

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): **February 19, 2020**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in charter)

Delaware
*(State or other jurisdiction
of incorporation)*

1-36598
*(Commission
File Number)*

04-3321804
*(I.R.S. Employer
Identification No.)*

100 Campus Drive, Florham Park, New Jersey 07932
(Address of principal executive offices, and zip code)

(608) 441-8120
(Registrant's telephone number, including area code)

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. below):

- ☐ 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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. ☐

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, par value \$0.00001	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 7.01 REGULATION FD DISCLOSURE

On February 19, 2020, we held a CLR 131 clinical data call reporting positive data from our Phase 2 CLOVER-1 study in patients with relapsed/refractory B-cell lymphomas. A copy of the clinical data call presentation is furnished as Exhibit 99.1 and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
<u>99.1</u>	<u>Clinical data call presentation dated February 19, 2020</u>

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.

Dated: February 19, 2020

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer

Clinical Data Call

February 19, 2020



Forward-Looking Statements

This presentation contains forward-looking statements. Such statements are valid only as of today and we disclaim any obligation to update this information. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experiences and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital required to complete the development programs described herein, uncertainties related to the disruptions at our sole supplier of CLR 131, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, the ability of our pharmaceutical collaborators to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. This presentation includes industry and market data that we obtained from industry publications and journals, third-party studies and surveys, internal company studies and surveys, and other publicly available information. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this presentation, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions that were used in preparing the forecasts from the sources relied upon or cited herein. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2018.

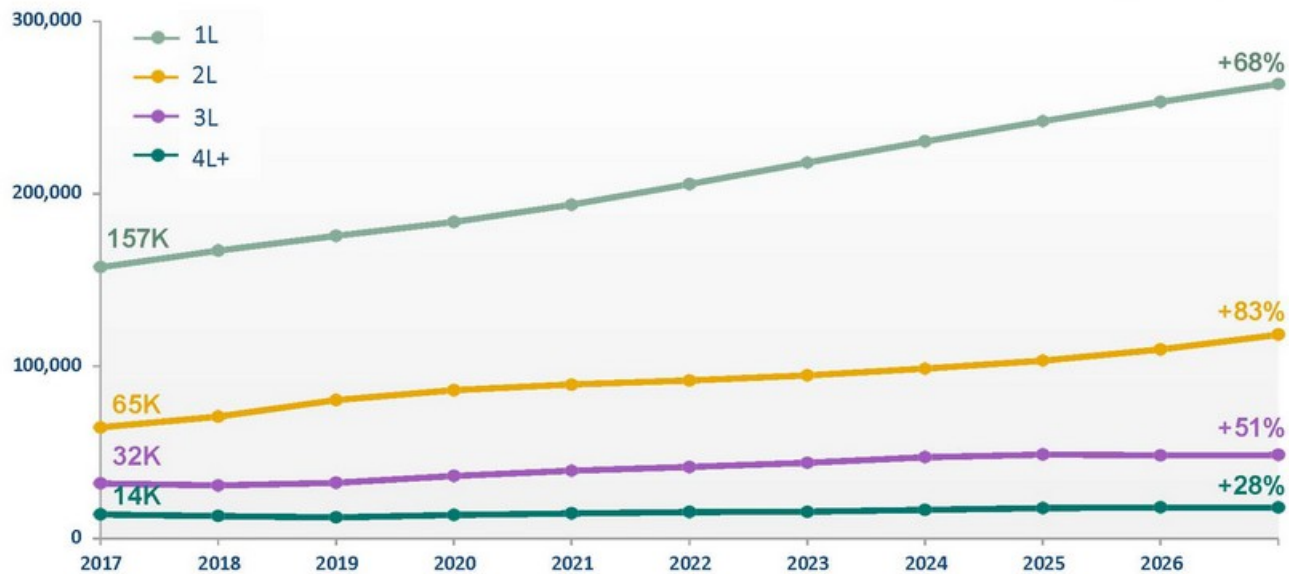
Presentation Topics

- 1 CLR 131 r/r Multiple Myeloma
- 2 CLR 131 r/r B-cell Non-Hodgkin's Lymphoma
- 3 CLR 131 Two Cycle Dosing Optimization
- 4 CLR 131 Clinical Development Next Steps
- 5 Conclusion

