
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): June 4, 2021

CULLINAN ONCOLOGY, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39856
(Commission
File Number)

81-3879991
(I.R.S. Employer
Identification No.)

Cullinan Oncology, Inc.
One Main Street, Suite 520
Cambridge, MA 02142
(Address of principal executive offices, including zip code)

(617) 410-4650
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	CGEM	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On June 4, 2021, Cullinan Oncology, Inc. (the “Company”) issued a press release, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

In addition, the Company has made available on its website the Company’s presentation from the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. The presentation has been added to the “Presentations” section of the Company’s website at <https://investors.cullinanoncology.com/>. A copy of the presentation is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 4, 2021, the Company announced Phase 1/2a interim data from its ongoing Phase 1/2a trial of CLN-081 in Non-Small Cell Lung Cancer (NSCLC) patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations. CLN-081 is an orally available, irreversible EGFR inhibitor, utilizing a unique pyrrolopyrimidine scaffold that was designed to selectively target cells expressing mutant EGFR variants, including exon 20, while sparing cells expressing wild type (WT) EGFR.

The current analysis of the ongoing trial evaluated a total of 45 NSCLC patients with EGFR exon 20 insertion mutations who received at least one dose of CLN-081 as of the April 1, 2021, data cutoff, and were evaluable for safety. CLN-081 was dosed orally, at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). As of the data cutoff, 42 of 45 patients were response evaluable across all dose cohorts tested.

Overall Safety:

Regarding treatment related adverse events (TRAEs) associated with WT EGFR inhibition:

- Rash has been limited to Grade 1 and 2 events (76% of patients experienced an event across all doses as of the data cutoff); events were manageable with conventional supportive care; no patients have experienced Grade 3 TRAE rash.
- Similarly, diarrhea has been mostly limited to Grade 1 and 2 events (22% across the dose range) as of the data cutoff, with a single Grade 3 TRAE at the highest dose tested to date, 150 mg BID, which resolved with supportive care. No prophylactic regimen has been required to ameliorate the incidence or severity of diarrhea to date.

Overall Efficacy:

Objective partial responses (PR) were observed in 21 of 42 (50%) response evaluable patients treated across all dose levels.

- Of the 21 PRs as of the data cutoff, 13 were confirmed (31% confirmed objective response rate), 5 were pending confirmation (i.e., patient had not reached their second post-baseline disease assessment as of the data cutoff), and 3 will remain unconfirmed.
- 41 of 42 (98%) response evaluable patients have achieved a best response of stable disease (SD) or PR, with 76% of all patients showing some degree of tumor regression at the initial scan post baseline (week 6).

100 mg BID Expansion Cohort:

In February 2021, Cullinan announced a Phase 2a expansion at the 100mg BID cohort, allowing enrollment of up to 36 patients.

- **Safety:** Treatment-related rash has been limited to Grade 1 and 2 events (66%), manageable with conventional supportive care; no patients have experienced Grade 3 TRAE rash. In addition, the overall incidence of treatment-related diarrhea was 26%, with no Grade 3 events to date.
- **Efficacy:** As of the data cutoff, objective responses were observed in 7 of 13 (54%) response evaluable patients; 6 of which were confirmed (46%) and 1 will remain unconfirmed.
- Of the 13 response evaluable patients, 9 (69%) patients achieved disease control (PR of any duration or SD \geq 6 months) as of the data cutoff; an additional 3 patients had stable disease and remained on treatment but had started therapy less than 6 months prior to data cutoff.

This disclosure under this Item 8.01 contains forward-looking statements of the Company within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding the Company's beliefs and expectations regarding its preclinical and clinical development plans, clinical trial designs, clinical and therapeutic potential, and strategy of its product candidates, including but not limited to expectations and beliefs around the safety and activity of CLN-081. Any forward-looking statements under this Item 8.01 are based on management's current expectations and beliefs of future events, and are subject to known and unknown risks and uncertainties that may cause the Company's actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of the Company's clinical trials and preclinical studies; risks related to the Company's ability to protect and maintain its intellectual property position; risks related to manufacturing, supply, and distribution of the Company's therapeutic candidates; risks related to the impact of COVID-19 affecting countries or regions in which the Company has operations or does business, including potential negative impacts on the Company's employees, customers, supply chain and production as well as global economies and financial markets; the risk that any one or more of the Company's product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in the Company's filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in the Company's most recent Quarterly Report on Form 10-Q and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. The Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Item 9.01. Exhibits

(d) Exhibits

- 99.1 [Press release issued by the Cullinan Oncology, Inc. on June 4, 2021.](#)
- 99.2 [Cullinan Oncology, Inc. 2021 ASCO Annual Meeting Presentation, dated June 4, 2021.](#)
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CULLINAN ONCOLOGY, INC.

