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 01, 2024

CULLINAN THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39856**	**81-3879991**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Main Street
Suite 1350
Cambridge, Massachusetts **02142**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 410-4650

(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	**Trading 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 1, 2024, Cullinan Therapeutics, Inc. (the "Company") issued a press release related to the announcement of initial clinical data from the pivotal Phase 2b portion of its REZILIENT1 clinical trial of zipalertinib in patients with non-small cell lung cancer ("NSCLC") harboring epidermal growth factor receptor exon 20 ("EGFRex20") insertion mutations who received zipalertinib after prior treatment with amivantamab. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this report furnished pursuant to Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 8.01 Other Events.

On June 1, 2024, the Company announced initial clinical data from the pivotal Phase 2b portion of its REZILIENT1 clinical trial of zipalertinib in patients with NSCLC harboring EGFRex20 insertion mutations who received zipalertinib after prior treatment with amivantamab. As of a January 12, 2024 data cut-off, 31 patients had been enrolled. Patients had received a median of three prior systemic anti-cancer regimens, including prior platinum-based chemotherapy, prior anti-PD1/L1 therapy, and prior EGFR tyrosine kinase inhibitor therapy.

At the data cut-off, 18 patients were evaluable for response and showed similar anti-tumor activity compared with those post prior chemotherapy in the previously reported Phase 1/2a part of the clinical trial, as shown below.

	Module C (post chemo and amivantamab +/- other exon 20 insertion treatment) (N=18)	Phase 1/2a results (post chemo)[1] (N=39)
Overall response rate (confirmed)	39%	41%
Disease control rate[2]	94%	97%
Duration of response (months)	NE	NE
Progression-free survival (months)	NE	12

NE = not yet estimable

[1] Piotrowska Z, et al. JCO 2023

[2] Disease control rate = (complete response + partial response + stable disease)/response-evaluable

Zipalertinib demonstrated a manageable safety profile, similar to what has been previously reported. There were no grade 4 or grade 5 treatment-related adverse events.

The Company is co-developing zipalertinib with an affiliate of Taiho Pharmaceutical Co., Ltd through a suite of REZILIENT clinical trials, including two ongoing pivotal clinical trials in first line and second line exon20 insertion NSCLC as well as clinical trials in other patient populations, such as patients with active brain metastases and those with uncommon EGFR mutations. Both Module B2 (post chemotherapy only) and Module C (post approved exon20 insertion mutation treatments) of the pivotal REZILIENT1 clinical trial remain on track to complete enrollment by year-end 2024.

The Company presented the initial clinical data at an investor event on June 1, 2024 through an investor presentation. A copy of the investor presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Cullinan Therapeutics, Inc. on June 1, 2024, furnished herewith
99.2	Investor presentation
104	Cover page from this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURES

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 THERAPEUTICS, INC.

Date: June 3, 2024

By: /s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer

Exhibit 99.1

Cullinan Therapeutics Announces Positive Initial Data from Pivotal Phase 2b REZILIENT1 Study of Zipalertinib

Objective response rate of 39% with manageable safety profile in patients with non-small cell lung cancer (NSCLC) harboring EGFR Exon 20 insertion mutations treated with zipalertinib who had progressed after prior amivantamab treatment

CAMBRIDGE, Mass., June 1, 2024 (GLOBE NEWSWIRE) -- Cullinan Therapeutics, Inc. (Nasdaq: CGEM), a biopharmaceutical company focused on developing modality-agnostic targeted therapies, today announced positive initial data in patients receiving zipalertinib after prior treatment with amivantamab enrolled in its pivotal Phase 2b REZILIENT1 clinical trial.

As of a January 12, 2024 data cut-off, 31 patients had been enrolled. Patients had received a median of three prior systemic anti-cancer regimens, including prior platinum-based chemotherapy, prior anti-PD1/L1 therapy, and prior EGFR tyrosine kinase inhibitor (TKI) therapy.

At data cut-off, 18 patients were evaluable for response and showed similar anti-tumor activity compared with those post prior chemotherapy in the previously reported Phase 1/2a part of the study.

	Module C (post chemo and Ami+/- other exon20ins treatment) (N=18)	Phase 1/2a results (post chemo)1 (N=39)
ORR (confirmed)	39%	41%
DCR[2]	94%	97%
DOR (months)	NE	NE
PFS (months)	NE	12

NE=not yet estimable.
[1] Piotrowska Z, et al. JCO 2023
[2] DCR=(CR+PR+SD)/response-evaluable

Zipalertinib demonstrated a manageable safety profile, similar to what has been previously reported. There were no grade 4 or grade 5 treatment-related adverse events.

“In an evolving treatment landscape, this is the first ever clinical data to systematically characterize the potential of an irreversible and selective EGFR exon20 insertion mutation TKI such as zipalertinib in patients who were heavily pre-treated and had received amivantamab. Given the recent approval of amivantamab as a first line treatment in combination with chemotherapy, we are encouraged by the initial results of the Phase 2b portion of the REZILIENT1 clinical trial, which show that in a post-amivantamab setting, zipalertinib demonstrated promising efficacy, similar to that in patients who progressed after platinum-based chemotherapy alone, and had a manageable safety profile” said Jeffrey Jones, MD, MBA, Chief Medical Officer, Cullinan Therapeutics. “With a comprehensive development plan for zipalertinib, this data further strengthens our confidence in its potential to address a significant

unmet need for patients with NSCLC harboring EGFR exon 20 insertion mutations. We remain on track to complete enrollment in the pivotal Phase 1/2b REZILIENT1 trial by the end of this year."

Zipalertinib has a unique chemical structure that is distinct from other exon20 insertion directed agents, which makes it highly selective for mutant exon 20 versus wild-type EGFR. Cullinan entered into a partnership with Taiho in 2022, with an upfront cash payment of $275M and additional payments totaling $130M to be made for US regulatory approvals in 1L and 2L+ NSCLC. Cullinan also retains a 50/50 profit share in the U.S.

Cullinan and Taiho have a broad development program for zipalertinib through a suite of REZILIENT studies, including two ongoing pivotal studies in 1L and 2L+ exon20 insertion NSCLC as well as studies in other patient populations such as patients with active brain metastases and those with uncommon EGFR mutations. Both Module B2 (post chemo only) and Module C (post approved ex20ins treatments) of the pivotal REZILIENT1 trial remain on track to complete enrollment by end of 2024, consistent with prior projections.

Virtual and Live Investor Event
Cullinan Therapeutics will host an Investor Event on Saturday, June 1, 2024, at 6:30 PM Central Time, during which Dr. Jeff Jones, Chief Medical Officer at Cullinan Therapeutics, will present an overview of this zipalertinib data along with CLN-619 data shared at the 2024 ASCO annual meeting. Alexander Spira MD, PhD, FACP, FASCO and Director, Virginia Cancer Specialists Research Institute and Director, NEXT Oncology Virginia, will share an overview of the current treatment landscape for EGFR mutated NSCLC. Investors and analysts are invited to register to attend in person by emailing Chad Messer, VP Investor Relations (cmesser@cullinantx.com). A live webcast will be available via the events page of the Company's investor relations website at https://cullinantherapeutics.com/events-and-presentations/, and a replay will be available shortly after the conclusion of the live event.

About Zipalertinib
Zipalertinib (CLN-081/TAS6417) is an orally available small molecule designed to target activating mutations in EGFR. The molecule was engineered to inhibit EGFR variants with exon 20 insertion mutations, while sparing wild-type EGFR. Zipalertinib is designed as a next generation, irreversible EGFR inhibitor for the treatment of a genetically defined subset of patients with non-small cell lung cancer. Zipalertinib has received Breakthrough Therapy Designation from the FDA.

