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): December 16, 2021

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

Delaware	**001-39856**	**81-3879991**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 (see General Instruction A.2):

☐ 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 December 16, 2021, Cullinan Oncology, Inc. (the "Company") issued a press release reporting updated data from the Company's ongoing Phase 1/2a trial of CLN-081 in non-small cell lung cancer patients whose tumors harbor epidermal growth factor receptor (EGFR) exon 20 insertion mutations that have progressed on or after prior therapy, 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 Cullinan Oncology Clinical Data Report Virtual Webcast. The presentation has been added to the "Events" 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 9.01. Exhibits

Exhibits

99.1	Press release issued by Cullinan Oncology, Inc. on December 16, 2021, furnished herewith.
99.2	2021 Cullinan Oncology Clinical Data Report Virtual Webcast Presentation, dated December 2021, furnished herewith.
104	Cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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.

Dated: December 16, 2021

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

Cullinan Oncology Announces Updated Phase 1/2a Data for CLN-081 in NSCLC EGFR Exon 20 Patients

CLN-081 continues to demonstrate a differentiated clinical profile at the recommended Phase 2 dose of 100mg BID

Continued high response rate with favorable safety and tolerability profile observed in heavily pre-treated patients at 100mg BID

Encouraging durable responses and progression free survival at 100mg BID

Cambridge, MA, December 16, 2021 – Cullinan Oncology, Inc. (Nasdaq: CGEM) ("Cullinan"), a biopharmaceutical company focused on developing a diversified pipeline of targeted therapies for cancer patients, today reported updated data from the Company'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 that have progressed on or after prior therapy.

"The updated data from our ongoing Phase 1/2a study in a larger number of patients further reinforce CLN-081's differentiated clinical profile. CLN-081 has demonstrated both a high response rate and durable responses in heavily pre-treated patients," said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. "For many lung cancer patients currently receiving EGFR inhibitors, treatment related side effects can significantly impact their daily lives. In this regard, we are encouraged by CLN-081's favorable safety profile at the 100mg BID dose."

The current analysis of the ongoing trial included a total of 73 NSCLC patients with EGFR exon 20 insertion mutations who received at least one dose of CLN-081 and were evaluable for safety as of the data cutoff. CLN-081 was administered orally, at dose levels including 30, 45, 65, 100 and 150 mg twice daily (BID). Based on prespecified safety and efficacy criteria, enrollment at the Phase 2a cohort for 100mg BID was expanded up to the planned maximum of 36 patients. Additional patients were also enrolled at the 150mg BID dose level, although enrollment was subsequently discontinued after a total of 11 patients based on overall assessment of the clinical profile at this dose level. Guided by these data,100mg BID was nominated as the Recommended Phase 2 Dose (RP2D) for CLN-081.

Efficacy Highlights:

Efficacy data from patients enrolled in the 100mg BID cohort:

- Of 36 response evaluable patients, 14 achieved a confirmed PR for a 39% confirmed response rate and one additional patient had a PR that was pending confirmation at the time of the data cut-off.
- The median duration of response was >15 months and the median progression free survival was 12 months in the initial cohort of phase 1 patients (N=13).

Safety and Tolerability Highlights:

Treatment related EGFR associated adverse event (AE) data for patients enrolled in the 100mg BID cohort:

- Rash has been limited to Grade 1 and 2 events (54% and 18% of patients, respectively). Events were manageable with conventional supportive care and no patients have experienced Grade 3 or greater treatment-related rash.
- Diarrhea has been limited to Grade 1 and 2 events (26% and 8% of patients, respectively). No prophylactic regimen has been required to ameliorate the incidence or severity of diarrhea to date, and no patients have experienced Grade 3 or greater treatment-related diarrhea.

“We are pleased with CLN-081’s safety and efficacy to date. CLN-081 has demonstrated antitumor activity among heavily pre-treated patients, including patients treated previously with other EGFR inhibitors or immunotherapy, 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 similarly encouraged by the emerging durability data shown in this update, which we believe could also reflect the benefit of the drug’s favorable safety and tolerability profile. Our goal now is to review these results and potential future clinical development with the FDA and to move CLN-081 as expeditiously as possible into late-stage development.”

Additional data are available in a presentation accompanying this press release on the Events section of our website.