Date: June 4, 2021

By: /s/ Jeffrey Trigilio
Jeffrey Trigilio
Chief Financial Officer



**Cullinan Oncology Announces Phase 1/2a Interim Data For
Cullinan Pearl's CLN-081 in NSCLC EGFR Exon 20 Patients**

- **CLN-081 Continues to Demonstrate Acceptable Overall Safety and Tolerability, With Encouraging GI Toxicity Profile**
- **As of the Data Cutoff, No Grade 3 TRAE Diarrhea at Doses Below 150mg BID; No Grade 3 Rash TRAEs**
- **Objective Responses Were Observed Across the Dose Range, with a Confirmed Objective Response Rate of 46% in Patients Treated at 100 mg BID**
- **Phase 2a Expansion Initiated at 100 mg BID**

Cambridge, MA, June 4, 2021 – Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), an oncology company seeking to drive shareholder returns by focusing on the patient, today announced additional details pertaining to Cullinan Pearl's ongoing Phase 1/2a trial of CLN-081 in Non-Small Cell Lung Cancer (NSCLC) patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations. CLN-081 is an orally available, irreversible EGFR inhibitor, utilizing a unique pyrrolopyrimidine scaffold that was designed to selectively target cells expressing mutant EGFR variants, including exon 20, while sparing cells expressing wild type (WT) EGFR.

These data will be featured in an on-demand poster presentation available this morning at 9:00 am EST at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and during a company sponsored webinar at 10:30 am EST today, which can be accessed here or in the 'Events' section on Cullinan's investor website.

"We remain encouraged with CLN-081's emerging profile" stated Owen Hughes, Cullinan's Chief Executive Officer. "In heavily pretreated patients, CLN-081 continues to show antitumor activity across the dose range, with a safety profile that appears to be differentiated, most specifically with respect to GI adverse events."

The current analysis of the ongoing trial evaluated a total of 45 NSCLC patients with EGFR exon 20 insertion mutations who received at least one dose of CLN-081 as of the April 1, 2021, data cutoff, and were evaluable for safety. CLN-081 was dosed orally, at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). As of the data cutoff, 42 of 45 patients were response evaluable across all dose cohorts tested.

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“We are pleased with the CLN-081 safety and efficacy data to date in our Phase 1/2a trial. CLN-081 has demonstrated antitumor activity in patients post systemic chemotherapy, including among patients who were also treated previously with other EGFR inhibitors and/or cancer immunotherapy, across the range of CLN-081 doses tested to date, and across a spectrum of Exon-20 mutational sub-types”, said Jon Wigginton, M.D., Chairman of the Cullinan Oncology Scientific Advisory Board and Senior Advisor. “We are working diligently to evaluate CLN-081 in additional patients, and to set the stage for further clinical advancement of CLN-081 in this group of patients with significant unmet need.”

About CLN-081

CLN-081 is an orally available, irreversible EGFR inhibitor that was designed to selectively target cells expressing mutant EGFR variants, including Ins20, while sparing cells expressing wild type EGFR. In preclinical studies, CLN-081 demonstrated inhibition against traditional sensitizing mutations (exon 19 deletions and L858R), Ins20 (the third most common EGFR mutation), and other less common mutations (G719X, L861Q, and S768I).

Cullinan is evaluating various doses of CLN-081 in a Phase 1/2a trial in patients with NSCLC harboring Ins20 mutations that have progressed post chemotherapy. Based on pre-specified efficacy and safety criteria, Cullinan recently initiated Phase 2a dose expansion in the 100 mg BID dosing cohort, which will enable enrollment of up to 36 patients at this dose level, inclusive of 13 previously enrolled patients.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that strives to deliver results for our various stakeholders through disciplined capital allocation, decisive action, prudent risk taking and creative business development. We seek to drive shareholder returns by focusing on the patient. The Company’s strategy is to build a diversified pipeline of targeted and immuno-oncology therapeutic candidates that are uncorrelated across multiple dimensions, with a focus on assets that it believes have novel technology, employ differentiated mechanisms, are in a more advanced stage of development than competing candidates, or have a combination of these attributes. Learn more about Cullinan at www.cullinanoncology.com.