Zipalertinib is being developed by Taiho Oncology, Inc., its parent company, Taiho Pharmaceutical Co., Ltd., and Cullinan Therapeutics, Inc. Cullinan Pearl Corp., which Taiho Pharmaceutical Co., Ltd., acquired from Cullinan Therapeutics, Inc. in 2022, previously licensed the rights to zipalertinib in Greater China to Zai Lab Limited in 2020.

About Cullinan Therapeutics
Cullinan Therapeutics, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients. We have strategically built a diversified portfolio of clinical-stage assets that inhibit key drivers of disease or harness the immune system to eliminate diseased cells in both oncology and autoimmune diseases. Our portfolio encompasses a wide range of modalities, each with the potential to be best and/or first in class.

Anchored in a deep understanding of oncology, immunology, and translational medicine, we create differentiated ideas, identify the most appropriate targets, and select the optimal modality to develop transformative therapeutics across a wide variety of cancer and autoimmune indications. We push conventional boundaries from candidate selection to differentiated therapeutic, applying rigorous go/no go criteria at each stage of development to fast-track only the most promising molecules to the clinic and, ultimately, commercialization. With deep scientific expertise, our teams exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients. Learn more about our Company at https://cullinantherapeutics.com/, and follow us on LinkedIn and X.

Forward-Looking Statements
This press release contains forward-looking statements 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 the potential benefits and therapeutic potential of zipalertinib; our clinical development plans and timelines; our plans regarding future data presentations and other statements that are not historical facts. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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 product candidates; 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, 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, except to the extent required by law. 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 the company 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.

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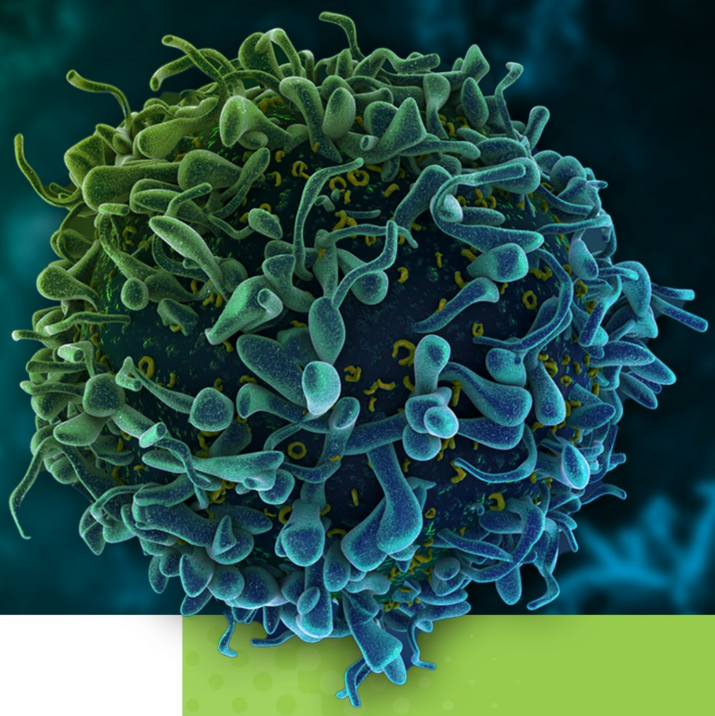
CLN-619 and Zipalertinib Updates at ASCO

June 2024



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Important Notice and Disclaimers

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “target,” “seek,” “predict,” “potential,” “continue” or the negative of these terms or other comparable terminology.

Forward-looking statements in this presentation include, but are not limited to, statements about: the commercial success, cost of development, and timing of the approval of our clinical-stage product candidates; the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or clinical trials and related preparatory work, and the period during which the results of the trials will become available; our ability to submit, and obtain clearance of, any investigational new drug applications on our expected timelines, or at all; our ability to initiate, recruit, and enroll patients in and conduct our clinical trials at the pace that we project; our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations, or warnings in the label of any of our product candidates, if approved; our ability to compete with companies currently marketing therapies or developing product candidates with targets or indications similar to our product candidates’ targets or indications; our reliance on third parties to conduct our clinical trials and to manufacture drug substance and drug product for use in our clinical trials; the size and growth potential of the markets for any of our current and future product candidates, and our ability to serve those markets; our ability to identify and advance through clinical development any additional product candidates; the commercialization of our current and future product candidates, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current and future product candidates; our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop current and future product candidates; our ability to retain and recruit key personnel; our ability to obtain and maintain adequate intellectual property rights; our expectations regarding government and third-party payor coverage, pricing, and reimbursement; our estimates of our expenses, ongoing losses, capital requirements, the sufficiency of our current resources, and our needs for or ability to obtain additional financing; the milestone payments that we may receive from Taiho Pharmaceutical Co., Ltd.; potential investments in our pipeline and the potential for such product candidates; the potential benefits of strategic collaboration agreements, our ability to enter into additional strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, and commercialization expertise; and developments and projections relating to our competitors or our industry. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

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, including the investigational new drug application that we intend to file for CLN-978; 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 product candidates; 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; success of any collaboration, partnership, license or similar agreements; and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, including under the caption “Risk Factors” in our most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other filings that we make with the SEC from time to time. These risks 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, even if subsequent events cause our views to change, except to the extent required by law. 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. Any forward-looking statement included in this presentation speaks only as of the date on which it was made.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source

Agenda

SECTION	PRESENTER
Opening Remarks	**Nadim Ahmed** CEO, Cullinan Therapeutics
CLN-619 +/- pembrolizumab in patients with advanced solid tumors **Zipalertinib in amivantamab pre-treated patients**	**Jeff Jones, MD** CMO, Cullinan Therapeutics
Unmet need and treatment landscape in EGFR mutated NSCLC	**Alexander Spira, MD, PhD** Co-Director, VCS Research Institute, Director, NEXT Oncology Virginia

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Our Mission: Create new standards of care for patients

- We use a unique R&D model of identifying high-impact targets and then applying the best modality to address each target
- We are rigorously advancing only highly-differentiated molecules, yielding a robust portfolio of clinical-stage programs
- We are expanding into autoimmune diseases, pursuing CD19xCD3 T Cell Engager, CLN-978, in systemic lupus erythematosus as first indication
- We are advancing a diversified pipeline of clinical-stage oncology programs, with multiple data catalysts through 2024 and early 2025
- We are well-positioned to execute on strategic goals and advance to commercial-stage organization, with cash runway into 2028

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Diversified portfolio leveraging novel technologies and differentiated mechanisms

Program Modality/MOA	IND-Enabling	Phase 1	Phase 2	Phase 3	Status	Geographic Rights
CLN-619 Anti-MICA/B antibody	Pan-cancer				Initial combo data and monotherapy update in 2Q24; Disease specific expansion data in 1H25	cullinan THERAPEUTICS or its subsidiary owns worldwide rights
CLN-978 CD19xCD3 T-cell engager	Systemic lupus erythematosus				IND submission expected in 3Q24	cullinan THERAPEUTICS owns worldwide rights
Zipalertinib (CLN-081/TAS6417) EGFRex20ins inhibitor	NSCLC with exon 20 insertion mutations 2+ line NSCLC with exon 20 insertion mutations frontline				Pivotal Phase 2b 2L+ study enrolled by YE24; Phase 3 1L study actively enrolling	cullinan THERAPEUTICS holds US co-development/-commercialization rights with TAIHO ONCOLOGY
CLN-049 FLT3xCD3 T-cell engager	R/R AML, MDS				Clinical update from ongoing Phase 1 study in 2H24	cullinan THERAPEUTICS or its subsidiary owns worldwide rights
CLN-418 B7H4x41BB bispecific immune activator	Multiple solid tumors				Clinical update from ongoing Phase 1 study in 2H24	cullinan THERAPEUTICS owns U.S. rights
CLN-617 Collagen-binding IL-12 and IL-2 fusion protein	Pan-cancer				Phase 1 study ongoing	cullinan THERAPEUTICS or its subsidiary owns worldwide rights

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Poised for multiple value-creation opportunities in the near-term