Multiple Myeloma Epidemiology

U.S. and Top 5 EU Prevalence

Patient Counts by Line of Therapy

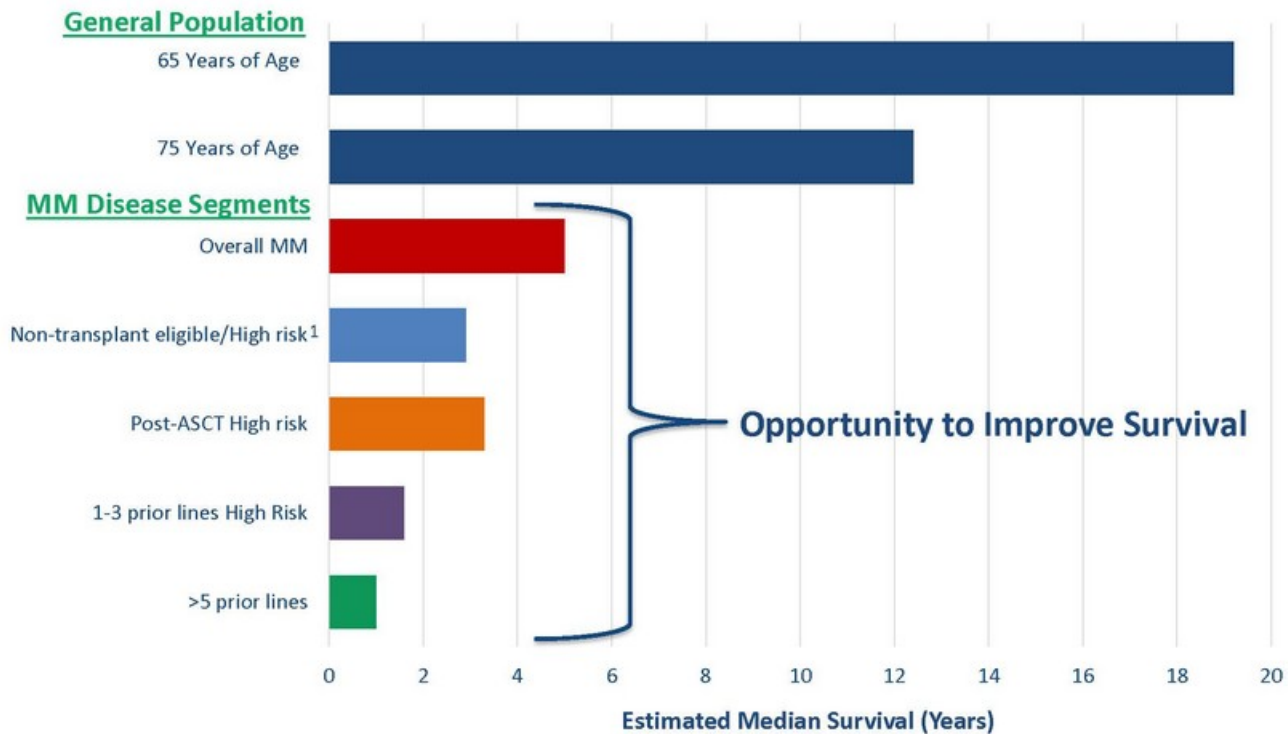


Multiple Myeloma Prevalence in U.S. (~131K²) and Key Global Markets are Projected to Increase Significantly Through 2030 Across All Lines of Therapy

Source: Putnam US and EU Epidemiology Evolution research, March 2018; Decision Resources Disease Landscape and Forecast; Epidemiology 2018 from Decision Resources. Disease Landscape and Forecast, Kantar Health CancerMPact database and Putnam Associates and internal data. 2. SEER Cancer Statistics Fact Sheet; Myeloma; Accessed April 22, 2019.