About CLN-081

CLN-081 is an orally available, irreversible EGFR inhibitor that selectively targets cells expressing EGFR exon 20 insertion mutations while sparing cells expressing wild type EGFR. Cullinan is evaluating various doses of CLN-081 in a Phase 1/2a trial in patients with NSCLC harboring exon 20 mutations whose disease has progressed on or after prior therapy.

About Cullinan Oncology

Cullinan Oncology is a biopharmaceutical company that is developing a diversified pipeline of targeted therapeutic candidates across multiple modalities in order to bring important medicines to cancer patients. The Company’s strategy is to source innovation through both internal discovery efforts and external collaborations, focusing on advanced stage assets with novel technology platforms and differentiated mechanisms. 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.

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Exhibit 99.2

cullinan PEARL

Mining for Tomorrow's Cures

CLN-081 Clinical Update

December 2021

Important Notice and Disclaimers

This presentation contains forward-looking statements of Cullinan Oncology, Inc. ("Cullinan," "we" or "our"). 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 statements concerning the safety and efficacy of CLN-081, development plans for CLN-081 and the potential therapeutic benefits of CLN-081. Any forward-looking statements in this presentation 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 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-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 presentation. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so except as required by law, 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 presentation. 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 presentation.

Executive hosts of today's webinar

Nadim Ahmed
Chief Executive Officer

Jon Wigginton, MD
Senior Advisor &
Chairman of SAB

Leigh Zawel, PhD
Chief Scientific Officer,
Small Molecules

Jeff Trigilio
Chief Financial Officer

Cullinan Oncology: Advancing a broad pipeline of targeted cancer therapeutics

Program (Subsidiary/Project) Modality / MOA	Discovery / Lead Optimization	IND-Enabling	Phase 1	Phase 2	Phase 3
CLN-081 (Pearl) EGFR ex20 inhibitor	NSCLC EGFRex20				
CLN-049 (Florentine) FLT3 x CD3 bispecific	r / r AML				
CLN-619 (MICA) Anti-MICA/B IgG1	Pan cancer				
CLN-978 (NexGem) CD19, CD3, HSA trispecific	B-cell ALL				
CLN-617 (Amber) IL2-IL12 fusion protein	Pan cancer				
Opal PD-1 x CD137L fusion protein	Pan cancer				
Jade TCR-based therapy targeting a novel senescence / cancer-related protein	HPV+/ RB-				

- **Strategy to select programs with First and/or Best in Class Potential**
- **Q4 Progress:**
  - ✓ **CLN-081 clinical update**
  - ✓ **FLT3 trial initiation**
  - ✓ **MICA trial initiation**
- **Further pipeline updates to come in early 2022**

CLN-081 Clinical update highlights

Data Summary

Status 1

- Nominated RP2D of 100mg BID

Efficacy 2

- High response rate in larger number of patients
- Durable responses and encouraging PFS

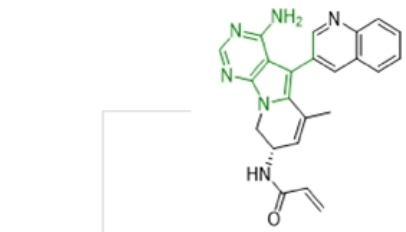
Safety 3

- Favorable safety and tolerability profile

CLN-081: A differentiated clinical profile

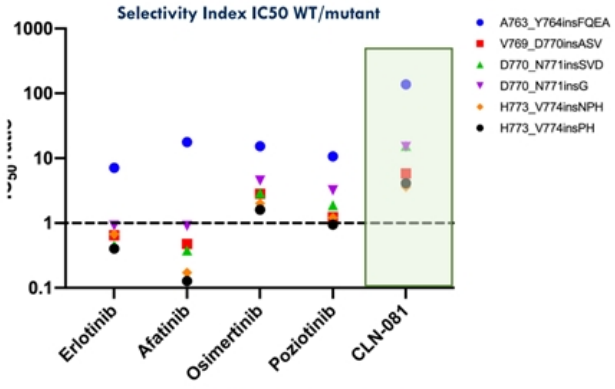
CLN-081: Selective EGFR inhibitor for NSCLC patients with exon 20 mutations