Forward-Looking Statements

This press release contains forward-looking statements of Cullinan Oncology, Inc. (“Cullinan,” “we” or “our”) within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cullinan’s beliefs and expectations regarding our preclinical and clinical development plans, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates, including but not limited to our expectations and beliefs around the safety and activity of CLN-081. Any forward-looking statements in this press release are based on management’s current expectations and beliefs of future events, and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; risks related to manufacturing, supply, and distribution of our therapeutic candidates; risks related to the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption “Risk

Factors” in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release. Moreover, except as required by law, neither Cullinan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Contacts:

Investor Relations

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jtrigilio@cullinanoncology.com



Cullinan Pearl

2021 ASCO Update on CLN-081

June 4, 2021

Important Notice and Disclaimers

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Executive Hosts of Today's Webinar



Owen Hughes
Chief Executive Officer



Jeff Trigilio
Chief Financial Officer



Jon Wigginton, MD
Senior Adviser &
Chairman of SAB



Leigh Zawel, PhD
Chief Scientific Officer,
Small Molecules





Cullinan Pearl (CLN-081)

Selective EGFR inhibitor targeting Exon 20 insertion mutant NSCLC



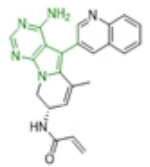
Hypothesis

- 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

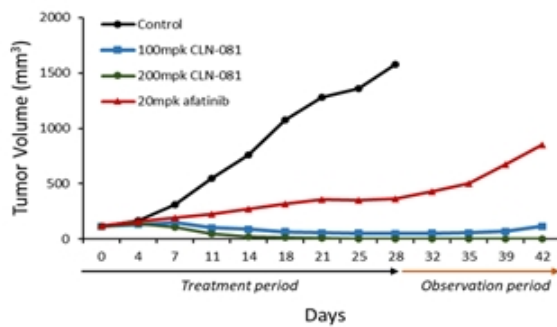


Design

- 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

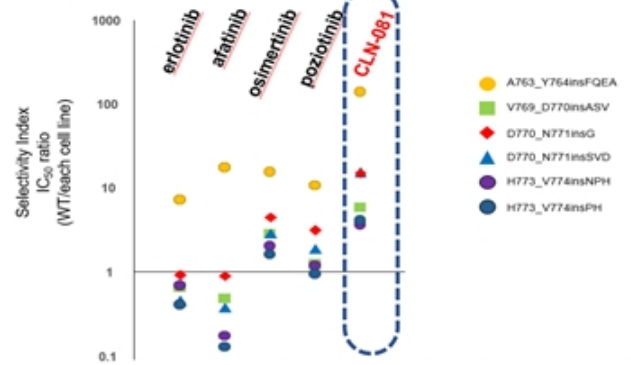


Antitumor activity in LXF2478 (PDX model for lung cancer harboring EGFR V769_D770INSASV)



Key PC Data

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



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

zaiLab.
Zai Lab has licensed CLN-081 for Greater China.

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**

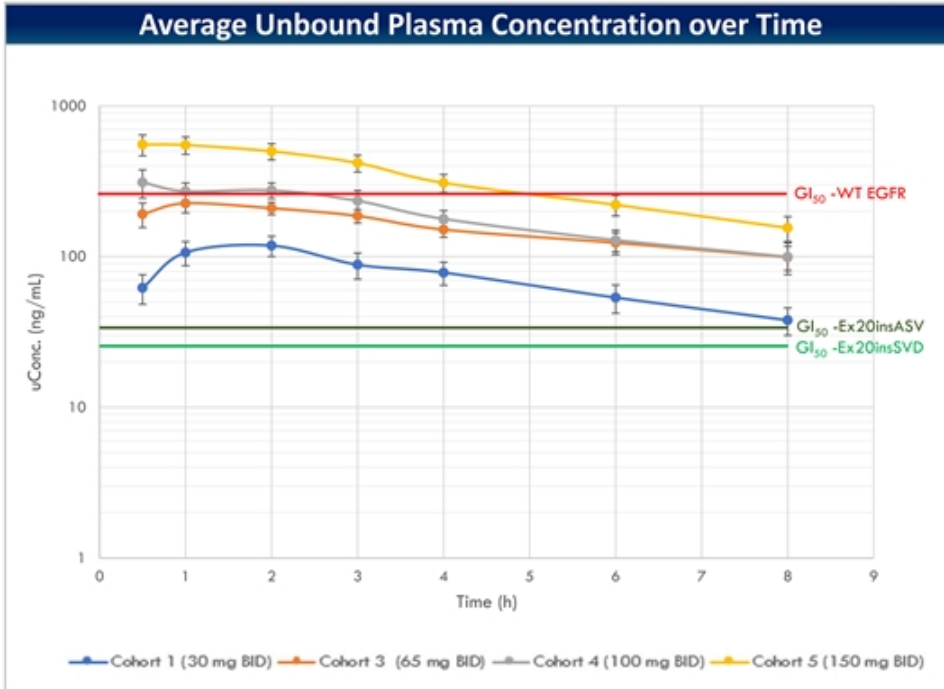
¹. Excludes 1 patient that does not have baseline demographic info.