High Unmet Need Remains in Multiple Myeloma

General Population Median Survival vs. MM Patient Disease Segments

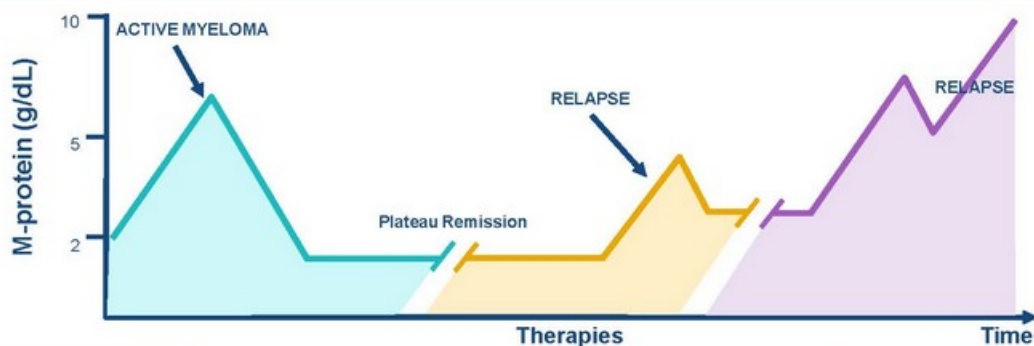


Multiple Myeloma is an Incurable Disease; Five Year Overall Median Survival

1. High Risk - Most aggressive type with poorer outcome, most difficult to treat and diagnosed based on cytogenetics/FISH test. Several cytogenetic abnormalities such as t(4;14), del(17/17p), t(14;16), t(14;20), non-hyperdiploid karyotype, and gain(1q) were identified that confer poor prognosis (International Myeloma Working Group consensus criteria)

High Unmet Need Remains in Multiple Myeloma

Overall Response Rate (ORR) & Depth of Response Decreases with Each Relapse¹



	1 st Line	2 nd Line	3 rd Line	4 th Line
ORR	58%	45%	30%	15%
	NDMM ASCT ²	NDMM No ASCT	Early Relapse (1-2 prior lines)	Late Relapse (>3 prior lines)
sCR/CR ³	Induction ~35%	~15-43%	~30-42%	<3%
	Post-ASCT ~45-60%			

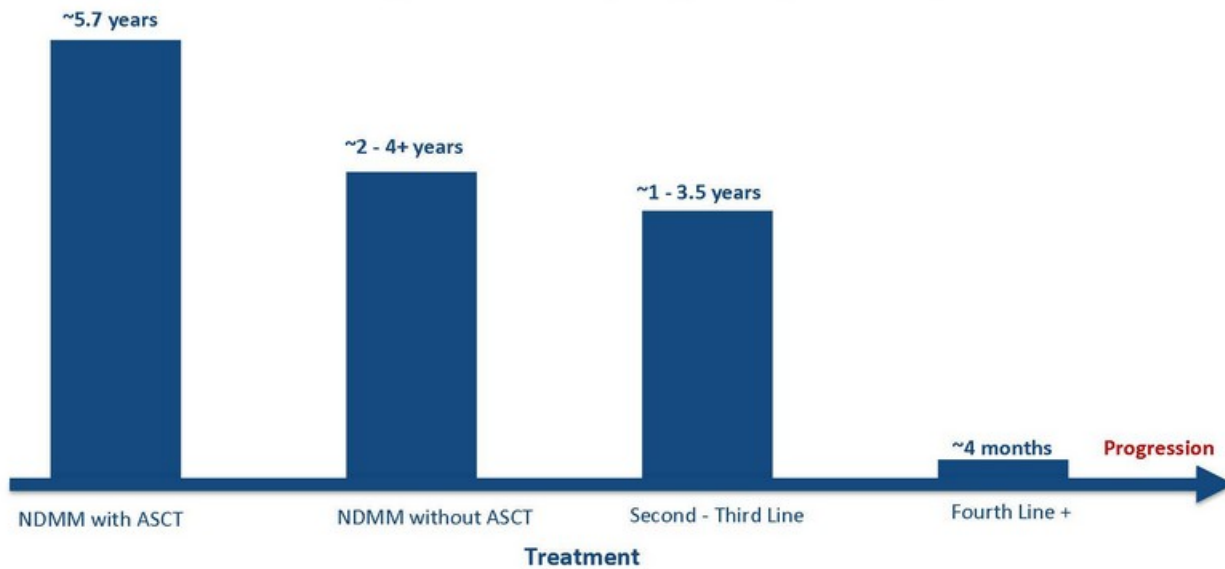
40% of Eligible 3rd Line+ Patients Decline Further Treatment Predominantly Due to Treatment Toxicities, Frequent Administration and Limited Clinical Benefits