	CLN-619 *Pan cancer anti-MICA/B mAb*	CLN-978 *CD19xCD3 TCE for SLE*	Zipalertinib *EGFR inhibitor for EGFR ex20ins NSCLC*	3 other clinical stage programs
Program highlights	▪ *First-in-class* potential ▪ Novel I/O target, multi-tumor potential, mono-therapy clinical efficacy	▪ *First-in-class* potential in autoimmune diseases ▪ Potent modality (TCE) & differentiated profile	▪ *Best-in-class* potential ▪ Attractive economics inc. $130m milestones + 50/50 US profit share	▪ CLN-049 FTL3xCD3 for r/r AML and MDS ▪ CLN-418 B7H4x41BB for solid tumors (STs) ▪ CLN-617 IL2/IL12 fusion protein for STs
Next milestone/ status	▪ Initial expansion data for endometrial and cervical cancers 1**H25**	▪ Being developed in SLE; reviewing development in additional autoimmune diseases ▪ IND submission for SLE expected **3Q24**	▪ Complete pivotal Ph 2b 2L+ study enrollment by **YE 24**	▪ Clinical update from ongoing Ph 1 studies for CLN-049 and CLN-418 in **2H24**

Cash of $435m* + gross proceeds of $280M from Q2 2024 equity raise supports progress into 2028

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**As of March 31, 2024 (unaudited), includes cash equivalents, investments, and interest receivable*


CLN-619 Phase I
Dose Escalation Data
Update
cullinan
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Today's Update

- Initial data from the CLN-619 + pembrolizumab dose escalation
- Updated observations from the CLN-619 monotherapy dose escalation
- Implications for future development

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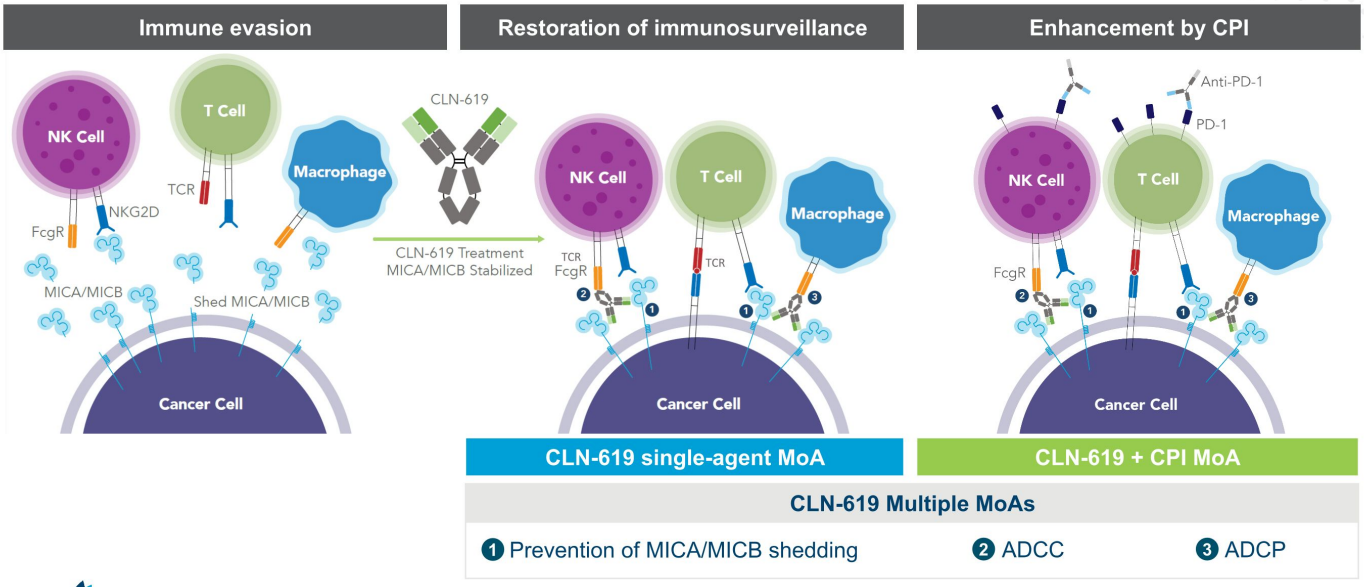
CLN-619 engages both innate and adaptive immune cells

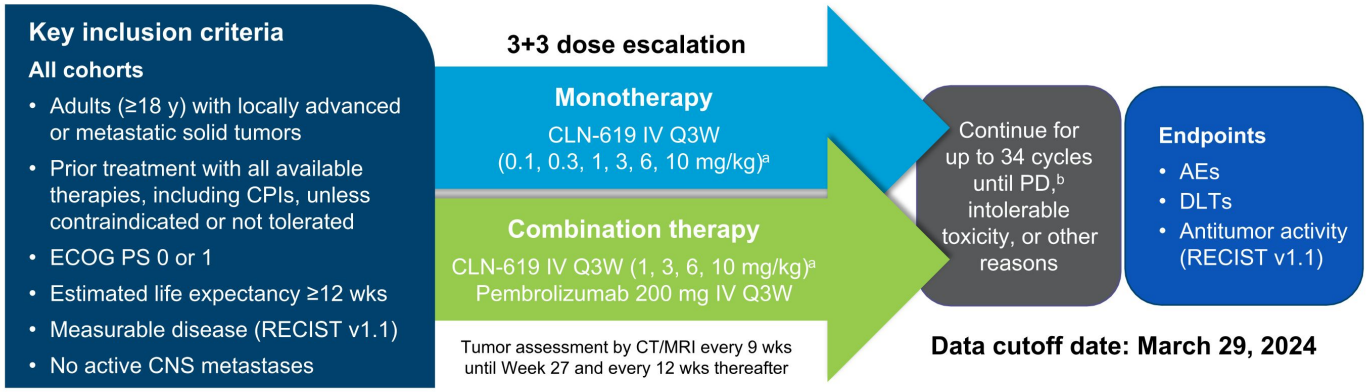


ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CPI, checkpoint inhibitor; FcgR, Fc gamma receptor; MoA, mechanism of action; NKG2D, natural killer group 2D receptor; NK, natural killer; PD-1, programmed cell death protein; TCR, T-cell receptor.

CLN-619 is being studied as monotherapy and in combination with a CPI, pembrolizumab

Phase 1 study design

NCT05117476



Data cutoff date: March 29, 2024

- Corticosteroid, antihistamine, and antipyretic premedications for IRR prophylaxis were required 30–60 minutes before Cycle 1 Day 1
- Patients in extension cohorts were required to provide pre- and on-treatment (Cycle 2 Day 8) biopsy samples for biomarker assessments

Note: 1 cycle=3 wks.
AE, adverse event; CNS, central nervous system; CPI, checkpoint inhibitor; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; IRR, infusion-related reaction; PD, progressive disease; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors.
[a]CLN-619 was administered intravenously over 1 hour Q3W.
[b]Patients who met criteria for treatment discontinuation but were otherwise deriving clinical benefit could continue at the discretion of the investigator.

