 Pharmacokinetics

Average Unbound Plasma Concentration over Time

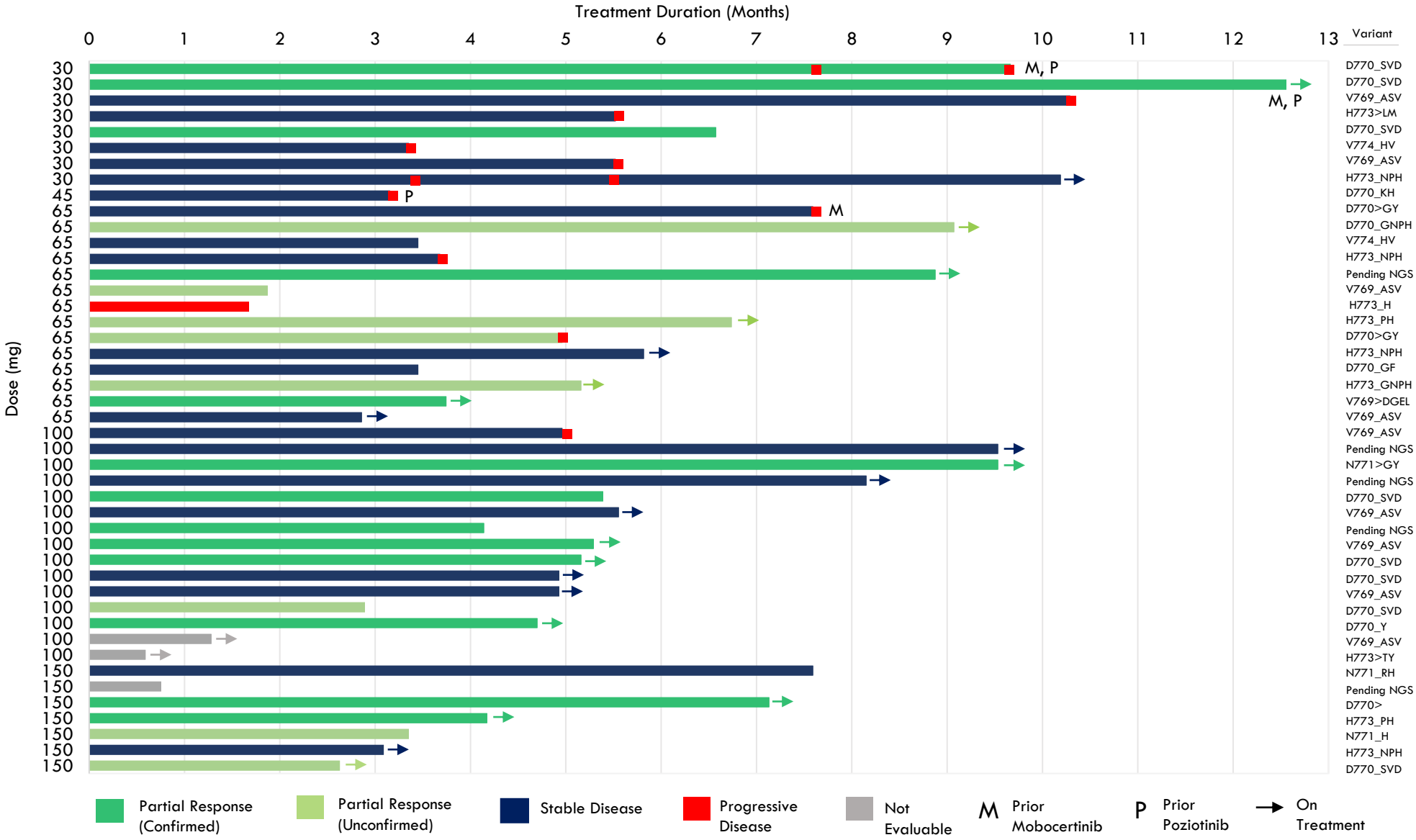


- **CLN-081 well behaved to date**
- **Sustained Coverage Over 8h Period**
  - Unbound plasma concentrations are greater than GI50 values for Ex20Ins cell-lines