1. Roman Hajek (April 10th 2013). Strategies for the Treatment of Multiple Myeloma in 2013: Moving Toward the Cure, Multiple Myeloma Roman Hajek, IntechOpen, DOI: 10.5772/55366. 2. Newly diagnosed MM Autologous Stem Cell Transplant 3. Data from Ph III studies or package inserts of SoC therapies; SCT includes Rvd, VTd, R Maintenance; No ASCT includes Rd, VMP, DVMP; Early Relapse includes DRd (*PFS not reached), KRd, IRd, DVd; Late Relapse includes Pd, daratumumab monotherapy.

High Unmet Need Remains in Multiple Myeloma

Limited Progression Free Survival (PFS) for Patients in 3rd Line or Later

Disease Progression in Multiple Myeloma (Median PFS)



***Significant Opportunity Remains to Improve Clinical Benefits and
Provide More Patient Friendly Drug Administration and Treatments***

Source: Phase 3 studies or package inserts of SoC therapies; ASCT includes RVd, VTd, R Maintenance; No ASCT includes Rd, RVd, VMP, DVMP, DRd; Early Relapse includes DRd, KRd, ERd, IRd, DVd, Kd; Late Relapse includes Pd, Dara mono, Selinexor; Gandhi, et al. Leukemia 33

r/r Multiple Myeloma Competitive Landscape

Approved Products 3rd Line or Later Monotherapy

Data Used for Approval

	Overall Response Rate (ORR) - %	Progression Free Survival (PFS) - Months
Selinexor	25.3	2.3
Daratumumab	29.2	3.7
Pomalidomide	29.2	4
Bortezomib	27.7	3
Carfilzomib	22.9	3

- All approved drugs achieved an ORR between 22.9% and 29.2%; currently little difference reported in Progression Free Survival
 - All data except Selinexor's are based upon 3rd line treatment
- CAR-Ts & BCMA antibody drug conjugates have demonstrated increased ORR & PFS
 - If approved for MM, initial utilization likely in later treatment lines

CLR 131 - A Phospholipid Ether Radio-Conjugate

Validated Mechanism of Targeted Delivery

- Tumor cells utilize lipids at significantly greater quantities than normal tissue
 - Energy source (β -oxidation)
 - Cell membrane production
 - Signaling molecules
- Cellectar's phospholipid ethers exploit inherent tumor cell need for lipids to provide targeted delivery
 - Bind to specialized regions on tumor cells that provide more efficient uptake and internalization of lipids
- CLR 131 a phospholipid radio-conjugate
 - Provides delivery of the radioisotope I-131
 - Phase 3 pivotal study ready compound
 - Demonstrated efficacy in 4 different hematologic cancers in Phase 2