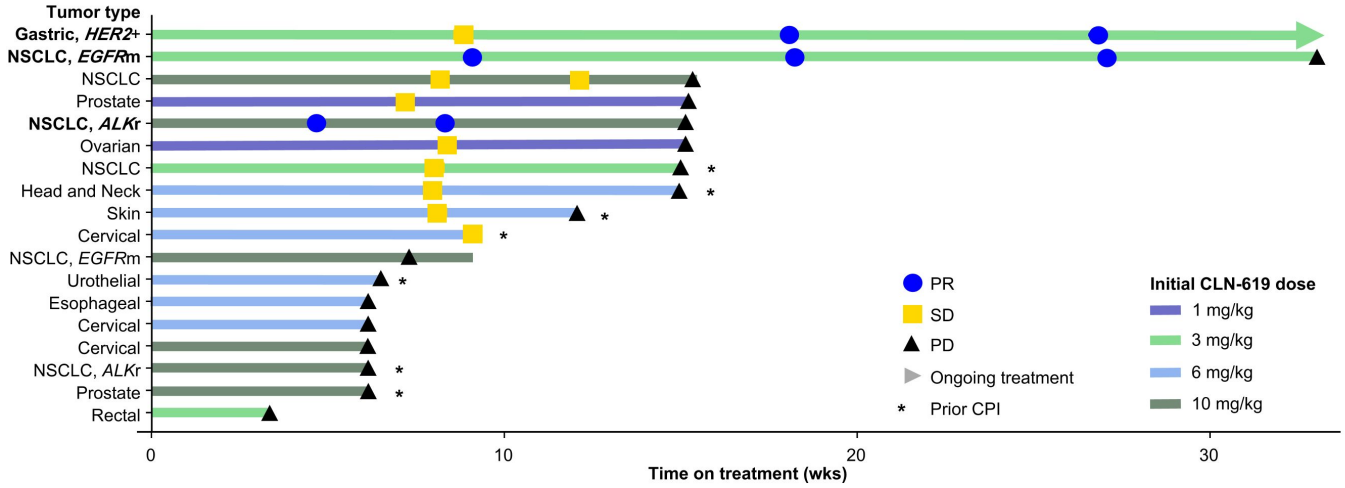
Enrolled patients had heavily pretreated advanced solid tumors; many had disease progression after prior treatment with a CPI

	CLN-619 + pembrolizumab (n=22)	CLN-619 monotherapy (n=42)
Age, y, median (range)	68.5 (38, 82)	62.5 (26, 83)
Female, n (%)	11 (50.0)	25 (59.5)
ECOG PS 1, n (%)	15 (68.2)	28 (66.7)
Tumor type, n (%)		
NSCLC	6 (27.3)	5 (11.9)
Cervical	4 (18.2)	5 (11.9)
Ovarian	3 (13.6)	3 (7.1)
Prostate	2 (9.1)	3 (7.1)
Colorectal	1 (4.5)	6 (14.3)
Endometrial	0	3 (7.1)
Other	6 (27.3)[a]	17 (40.5)[b]
Months since diagnosis, median (range)	46.3 (4, 160)	37.4 (9, 207)
No. of prior systemic therapies, median (range)	3 (1, 8)	3 (1, 7)
Prior CPI therapy, n (%)	9 (40.9)	21 (50.0)

CPI, checkpoint inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer.
[a]Other tumor types in the combination cohorts: gastric (2 patients), esophageal (1), head and neck (1), skin (1), and urothelial cancer (1); [b]Other tumor types in the monotherapy cohorts: breast (2), pancreatic (2), sarcoma (2), adenoid cystic carcinoma (1), caecal cancer (1), duodenum (1), head and neck (1), kidney (1), leiomyosarcoma (1), mediastinal intimal sarcoma (1), melanoma (1), parotid gland (1), peritoneal mesothelioma (1), and thyroid (1).

Pembrolizumab combination: Objective responses in patients with tumor types typically unresponsive to CPI therapy

- 22 patients treated with CLN-619 + pembrolizumab; 18 patients were RECIST-evaluable for response*
- Confirmed responses (all PR) were observed at CLN-619 doses ≥ 3 mg/mg



*ALK*r, anaplastic lymphoma kinase gene rearrangement; CPI, checkpoint inhibitor; *EGFR*m, epidermal growth factor receptor mutation; *HER2*, human epidermal growth factor receptor 2; NSCLC, non-small cell lung cancer; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.
[a]RECIST-evaluable patients had ≥1 post-baseline imaging tumor assessment. 4 patients did not have post-baseline imaging for response evaluation due to withdrawal of consent (n=2), death due to disease progression (n=1), and transfer to hospice and acute kidney injury (n=1).

Pembrolizumab combination: Objective responses in patients with tumor types typically unresponsive to CPI therapy

Characteristics of responders

Tumor type	No. of prior lines of therapy	Prior CPI	CPI Responsive Tumor	Best response	DoR, wks
NSCLC, *ALK*r	2	No	No	PR	12.7
Gastric, *HER2*+	3	No	Yes	PR	8.9+ (ongoing)
NSCLC, *EGFR*m exon 18/21	6	No	No	PR	24.0

*ALK*r, anaplastic lymphoma kinase gene rearrangement; CPI, checkpoint inhibitor; DoR, duration of response; *EGFR*m, epidermal growth factor receptor mutation; *HER*2, human epidermal growth factor receptor 2; PR, partial response.

- Responding patients were treated with CLN-619 at doses ≥ 3 mg/kg
- All three partial responses were confirmed
  - NSCLC responses first observed at 5 and 9 weeks after starting treatment, respectively

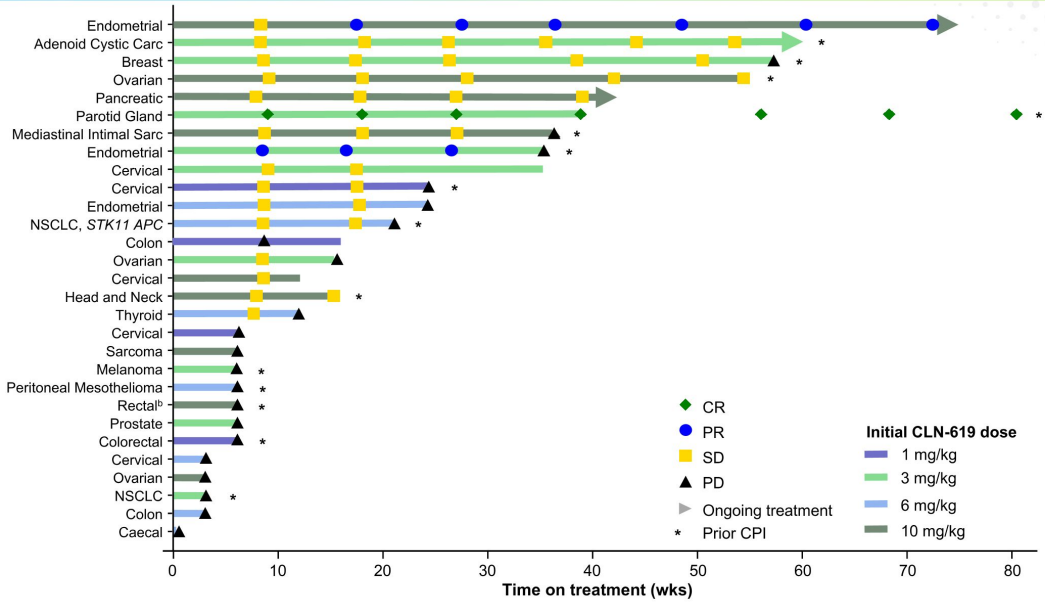
Enrolled patients had heavily pretreated advanced solid tumors; many had disease progression after prior treatment with a CPI

	CLN-619 + pembrolizumab (n=22)	CLN-619 monotherapy (n=42)
Age, y, median (range)	68.5 (38, 82)	62.5 (26, 83)
Female, n (%)	11 (50.0)	25 (59.5)
ECOG PS 1, n (%)	15 (68.2)	28 (66.7)
Tumor type, n (%)		
NSCLC	6 (27.3)	5 (11.9)
Cervical	4 (18.2)	5 (11.9)
Ovarian	3 (13.6)	3 (7.1)
Prostate	2 (9.1)	3 (7.1)
Colorectal	1 (4.5)	6 (14.3)
Endometrial	0	3 (7.1)
Other	6 (27.3)[a]	17 (40.5)[b]
Months since diagnosis, median (range)	46.3 (4, 160)	37.4 (9, 207)
No. of prior systemic therapies, median (range)	3 (1, 8)	3 (1, 7)
Prior CPI therapy, n (%)	9 (40.9)	21 (50.0)

CPI, checkpoint inhibitor; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer.
[a]Other tumor types in the combination cohorts: gastric (2 patients), esophageal (1), head and neck (1), skin (1), and urothelial cancer (1); [b]Other tumor types in the monotherapy cohorts: breast (2), pancreatic (2), sarcoma (2), adenoid cystic carcinoma (1), caecal cancer (1), duodenum (1), head and neck (1), kidney (1), leiomyosarcoma (1), mediastinal intimal sarcoma (1), melanoma (1), parotid gland (1), peritoneal mesothelioma (1), and thyroid (1).