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

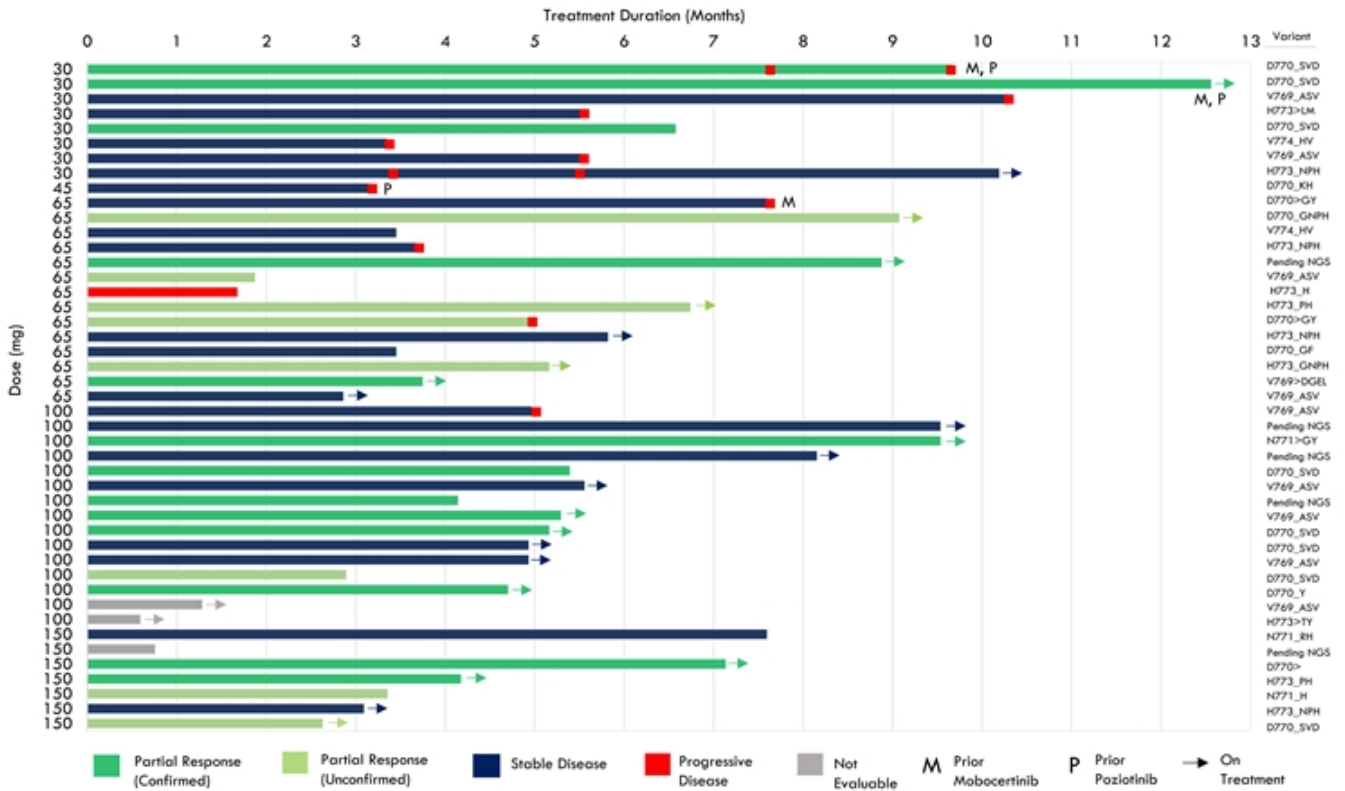
Preliminary CLN-081 Pharmacokinetics

Average Unbound Plasma Concentration over Time