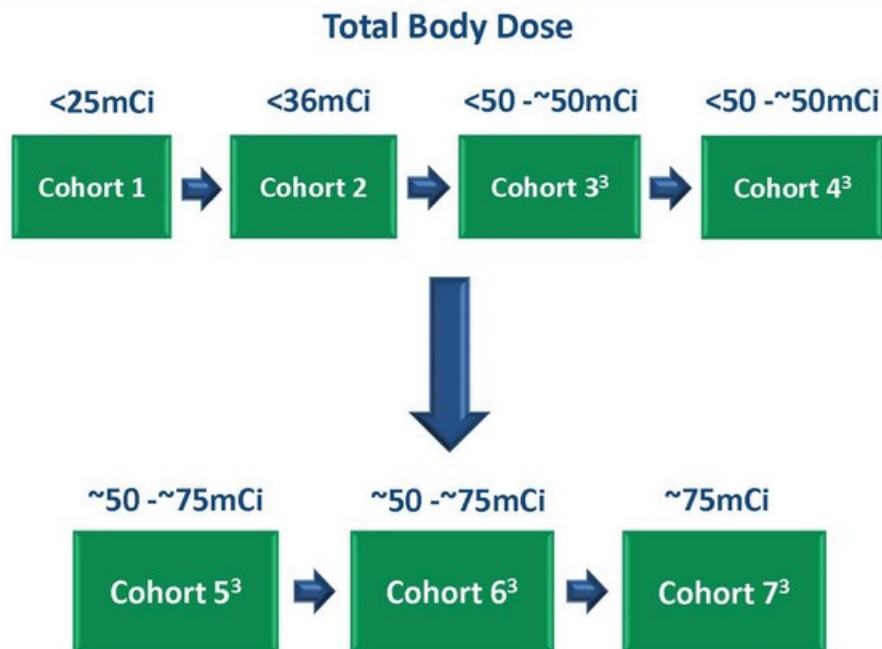
MOA Video



Combination of a Validated Delivery Platform and Therapeutic Payload

CLR 131 r/r Multiple Myeloma Phase 1¹ Study

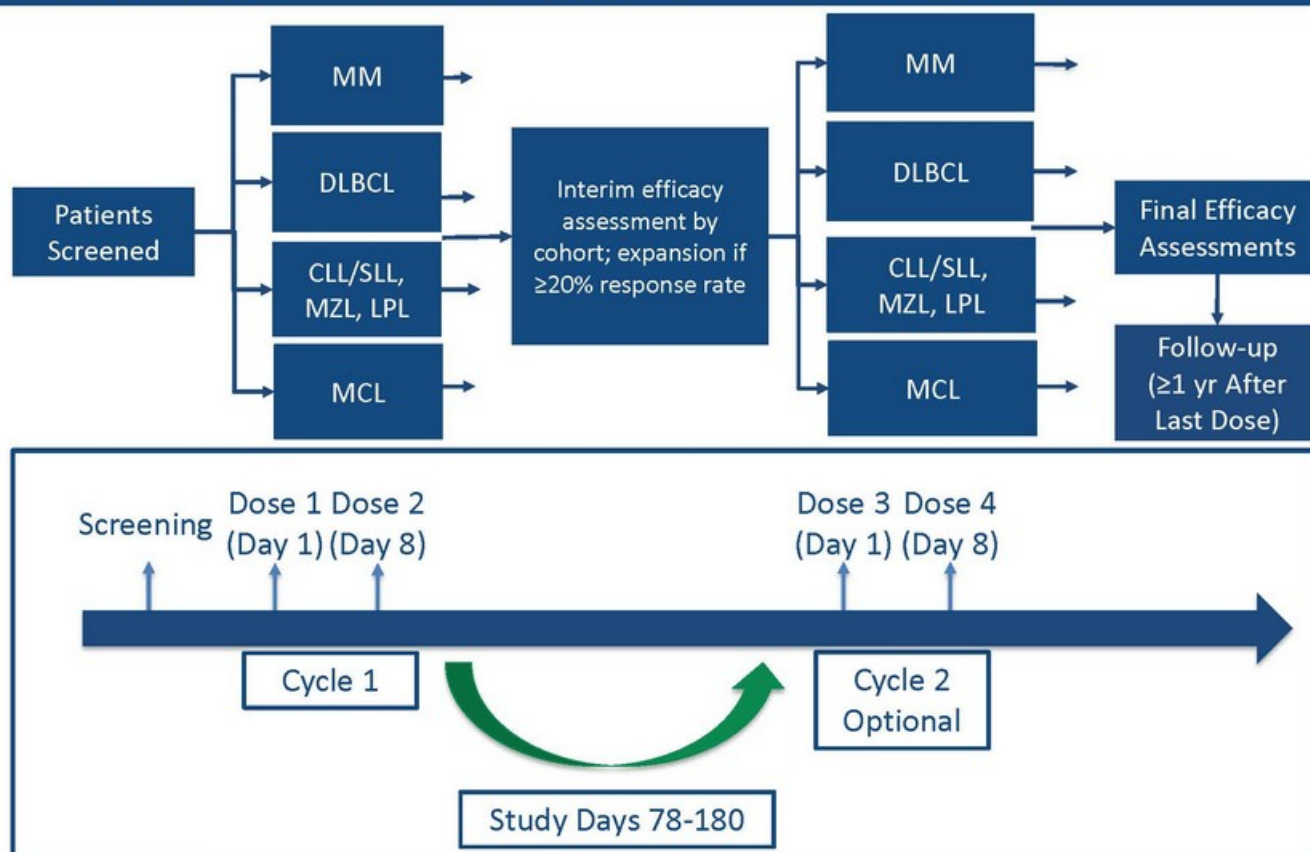
Total Body Dose (TBD)² ≤ 30 Minute Infusion