Using STD error of the mean

As of April 1, 2021

Activity Across Dose Levels & Insertion Mutations



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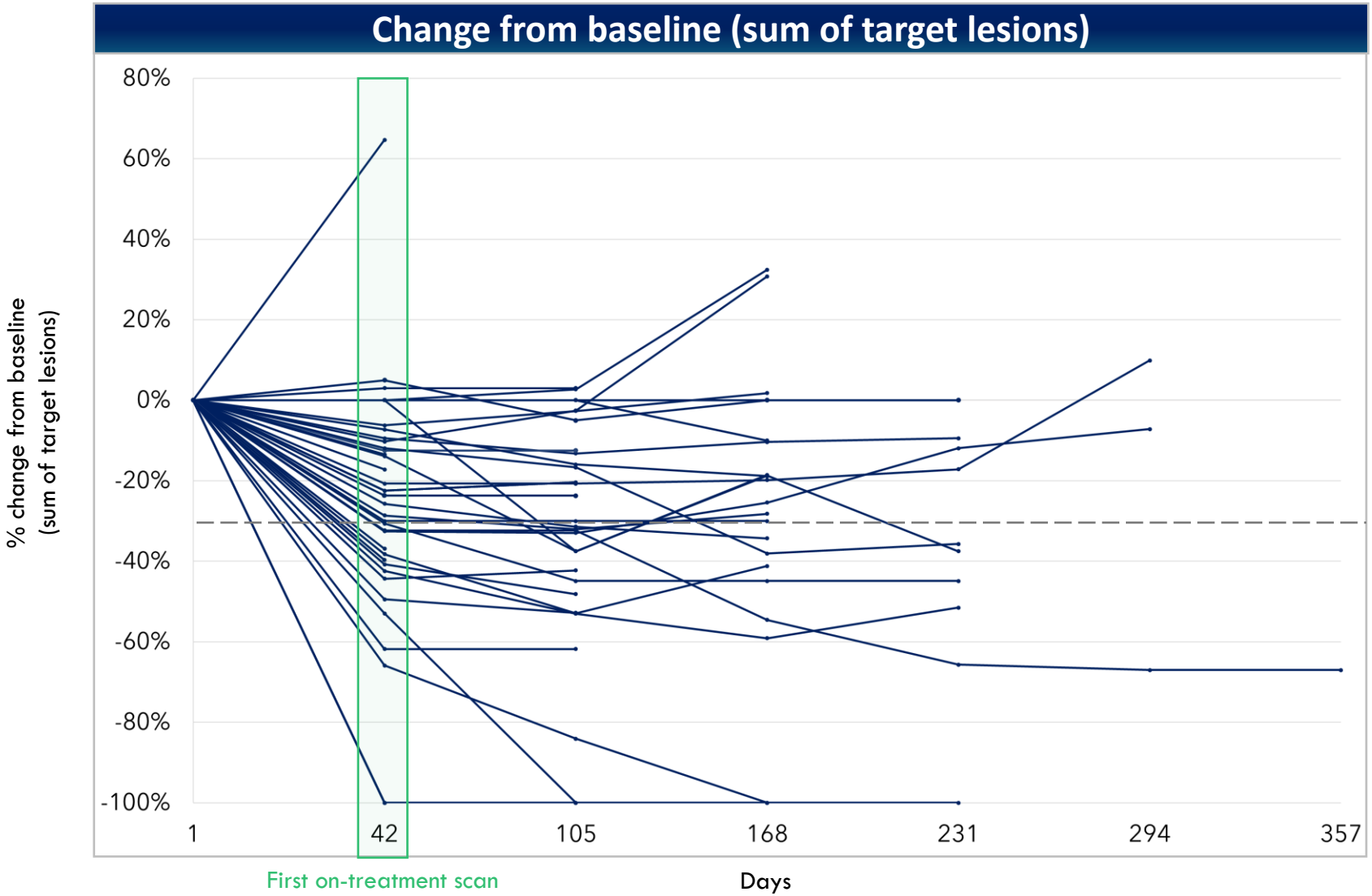
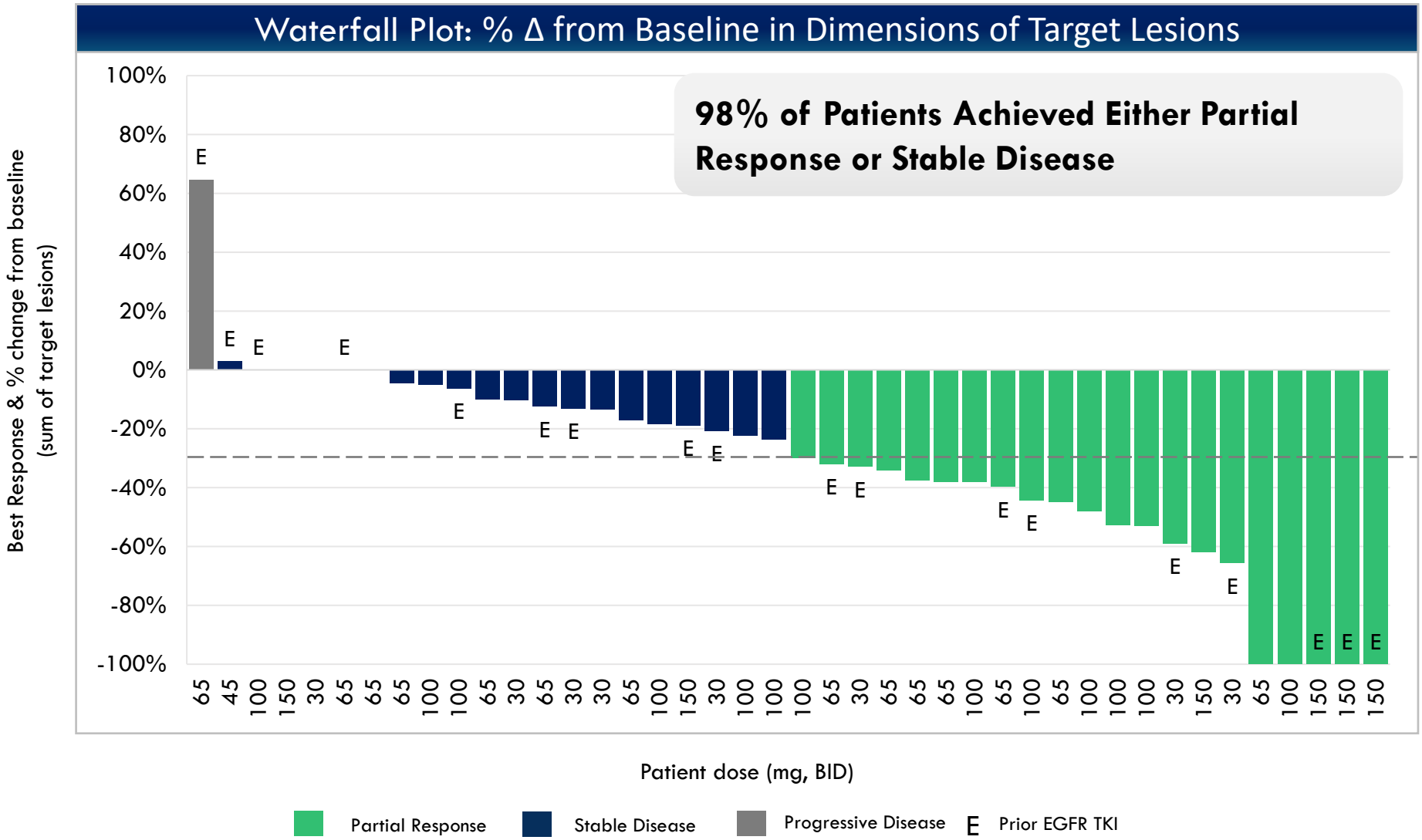
CLN-081 Acts Rapidly: 76% Of Patients With Tumor Regression At First Post-Baseline Scan