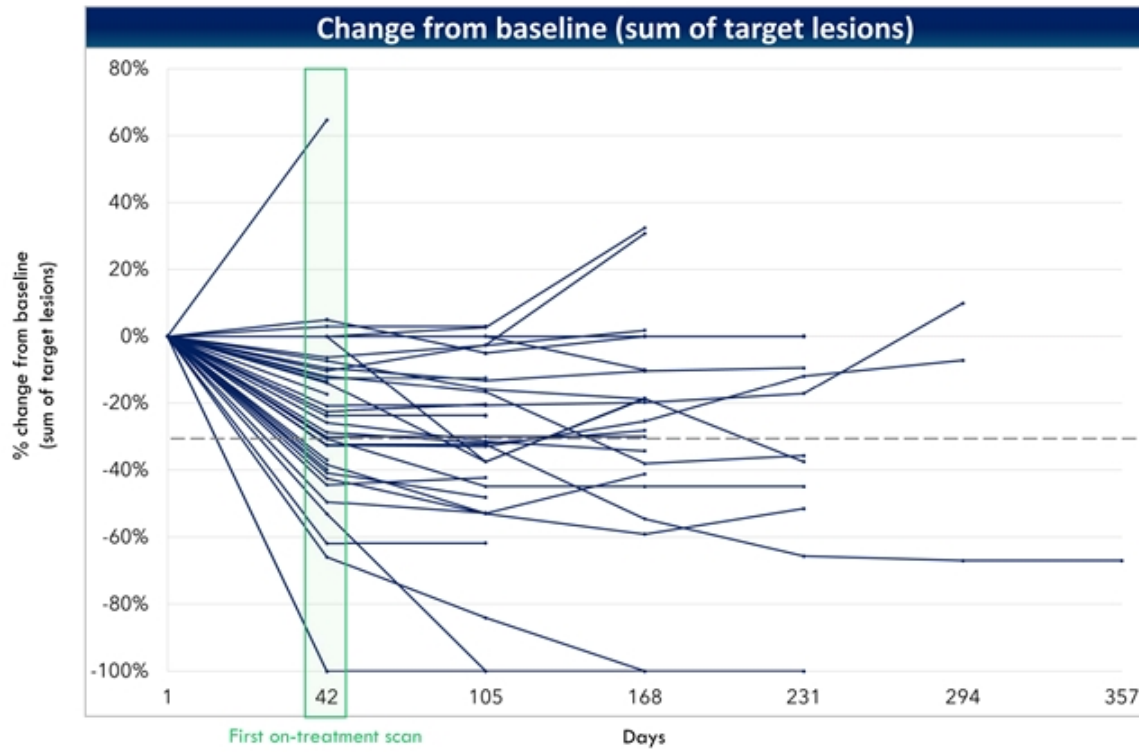


- ▶ **CLN-081 well behaved to date**
- ▶ **Sustained Coverage Over 8h Period**
 - Unbound plasma concentrations are greater than GI₅₀ values for Ex20ins cell-lines