***Primary Study Endpoints are Safety, Tolerability
and Determination of Maximum Tolerated Dose***

CLR 131 r/r MM and NHL Phase 2¹ Study Design

U.S. Fast Track Designation Granted for Multiple Myeloma and DLBCL



CLR 131 r/r Multiple Myeloma

Challenging Patient Population - Characteristics¹

Criteria	Total Body Dose <50mCi (n=10)	Total Body Dose ~50mCi (n=20)	Total Body Dose ~75mCi (n=17)	Total (n=47)
Median Age (Min-Max)	68.5 (55-85)	70 (51-82)	70 (59-83)	70 (51-85)
Male (%)	50	60	71	62
Median ECOG PS ²	1	1	0.5	1
Median Prior Therapies (Min-Max)	4 (3-12)	5 (2-13)	5 (3-17)	5 (2-17)
Quad-refractory ³ or Greater (%)				23 (51.1)
Median Days Since Last Treatment (Range)	49 (28,485)	69 (22,1035)	54 (13,407)	52 (13,1035)
ISS Stage at Diagnosis [n (%)]				
Stage I	5 (50)	6 (30)	7 (41)	18 (38)
Stage II	4 (40)	4 (20)	5 (29)	13 (28)
Stage III	0	5 (25)	1 (6)	6 (13)
Unknown	1 (10)	5 (25)	4 (24)	10 (21)
Cytogenetics at Diagnosis				
High Risk [n (%)]	2 (20)	6 (30)	6 (35)	14 (30)
Unknown [n (%)]	0	3 (15)	3 (18)	6 (13)
Median Beta-2 Macroglobulin (Range)	2.62 (2.09,4.4)	3.9 (1.98,9.49)	2.65 (1.1,4.4)	2.83 (1.1, 9.49)

Patient Median Age ~70, Median of 5 Prior Therapies with 51% Quad Refractory or Greater and 30% Diagnosed as High Risk

1. Data as of 31Jan2020 2. Eastern Cooperative Oncology Group Performance Status 3. When patients are refractory to 4 therapeutic agents

CLR 131 r/r Multiple Myeloma

Well Tolerated Safety Profile

Treatment Emergent Adverse Events in Multiple Myeloma Patients¹ (>25%) (n=43)