Percent Change from Baseline



As of April 1, 2021

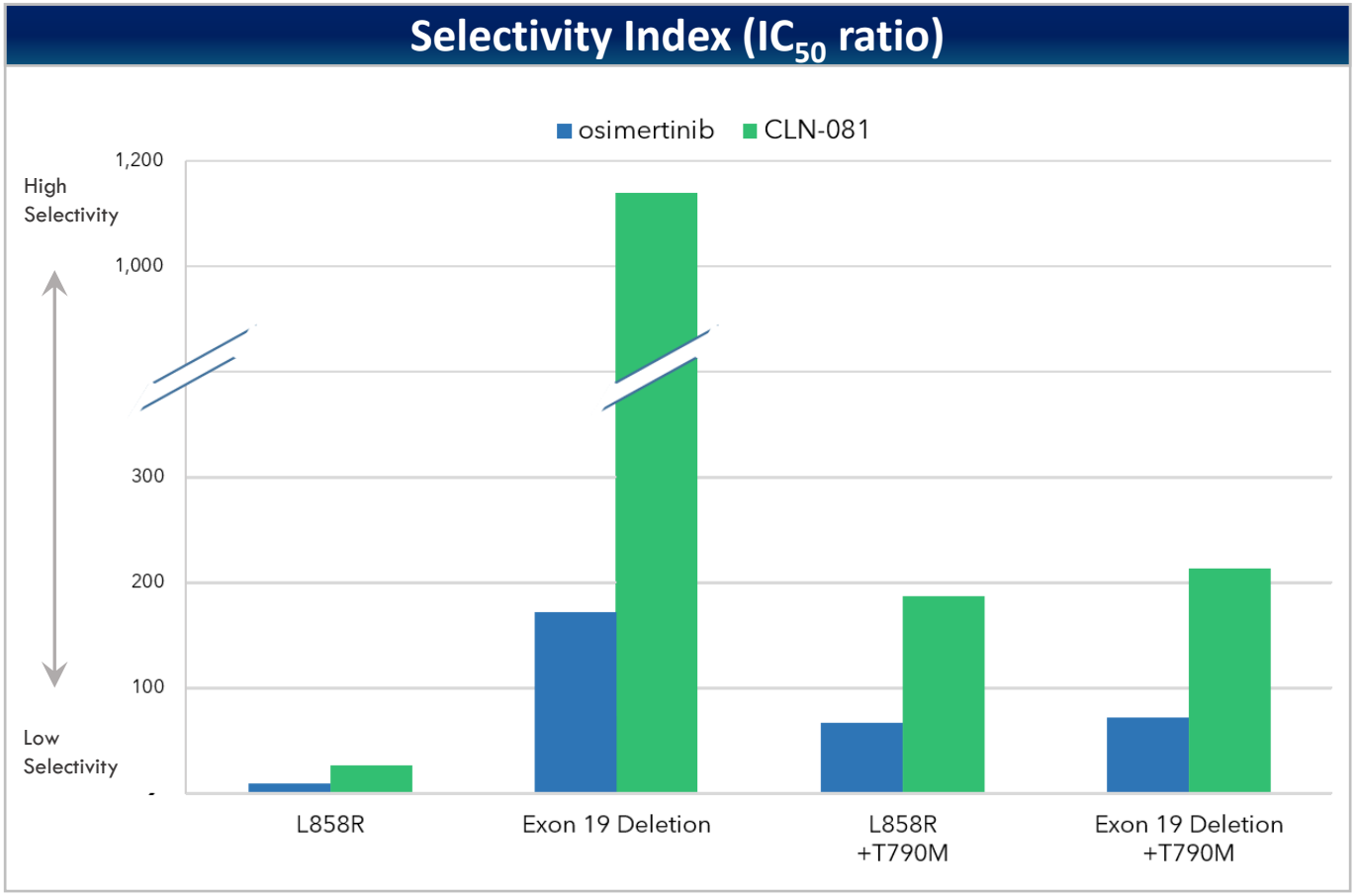
Response Characteristics by Dose

Best Response n, (%)	30 mg (n=8)	45 mg (n=1)	65 mg (n=14)	100 mg (n=13)	150 mg (n=6)	Total (n=42)
PR	3 (38)	0	7 (50)	7 (54)	4 (67)	21 (50)
SD	5 (62)	1 (100)	6 (43)	6 (46)	2 (33)	20 (48)
PD	0	0	1 (7)	0	0	1 (2)
Confirmed Response	3 (38)	0	2 (14)	6 (46)	2 (33)	13 (31)
Unconfirmed Response	0	0	2 (14)	1 (8)	0	3 (7)
Pending Confirmation	0	0	3 (21)	0	2 (33)	5 (12)
Disease Control Rate (PR + SD ≥ 6 mos)	5 (62)	0	8 (57)	9 (69) *	5 (83)	27 (64)

- Objective responses in 7/13 (54%) response evaluable patients at 100 mg, including 6 confirmed responses (46%), and 1 that will remain unconfirmed
- Objective responses in 21/42 (50%) of patients across all doses, including 13 confirmed (31%), and 8 unconfirmed, including 5 patients pending confirmatory scan at cutoff and 3 that will remain unconfirmed
- Disease control in 9 of 13 (69%) patients at 100 mg; 3 patients with ongoing SD followed less than 6 months