Updated monotherapy efficacy shows durability of clinical benefit, including objective responses across multiple tumor types

- Total treated: N=42
- Dose ≥1 mg/kg and RECIST evaluable: N=29
- CBR = 41.4%
  (1 CR, 2 PR, 9 SD ≥18 weeks)



Carc, carcinoma; CBR, clinical benefit rate; CPI, checkpoint inhibitor; CR, complete response; NSCLC, non-small cell lung cancer; PD, progressive disease; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; Sarc, sarcoma; SD, stable disease.
[a]Patient maintained CR after study treatment discontinuation. [b]Rectal squamous cell carcinoma.

* 4 patients did not have post-baseline imaging for response evaluation due to withdrawal of consent (n=2), death due to disease progression (n=1), and transfer to hospice and acute kidney injury (n=1)

Durable clinical benefit of CLN-619 monotherapy has been observed across a range of tumor types

Characteristics of patients with response or SD ≥18 wks

Tumor type	No. of prior lines of therapy	Best response	DoR, wks
Responders (n=3)			
Mucoepidermoid parotid	2	CR	71
Endometrial (serous, MMRp)	5	PR	31
Endometrial (endometrioid, MMRp)	3	PR	55+ (ongoing)
SD ≥18 wks (n=9) **Cervical squamous (n=2); breast (ER/PR+, *HER2*–; n=1); ovarian (n=1); endometrial carcinosarcoma (n=1); mediastinal intimal sarcoma (n=1); adenoid cystic carcinoma (n=1); pancreatic adenocarcinoma (*KRAS* G12V; n=1); NSCLC (*STK11*; n=1)**	Mean: 3.6 Range: 1–7	SD ≥18 wks	Range: 18–56

CR, complete response; ER/PR+, estrogen receptor/progesterone receptor positive; *HER2*–, human epidermal growth factor receptor 2 negative; MMRp, mismatch repair proficient; NSCLC, non-small cell lung cancer; PR, partial response; SD, stable disease.

- Durable objective response observed in patients with disease progression after prior CPI
- Durable stable disease observed in a more extensive group of tumors, including gynecologic malignancies (cervical, endometrial, and ovarian) and NSCLC

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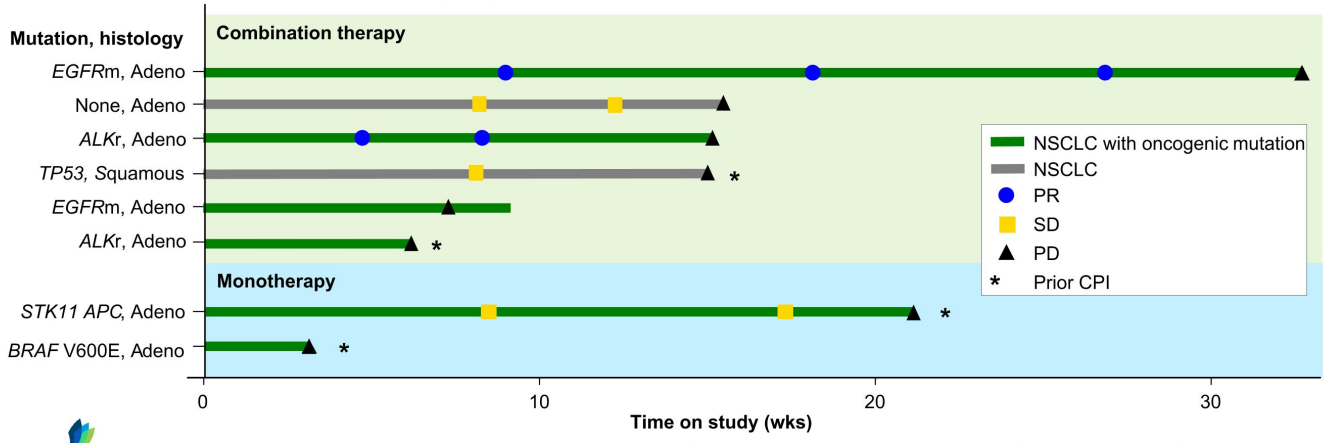
Patients with NSCLC harboring oncogenic mutations experienced clinical benefit with both monotherapy and combination therapy

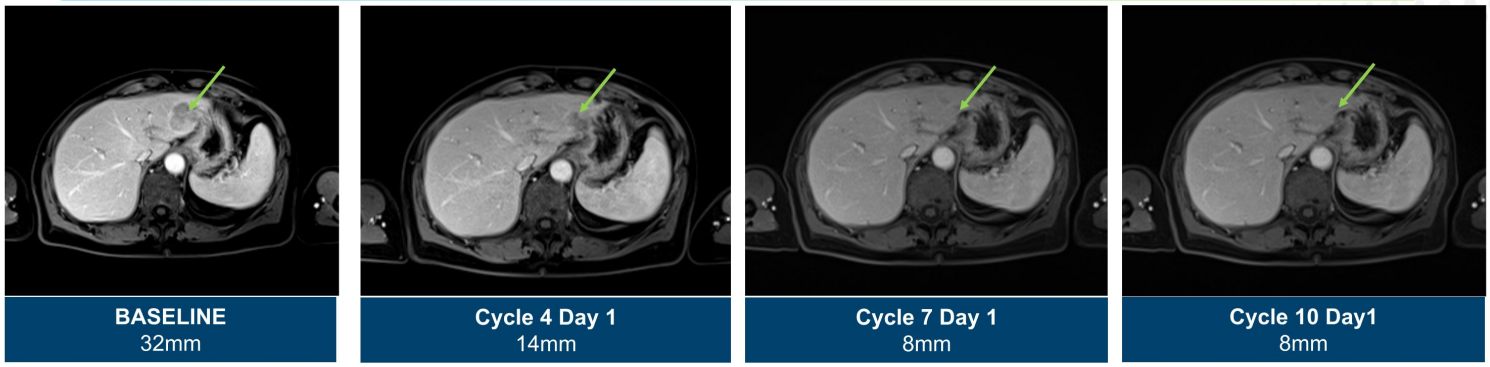
- 8 of the 11 patients with NSCLC were RECIST evaluable; of these, 6 had oncogenic mutations
  - 3 of the 6 patients with oncogenic mutations experienced clinical benefit
    - 2 PRs and 1 SD lasting >18 weeks

Time on treatment and clinical activity in patients with NSCLC



Adeno, adenocarcinoma; *ALK*r, anaplastic lymphoma kinase gene rearrangement; CPI, checkpoint inhibitor; CR, complete response; *EGFR*m, epidermal growth factor receptor mutation; NSCLC, non-small cell lung cancer; PD, progressive disease; PR, partial response; SD, stable disease; squamous, squamous cell carcinoma.