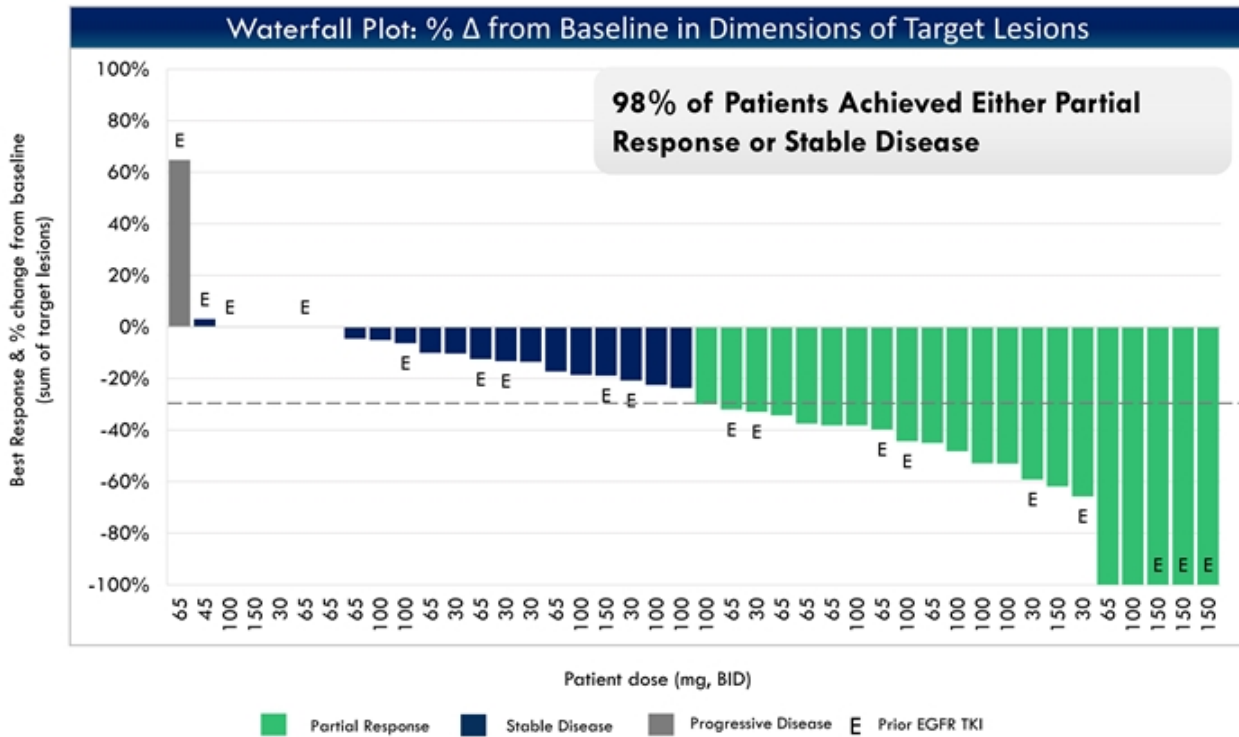
Activity Across Dose Levels & Insertion Mutations



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



Percent Change from Baseline

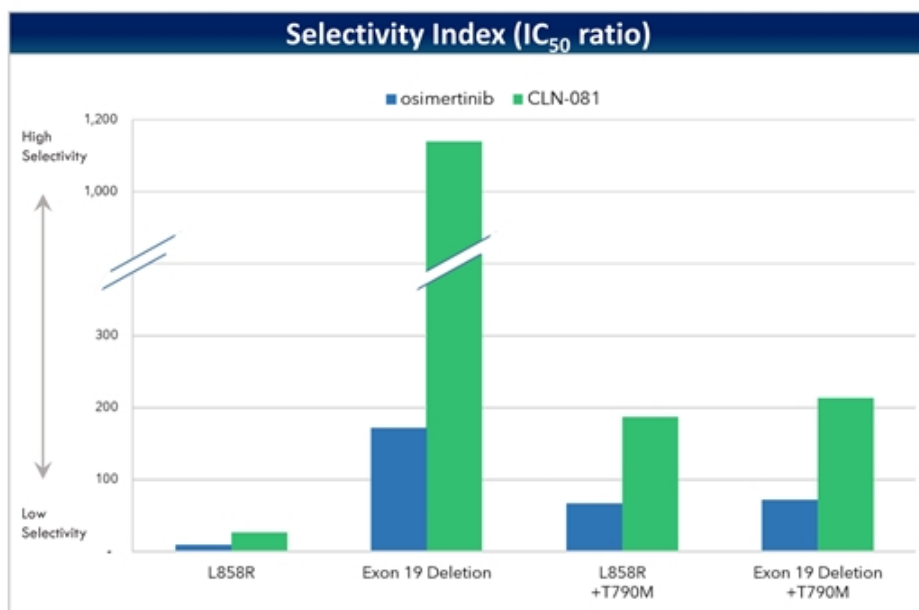


Response Characteristics by Dose

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 \geq 6 mos)	5 (62)	0	8 (57)	9 (69) *	5 (83)	27 (64)