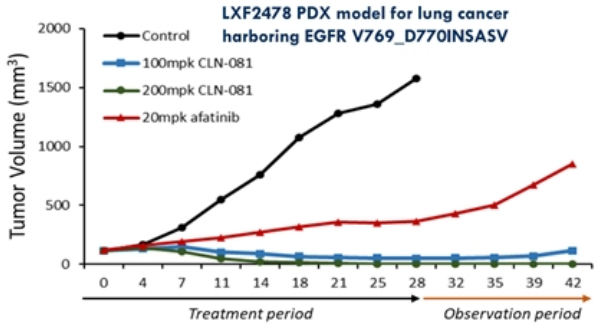
CLN-081: Unique design properties



- Distinct chemical scaffold
- HER2-sparing
- High selectivity to mutant vs WT EGFR

Select CLN-081 pre-clinical data





CLN-081 Phase 1/2a trial design

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 = 23
150 mg		N = 7 →	N = 4	

Geographic Footprint

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

- 36 patients enrolled in Phase 1/2a at 100 mg BID
- Expanded enrollment at 150 mg BID stopped after 11 patients based on clinical profile
- Dose of 100 mg BID nominated as RP2D

Zai Lab has licensed CLN-081 for Greater China.

Clinical data cutoff as of 1 Dec 2021

Heavily pretreated patient population including prior EGFR TKI or immunotherapy

Select Baseline Characteristics	
Characteristic	**All patients (n=73)**
Median age (range)	64 (36-82)
Number of prior systemic anticancer regimens	
1 (%)	22 (30%)
2 (%)	32 (44%)
≥3 (%)	16 (22%)
Median (range)	2 (0-9)
Prior EGFR TKI (non-Ex20)	27 (37%)
Prior pozio and/or mobo (%)	4 (5%)
Prior checkpoint inhibitor therapy (%)	39 (53%)
Brain mets at baseline (%)	28 (38%)

- Heavily pretreated population
- Over 65% of patients with 2 or more prior lines of treatment
- Prior EGFR TKI treatment in 37% of patients
- Over 50% of patients treated previously with checkpoint inhibitor

Differentiated safety and tolerability profile of CLN-081 at proposed RP2D

Dose (BID)	100 mg	150 mg	Overall
Safety Population (n, %)	39	11	73
Grade 1 TRAE of interest			
Skin Rash	21 (54)	4 (36)	38 (52)
Diarrhea	10 (26)	1 (9)	14 (19)
Elevated ALT / AST	2 (5)	1 (9)	6 (8)
Anemia	3 (8)	--	5 (7)
Grade 2 TRAE of interest			
Skin Rash	7 (18)	1 (9)	14 (19)
Diarrhea	3 (8)	1 (9)	4 (5)
Elevated ALT / AST	2 (5)	--	2 (3)
Anemia	1 (3)	--	2 (3)
Grade 3 TRAE of interest			
Skin Rash	--	1 (9)	1 (1)
Diarrhea	--	2 (18)	2 (3)
Elevated ALT / AST	2 (5)	2 (18)	6 (8)
Anemia	1 (3)	2 (18)	5 (7)
Treatment Related Dose Reduction	5 (13)	3 (27)	10 (14)
Treatment Related Dose Discontinuation	1 (3)	2 (18)	5 (7)

100 mg BID nominated as RP2D

At 100 mg BID (N=39):

- **No Gr ≥3 rash/diarrhea**
- **Rash/diarrhea 3:1 Gr 1:2 ratio**
- **No systematic GI prophylaxis**
- **One pt with G3 pneumonitis***