Durable partial response in EGFRm NSCLC with liver metastasis



BASELINE	Cycle 4 Day 1	Cycle 7 Day 1	Cycle 10 Day1
32mm	14mm	8mm	8mm

- **69y patient with NSCLC (EGFR mutation: G719 X in exon18 + L861 in exon 21)**
- Entered study after 6 prior lines of prior therapy, including **c**isplatin + etoposide, gefitinib, pemetrexed + cisplatin, docetaxel, gemcitabine, and afatinib
- PR observed at first response assessment after 3 cycles of CLN-619 + pembrolizumab, subsequently confirmed at Cycle 7 Day 1

CLN-619 was well tolerated as a monotherapy and in combination with pembrolizumab

Any-grade TEAEs in ≥15% of patients or grade ≥3 TEAEs[a] in ≥5% of patients in either group

TEAEs, n (%)	CLN-619 + pembrolizumab (n=22)		CLN-619 monotherapy (n=42)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Fatigue	8 (36.4)	0	10 (23.8)	0
Nausea	5 (22.7)	1 (4.5)	8 (19.0)	1 (2.4)
Constipation	5 (22.7)	0	4 (9.5)	0
IRR	4 (18.2)	0	12 (28.6)	0
Anemia	4 (18.2)	1 (4.5)	5 (11.9)	3 (7.1)
Back pain	4 (18.2)	1 (4.5)	5 (11.9)	0
Headache	4 (18.2)	0	2 (4.8)	0
Hyponatremia	4 (18.2)	0	1 (2.4)	0
Abdominal pain	3 (13.6)	0	10 (23.8)	2 (4.8)
AST increased	2 (9.1)	0	4 (9.5)	3 (7.1)
Hypertension	2 (9.1)	2 (9.1)	0	0
Pyrexia	0	0	8 (19.0)	0

- Treatment-related AEs reported in ≥10% of patients were fatigue (combination: 18.2%; monotherapy: 9.5%) and infusion related reactions (IRRs combination: 18.2%; monotherapy: 28.6%)
- Most IRRs were grade 1 or 2, occurred on day 1 of Cycle 1, and were mitigated with standard pre-medications including corticosteroids.

AE, adverse event; AST, aspartate aminotransferase; IRR, infusion related reaction; TEAE, treatment-emergent adverse event.
[a]One case of grade 3 laryngeal edema in the setting of IRR occurred at the monotherapy 10 mg/kg dose level in the absence of mandated steroid premedication (not captured in the table).
[b]AEs considered related to treatment with CLN-619 and/or pembrolizumab.

Key Takeaways

- Objective responses were observed with **CLN-619 + pembrolizumab** in patients with tumor types typically unresponsive to pembrolizumab (e.g., NSCLC with *ALK*r and *EGFR*m)
- **CLN-619 + pembrolizumab** was well tolerated
- Longer follow-up for patients treated with **CLN-619 monotherapy** confirms durable clinical benefit and favorable safety profile
  - Objective responses and prolonged stable disease were observed in multiple tumor types, including patients with disease progression after CPI therapy
- Based on these findings, new monotherapy and combination expansion cohorts have been opened in NSCLC
  - Enrollment continues to previously declared cervical (mono) and endometrial cancer (mono and combo) expansion cohorts
  - **Chemotherapy + CLN-619** combinations will be explored in future expansion cohorts, starting with platinum-resistant ovarian cancer

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CLN-619 + Chemotherapy

HYPOTHESIS

Chemotherapy induces cell stress leading to **upregulation of MICA/B** and can simultaneously have **positive immuno-modulatory properties**

- Platinums and taxanes **upregulate MICA/B expression** *in vitro*
- Chemotherapy leads to **increased infiltration/ activation of immune cells** including CD8 T/NK cells in preclinical models
- Several chemotherapeutic agents are known **inducers of immunogenic cell death**

CLINICAL RATIONALE

Why combine CLN-619 with chemotherapy?

- CLN-619 has demonstrated **monotherapy objective responses** across multiple tumor types.
- Chemotherapy can **enhance CLN-619 activity** by inducing cellular stress
- **Immunotherapy and chemotherapy have been successfully combined** in various tumors

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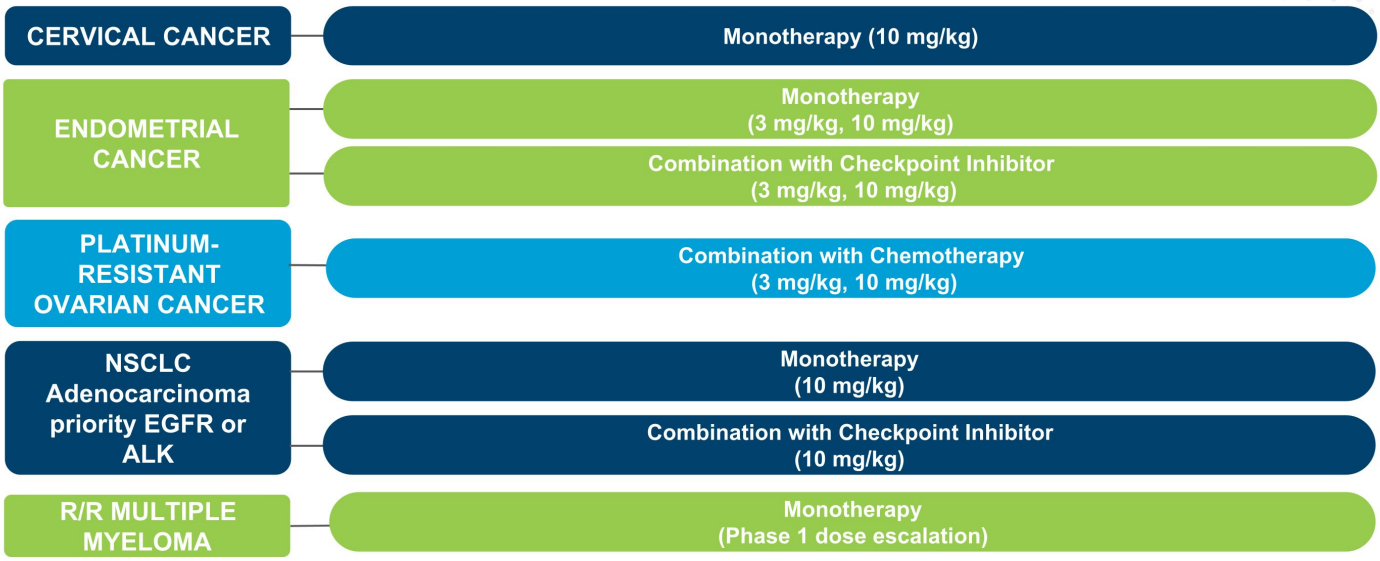
CLN-619 current development plan in solid and hematologic tumors



- Additional monotherapy and checkpoint combination cohorts may be defined
- Additional chemotherapy combination cohorts in development


ZIPALERTINIB Data
Update
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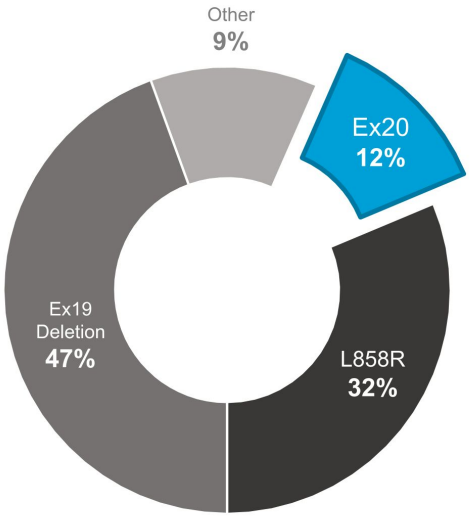
Patients with insertions at exon 20 make up the largest unmet need segment of the lung cancer population with EGFR mutations

EGFR MUTATED NSCLC[1]



U.S. EXON 20 INCIDENCE

U.S. Lung cancer incidence[1]:
234,580

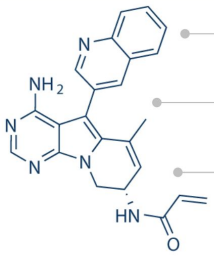
NSCLC[1]:
80%-85%

Exon 20[2-4]:
1.5%-2.0% of NSCLC
~2,800-4,000 patients

References 1. American Cancer Society (2024) **2.** Riess JW, et al. *J Thorac Oncol.* 2018;13(10):1560-1568. doi:10.1016/j.jtho.2018.06.019. **3.** Zhang YL, et al. *Oncotarget.* 2016;7(48):78985-78993. doi:10.18632/oncotarget.12587. **4.** Burnett H, et al. PLoS ONE. 2021;16(3):e0247620. doi:10.1371/journal.pone.0247620.