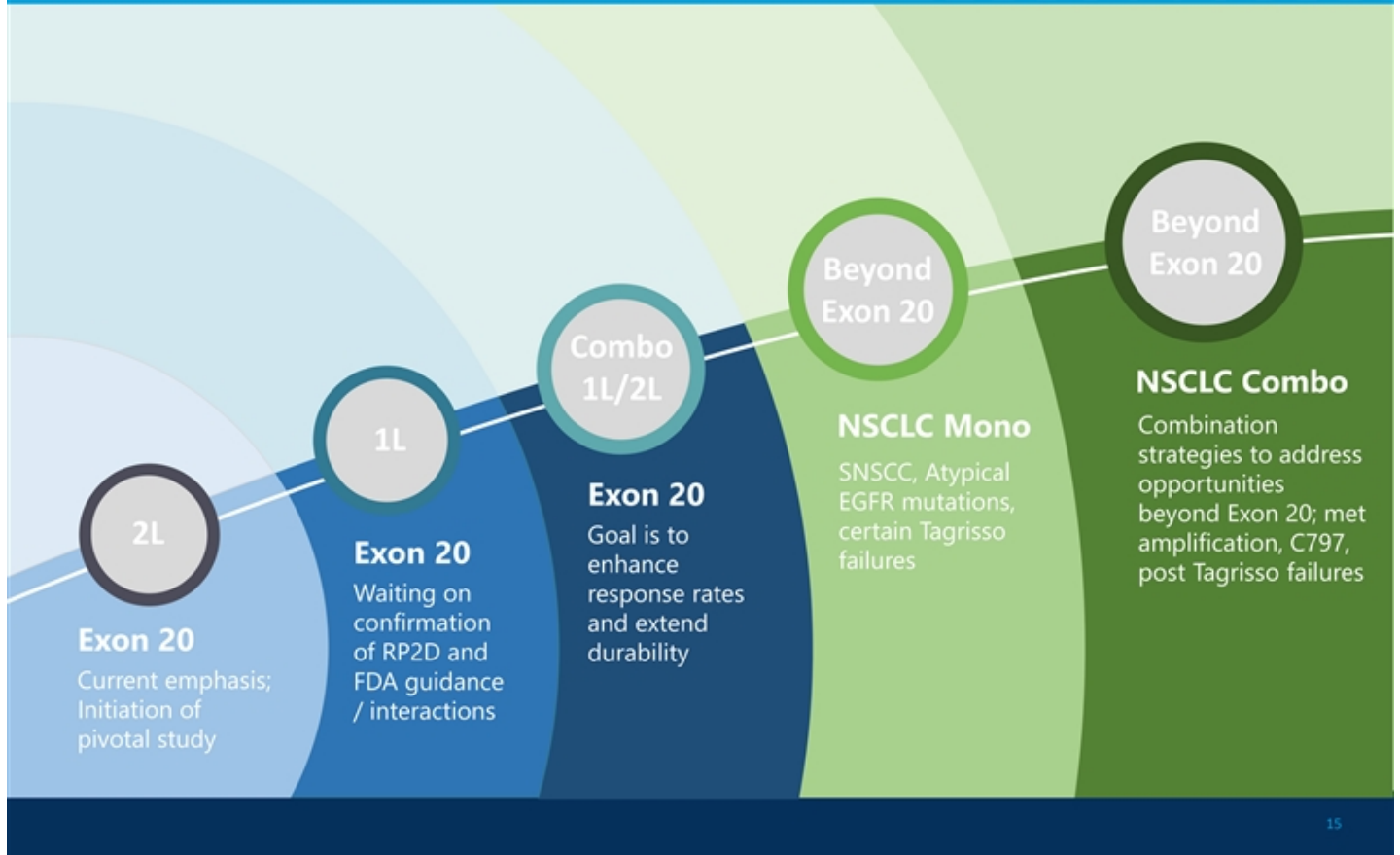
- ▶ Objective responses in 7/13 (54%) response evaluable patients at 100 mg, including 6 confirmed responses (46%), and 1 that will remain unconfirmed
- ▶ Objective responses in 21/42 (50%) of patients across all doses, including 13 confirmed (31%), and 8 unconfirmed, including 5 patients pending confirmatory 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

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 IC₅₀ 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

1 >



Safety

2 >



Efficacy

3 >



Next Steps



Owen Hughes
Chief Executive Officer



Jeff Trigilio
Chief Financial Officer

Q&A



Jon Wigginton, MD
Senior Adviser &
Chairman of SAB



Leigh Zawel, PhD
Chief Scientific Officer,
Small Molecules