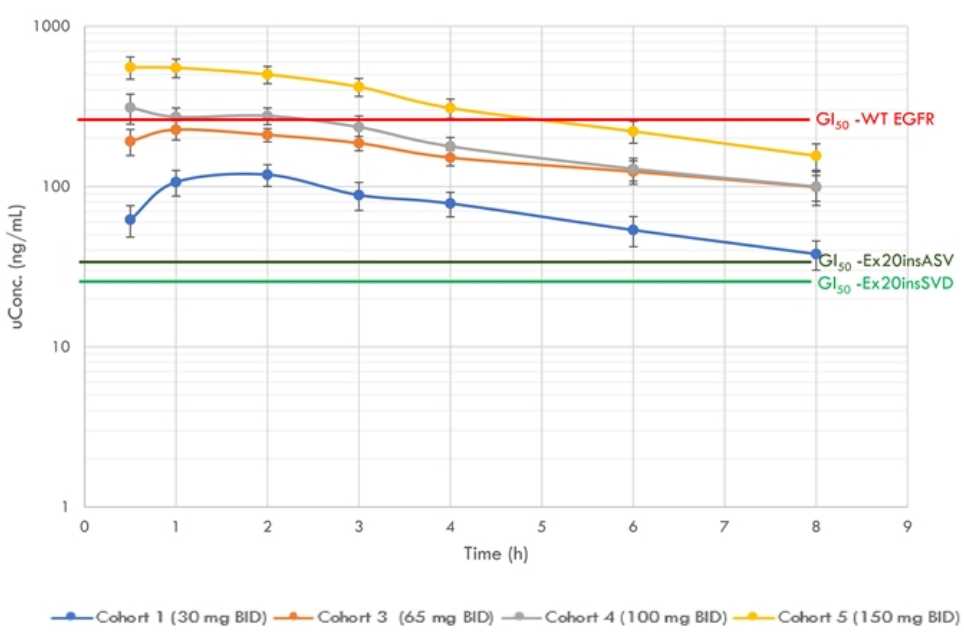
At 150 mg BID (N=11):

- **Expanded enrollment discontinued after 11 patients**
- **G3: diarrhea (2), rash (1), pneumonitis (1)**, Transaminitis (1); G4 Transaminitis (1)**
- **Increased dose reduction and/or discontinuation**

*Patient reported as G3 drug-related pneumonitis (confounded by recent treatment with CPI, concurrent hydropneumothorax in contralateral lung)
**Patient reported as G3 drug-related pneumonitis (confounded by concurrent pneumocystis infection, had stopped CLN-081 3 weeks prior to event)

PK profile consistent with clinical safety profile

Average Unbound Plasma Concentration over Time



- **CLN-081 PK well-behaved to date**
- **Sustained PK exposure over GI50 for ex20ins EGFR for 8h post dose**
- **Limited time of exposure over GI50 for WT EGFR at doses ≤ 100 mg BID**
- **Consistent with clinical safety profile at 100 mg versus 150 mg BID dose**