Zipalertinib (CLN-081/TAS6417): Selective EGFR inhibitor with best-in-class potential for NSCLC patients with exon20 mutations

ZIPALERTINIB: UNIQUE DESIGN PROPERTIES



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

KEY DATA FROM PH 1/2A STUDY @ 100 MG BID

41%
confirmed overall rate of response (16/39)

12-month
median progression-free survival

Favorable
safety and tolerability profile

STATUS UPDATE

- **Granted Breakthrough Therapy Designation** — JAN 2022
- **Entered into co-development / co-commercialization with Taiho Oncology, $275M upfront + $130M in U.S. regulatory milestones, retaining 50% of U.S. profit share** — Q2 2022
- **Pivotal Phase 2b cohorts in second line+ initiated** — Q4 2022
- **Pivotal Phase 3 study in frontline launched** — AUG 2023

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Zipalertinib: Superior safety and efficacy observed at 100mg BID dose level in REZILIENT1 Phase 1/2a cohorts

	<65 mg (N=23)	100 mg (N=39)	150 mg (N=11)	Total (N=73)
ORR	8 (35%)	16 (41%)	4 (36%)	28 (38%)
Median PFS	8 mo	12 mo	8 mo	10 mo
Gr3+ Rash	0	0	1 (9%)	1 (1%)
Gr3+ Diarrhea	0	0	2 (18%)	2 (3%)
Dose Reductions	2 (9%)	5 (13%)	3 (27%)	10 (14%)
Dose Discontinuations	2 (9%)	2 (5%)	2 (18%)	6 (8%)

- Heavily treated patient population: 66% of patients with ≥2 prior lines of treatment
- 36% with prior EGFR TKI treatment, including 3 patients w/ prior poziotinib and/or mobocertinib
- 55% received prior immunotherapy

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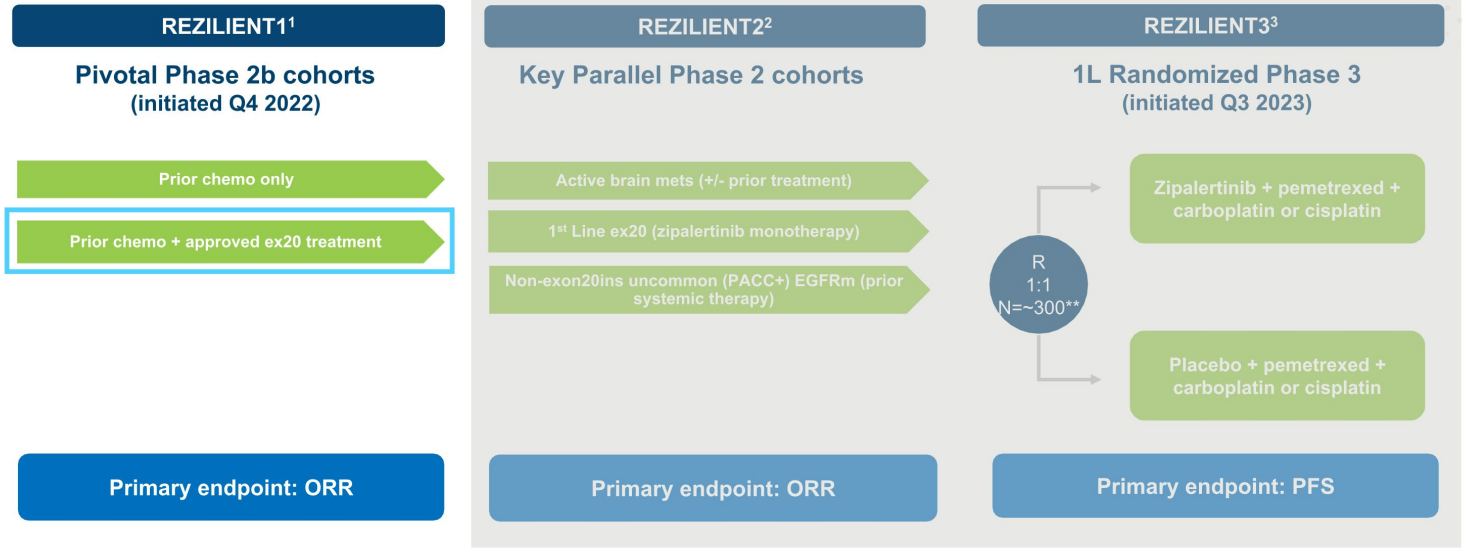
Update on initial patients treated in the prior chemo + amivantamab cohort of REZILIENT1



Clinicaltrials.gov identifiers: [1]NCT04036682, [2]NCT05967689 and [3]NCT05973773; * includes both approved and investigational exon20 therapies ** following 6-12 patient safety lead in. PACC = P-loop and αC-helix

Enrolled patients were heavily pre-treated, and nearly 50% had history of brain metastases

Characteristic	All Patients (N=31)
Age (years), **median** (range)	**62.5** (39-77)
Female	**23** (74.2)
Male	**8** (25.8)
ECOG Performance Status, N (%)	
0	**8** (25.8)
1	**23** (74.2)
Prior systemic cancer regimens, N (%)	
1	**2** (6.5)
2	**9** (29.0)
3	**7** (22.6)
>3	**13** (41.9)
Median (range)	**3** (1-6)
Prior platinum-based chemotherapy, N (%)	**30** (96.8)
Prior anti-PD1/L1, N (%)	**16** (51.6)
Prior EGFR TKIs, N (%)	**18** (58.1)
History of Brain Metastasis, N (%)	**15** (48.4)

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Zipalertinib treatment after prior amivantamab shows similar efficacy to Phase 1/2a results in patients receiving prior chemo alone

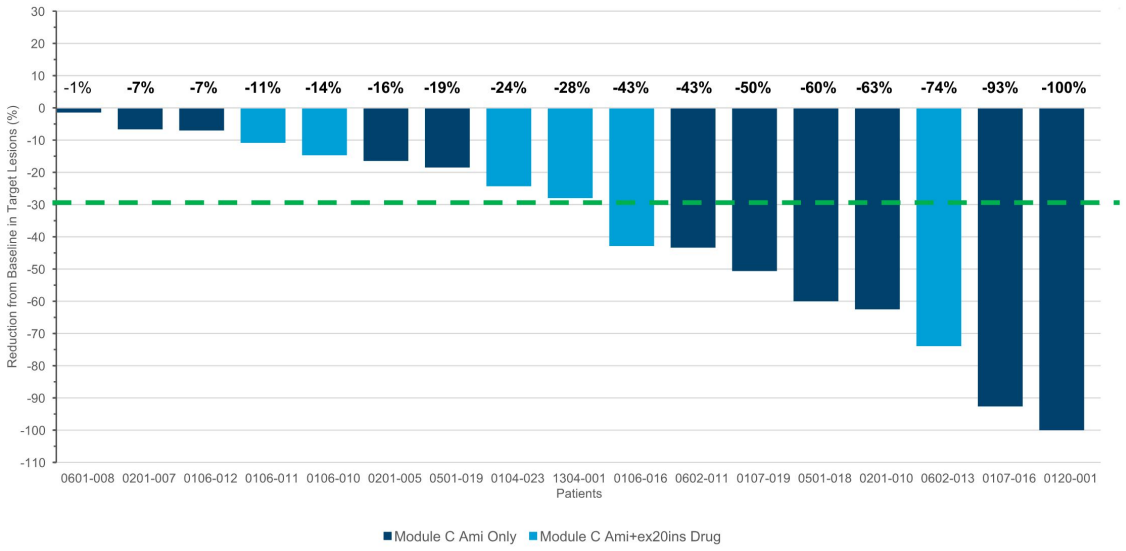
	post chemo and Ami +/- other ex20ins treatment (N=18*) *Data cut-off 12 January 2024*	Phase 1/2a results (post chemo)[1] (N=39)
ORR (confirmed)	**39%**	**41%**
DCR[2]	**94%**	**97%**
DOR (months)	**NE**	**NE**
PFS (months)	**NE**	**12**