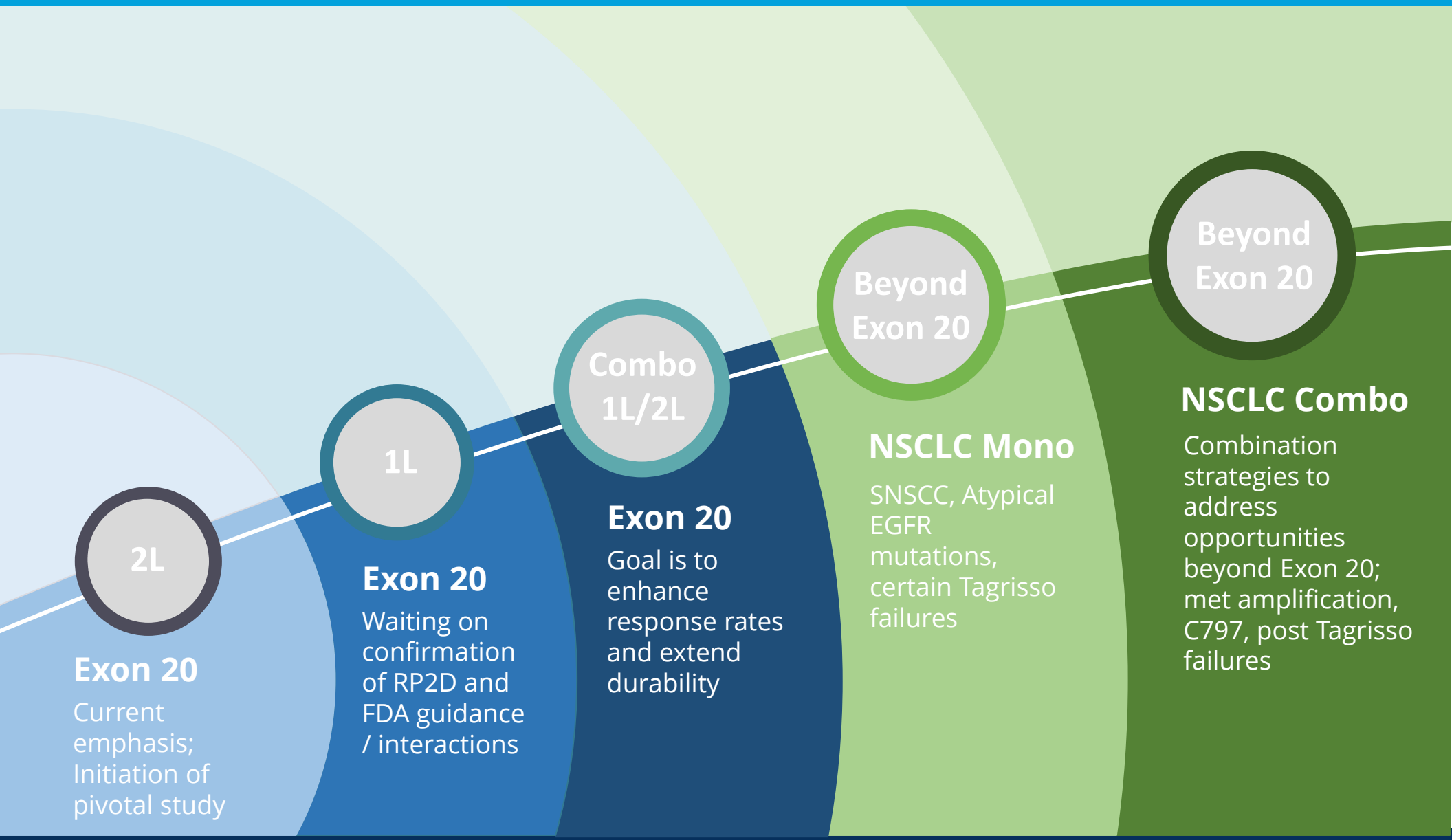
All dosing is BID
* 3 patients with stable disease have been on therapy for ~5 months; if patients remain on therapy for one additional month, DCR would increase to 92%

CLN-081 Selectivity Index Supports Utility In Traditional Sensitizing Mutations



- CLN-081 activity evaluated in Ba/F3 cell-lines expressing EGFR mutations
  - Selectivity index is calculated as ratio of IC_{50} values for WT vs indicated EGFR mutation
- **For each cell line, CLN-081 demonstrates higher selectivity than osimertinib**

Cullinan Pearl Life Cycle Management



Conclusions To Date

Safety

Efficacy

Next Steps

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Chief Executive Officer

Jeff Trigilio
Chief Financial Officer

Q&A

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