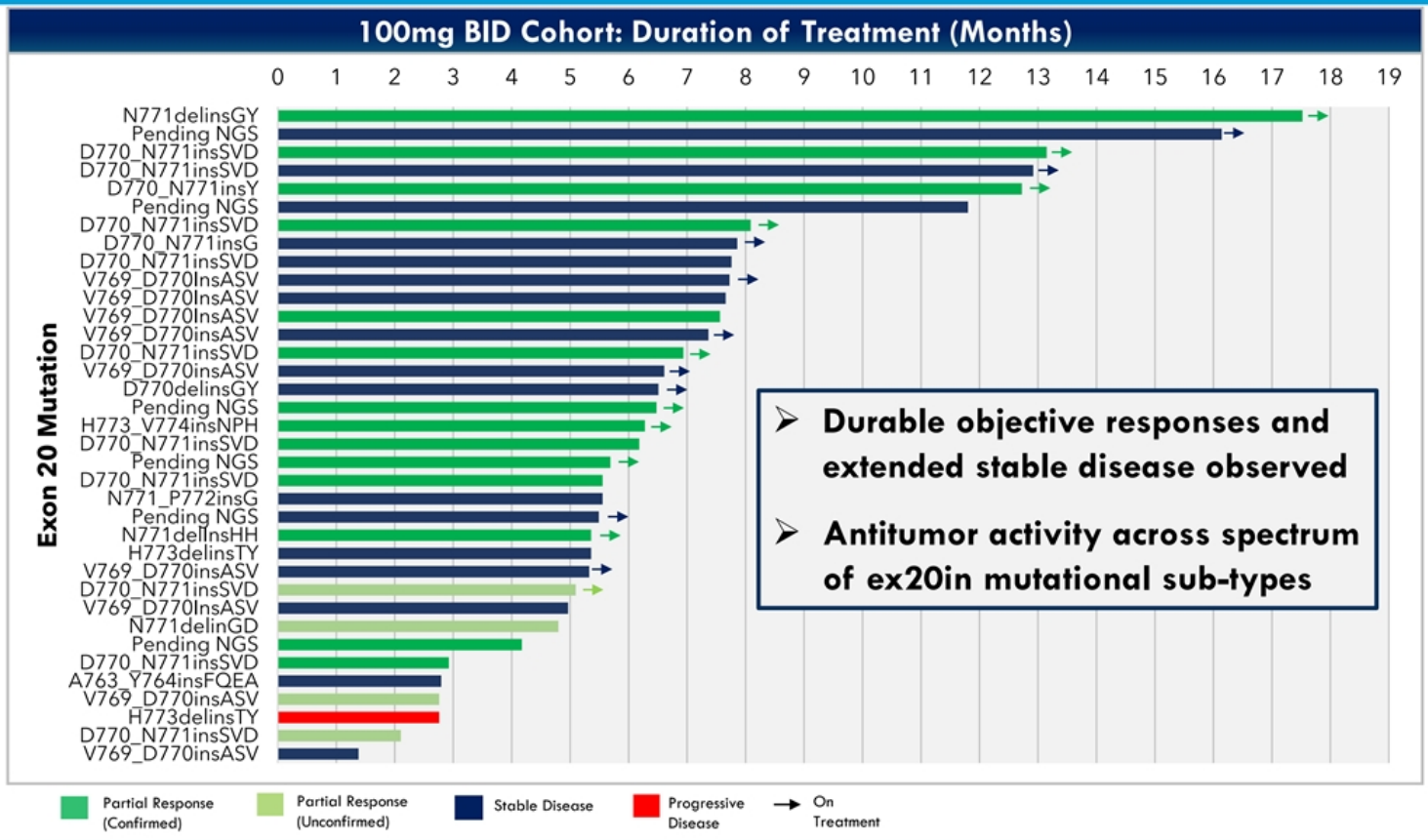
Data from Phase 1 patients. Uses standard error of the mean.