Preferred Term	All Grades			Grade 3			≥ Grade 4		
	< 50mCi n=10 (%)	~50mCi n=20 (%)	~75mCi n=17 (%)	< 50mCi n=10 (%)	~50mCi n=20 (%)	~75mCi n=17 (%)	< 50mCi n=10 (%)	~50mCi n=20 (%)	~75mCi n=17 (%)
Thrombocytopenia	10 (100)	18 (90)	11 (65)	1 (10)	1 (5)	1 (6)	4 (40)	16 (80)	10 (59)
Lymphocyte Count Decreased	10 (100)	13 (65)	6 (35)	6 (60)	4 (20)	5 (29)	4 (40)	7 (35)	1 (6)
Decreased White Blood Cell Count	9 (90)	17 (85)	7 (41)	5 (50)	6 (30)	1 (6)	1 (10)	9 (45)	4 (24)
Anemia	6 (60)	16 (80)	8 (47)	3 (30)	11 (55)	4 (24)	0	0	0
Neutropenia	5 (50)	16 (80)	7 (41)	2 (20)	6 (30)	2 (12)	2 (20)	9 (45)	5 (29)
Fatigue	0	10 (50)	9 (53)	0	6 (30)	0	0	0	0
Nausea	3 (30)	7 (35)	0	0	0	0	0	0	0
Hypophosphatemia	4 (40)	7 (35)	0	1 (10)	4 (20)	0	0	0	0
Diarrhea	4 (40)	5 (25)	0	0	0	0	0	0	0
Hypoalbuminemia	3 (30)	6 (30)	0	0	0	0	0	0	0
Hyponatremia	0	6 (30)	0	0	1 (5)	0	0	0	0
Dyspnea	0	6 (30)	0	0	1 (5)	0	0	0	0

- Most frequent TEAEs² are cytopenias
- The cytopenias are very predictable and manageable
 - Nadir occurs ~34 days post initial dose; recovery occurs within ~21 days post nadir
- No deaths, cardiotoxicities, liver, renal or neurologic toxicities, keratopathy, etc.

1. Data as of 31Jan2020 2. Treatment Emergent Adverse Events

CLR 131 r/r Multiple Myeloma

Heavily Pretreated Patient Population - Prior Treatments

	Total Evaluable Patients n=43 ¹	
MM Prior Therapies - Median (Range)	5 (2,17)	
Prior Autologous SCT ² [n (%)]	29 (64%)	
	Exposed n (%)	Refractory n (%)
Bortezomib	42 (97.7)	24 (57.1)
Carfilzomib	17 (39.5)	13 (76.5)
Lenalidomide	43 (100)	26 (60.5)
Pomalidomide	25 (58.1)	21 (84)
Daratumumab	20 (46.5)	20 (100)
Refractory to Immediate Prior Therapy	38 (88.4%)	
Single Class Refractory	43 (100)	42 (97.7)
Dual Class Refractory	43 (100)	35 (81.4)
Triple Class Refractory ³	20 (46.5)	19 (95)

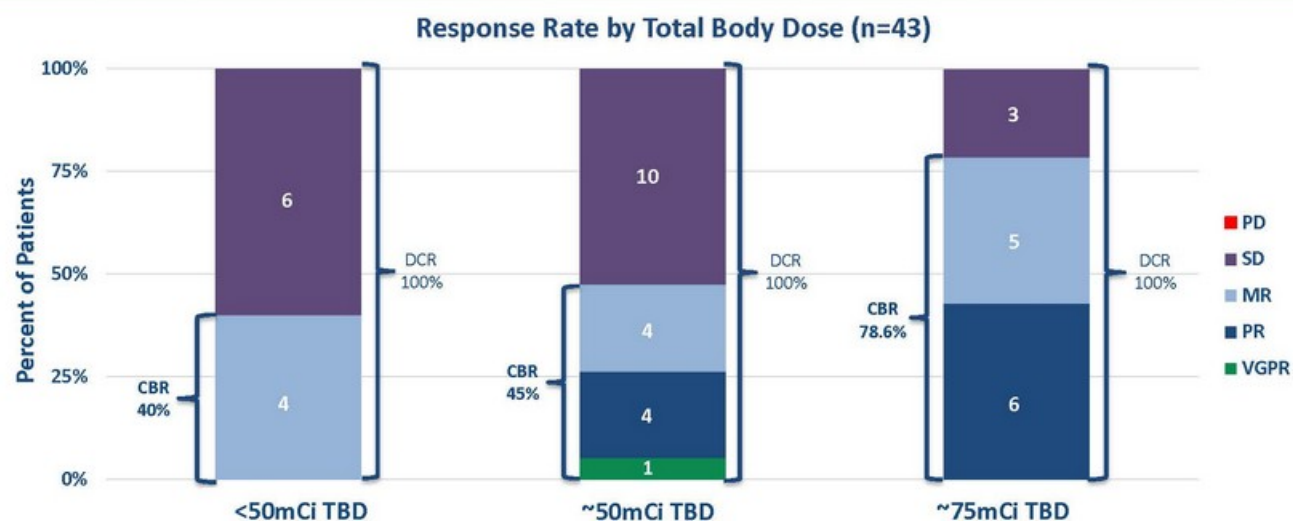
- Patients were most often refractory to lenalidomide, pomalidomide, bortezomib, daratumumab
- 23% of patients were previously treated in clinical trials (100% refractory to those treatments)