1. Piotrowska Z, et al: JCO 2023
2. Disease Control Rate = (PR+SD) / response evaluable patients

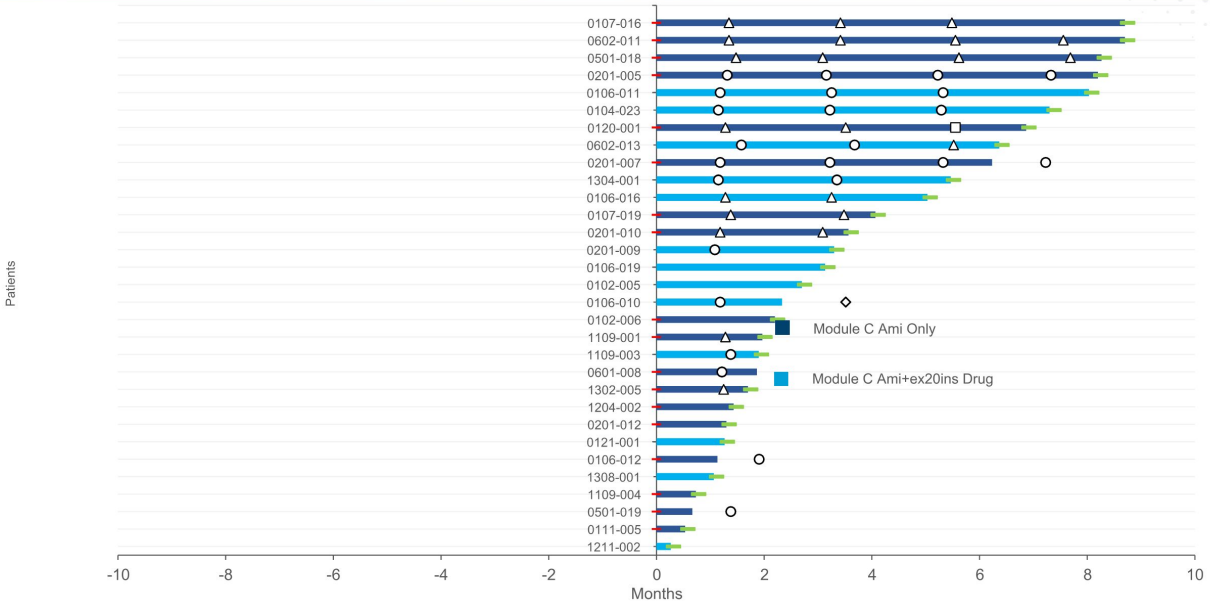
*Efficacy population includes all treated patients with measurable disease at baseline who have received at least one dose of CLN-081 and one of the following: 1) at least two on-treatment tumor assessments, 2) death, or 3) discontinuation due to disease progressions (either clinical or per RECIST).

Best Percentage Change from Baseline of Target Lesions

- Radiographic tumor regression in all but 1 patient who died prior to 1st on study imaging
- Zipalertinib was clinically active in patients who had received both amivantamab and other exon20ins drugs



Time on treatment and activity



No new safety signals observed in the post amivantamab population

AE Any Grade

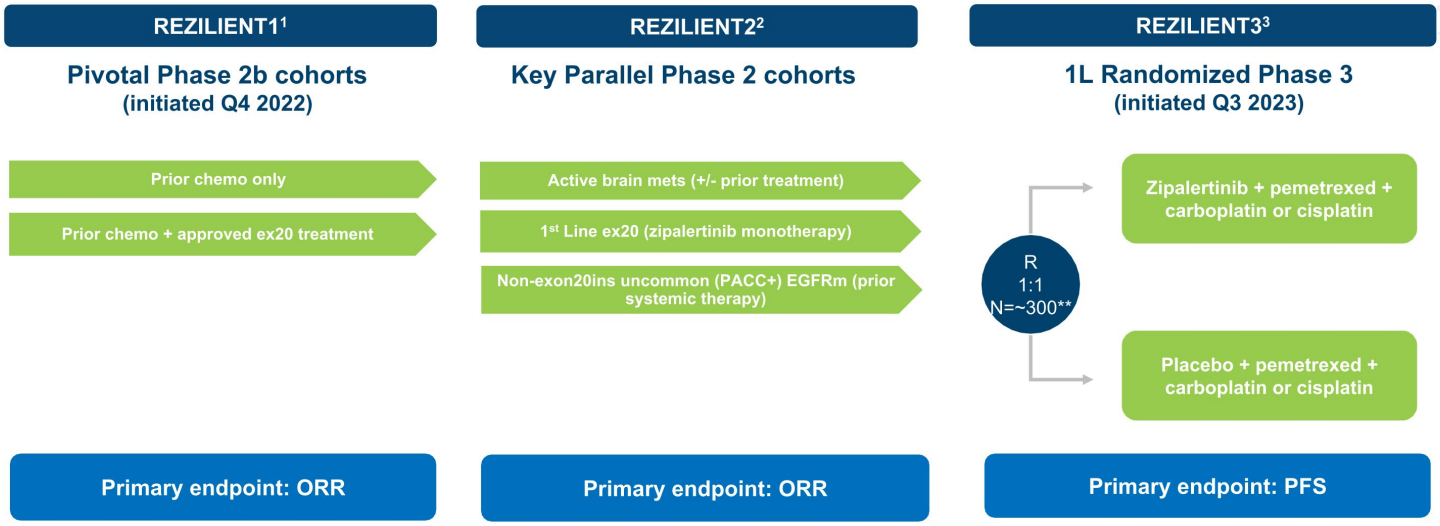
Overall	All Patients (N=31) Any Grade
Any TEAE	29 (93.5)
Any TRAE	27 (87.1)
TRAE of Any Grade in ≥10% of Patients	
Rash	12 (38.7)
Anemia	8 (25.8)
Paronychia	7 (22.6)
Dry skin	6 (19.4)
Nausea	6 (19.4)
Stomatitis	4 (12.9)
Pruritis	4 (12.9)
Folliculitis	4 (12.9)

Grade 3 TRAE

Preferred Term	All Patients (N=31) Grade 3
Any TRAE	6 (19.4)
Anemia	1 (3.2)
Amylase increased	1 (3.2)
Lymphocyte decrease	1 (3.2)
Hypoxia	1 (3.2)
ILD	1 (3.2)
Pneumonitis	1 (3.2)
Folliculitis	1 (3.2)
Rash	1 (3.2)
Rash maculo-papular	1 (3.2)
Hypertension	1 (3.2)

- No new safety signal identified
- There were no grade 4 or grade 5 treatment-related adverse events

REZILIENT program: zipalertinib development across multiple studies and indications, including 2 pivotal trials, in collaboration with Taiho Oncology



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Key Takeaways

- Zipalertinib shows promising anti-tumor activity in patients with exon20ins mutation NSCLC who have received prior treatment with amivantamab
  - Objective response rate was similar to prior reports in patients with disease relapsed after prior platinum chemotherapy
- Zipalertinib demonstrated a favorable safety profile when administered after prior amivantamab with no new safety signals identified
- Zipalertinib is a potential future treatment option for patients with relapsed exon20ins mutation NSCLC
- Pivotal Phase 2b cohorts remain on track to complete enrollment by YE2024
- Broad development plan including randomized frontline study comparing zipalertinib + chemo to chemo alone is ongoing

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