Encouraging response rate in expanded cohort at RP2D

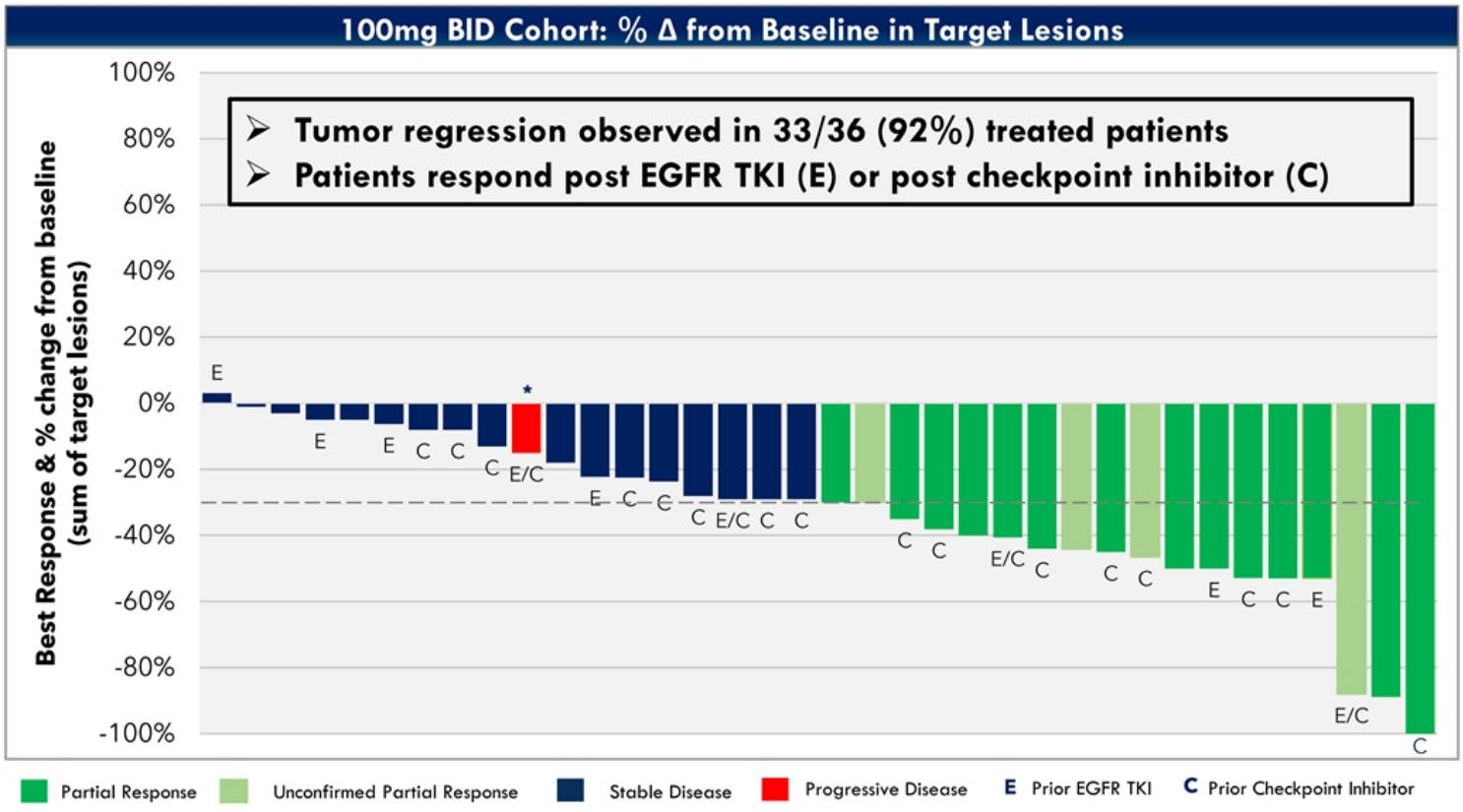
Response	100 mg BID (n=36), RP2D	150 mg BID (n=11)	Overall (n=70)
Best Response, n (%)			
PR (Confirmed)	14 (39)	3 (27)	25 (36)
PR (Pending)	1 (3)	--	1 (1)
PR (Unconfirmed)	3 (8)	2 (18)	7 (10)
Stable Disease (SD)	17 (47)	5 (45)	34 (49)
Progressive Disease (PD)	1 (3)	1 (9)	3 (4)

- Stable disease or PR observed in 35/36 (97%) of patients at RP2D

Durable objective responses and extended stable disease in patients treated at 100 mg BID

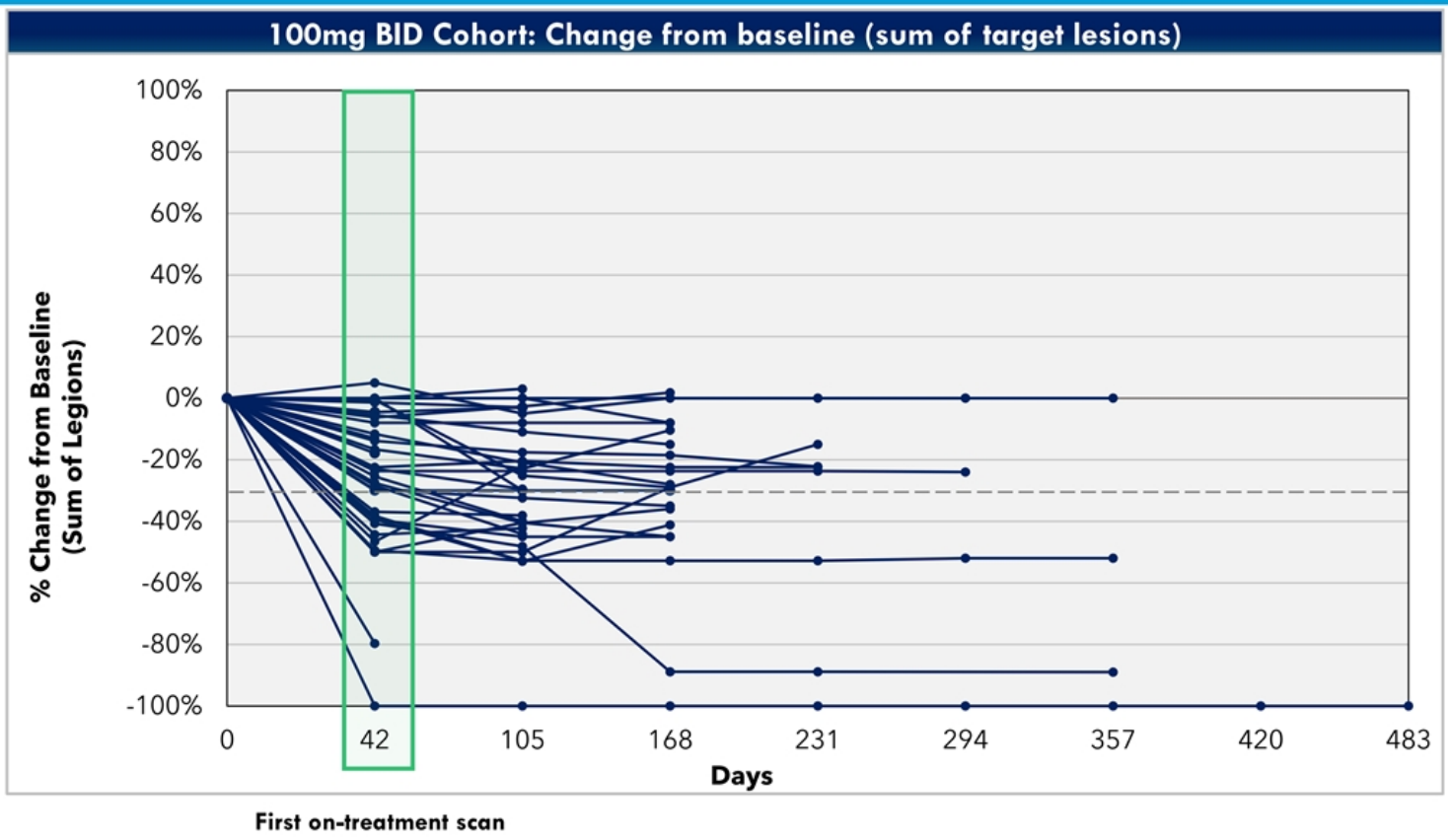


Tumor regression observed in majority of patients treated at 100 mg BID



** PD due to progression of non-target lesions.*

CLN-081 acts rapidly: Tumor regression in 86% of 100mg BID patients at first assessment



Durability profile building for patients treated at RP2D

Phase 1 Patients at 100 mg BID (n = 13)	
*Duration of Response, Median	>15 months
*Progression Free Survival, Median	12 months
**Disease Control Rate	92%

* Based upon Kaplan-Meier estimates
** Disease control rate (DCR): % of patients with stable disease ≥6 months or any PR

- **Follow-up on Phase 1 patients at 100 mg BID shows encouraging response duration, progression-free survival and disease control rates.**
- **Follow-up ongoing in Phase 2a patients at 100 mg BID.**

Disease control rates in patients treated at 100 mg BID based on baseline CNS status

Phase 1 Patients at 100 mg BID*	
Disease Control Rate (DCR)**, All (N=13)	92%
➢ CNS Disease History at Baseline (N=4)	100%
➢ No CNS Disease History at Baseline (N=9)	89%

* Patients with stable, treated brain metastases included; active, untreated brain metastases excluded
** Disease control rate (DCR): % of patients with stable disease ≥6 months or any PR

- **Disease control rates comparable, irrespective of CNS disease status at baseline in patients treated at 100 mg BID**
- **Examples of patients with reductions in CNS lesions have been noted**

CLN-081 Conclusions and next steps

Summary

- Updated data at the proposed RP2D of 100 mg BID, reaffirms differentiated clinical profile for CLN-081 (an oral TKI)

Efficacy

- High response rate maintained with expanded patient numbers at RP2D
- Durable responses and encouraging PFS
- Antitumor activity across a spectrum of EGFR ex20ins mutational sub-types, and in patients who progress on other EGFR ex20ins TKI

Safety

- Differentiated safety and tolerability profile with reduced rate of all-grade diarrhea, and no grade 3 diarrhea or rash to date at RP2D
- Reduced rates of dose reduction/discontinuation

Next Steps

- Move rapidly toward a potentially pivotal 2L trial, and expand clinical development to the 1L setting
- Regulatory update planned in Q1 2022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Q&A
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