**95% of Patients Were Exposed & Refractory to 3 Classes
of Drugs, Representing 44% of All Patients Studied**

1. Data as of 31Jan2020 2. Stem Cell Transplant 3. When patients are refractory to proteasome inhibitor, immunomodulatory drug, and CD38 antibodies

CLR 131 r/r Multiple Myeloma

Achieves Efficacy Endpoint

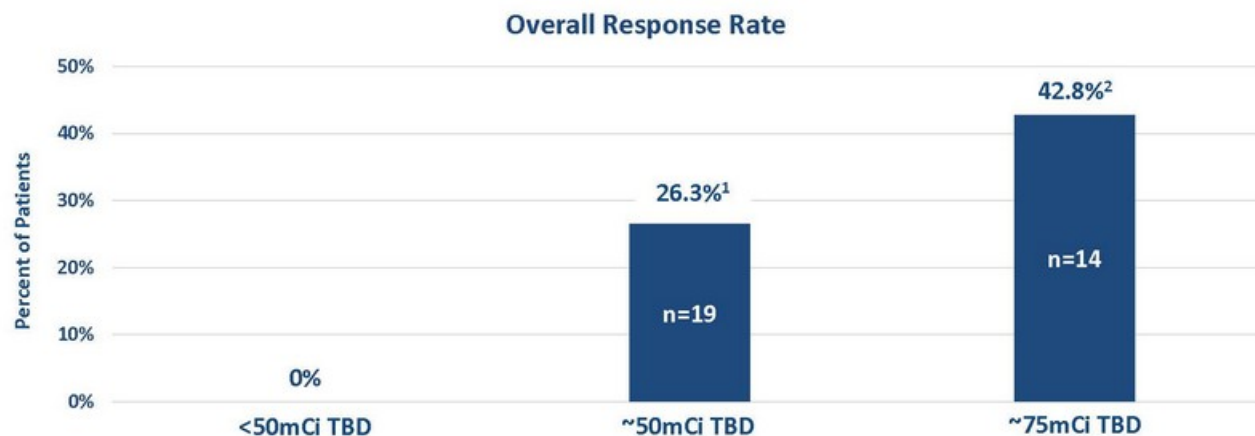


- 100% of patients achieved stable disease or better (Disease Control Rate)
- 85.7% of patients treated experienced tumor reduction at 75mCi Total Body Dose
- 76.7% of patients treated experienced tumor reduction across all Total Body Doses
- Progression Free Survival
 - <50mCi Total Body Dose - 3.6 months
 - ~50mCi and ~75mCi Total Body Dose - Assessment ongoing

1. (CBR) Clinical Benefit Rate measures reduction in tumor by FLC or M protein 2. (DCR) Disease Control Rate - Patients experiencing stable disease or better

CLR 131 r/r Multiple Myeloma

Meets & Exceeds ORR's Provided For All Prior Approvals



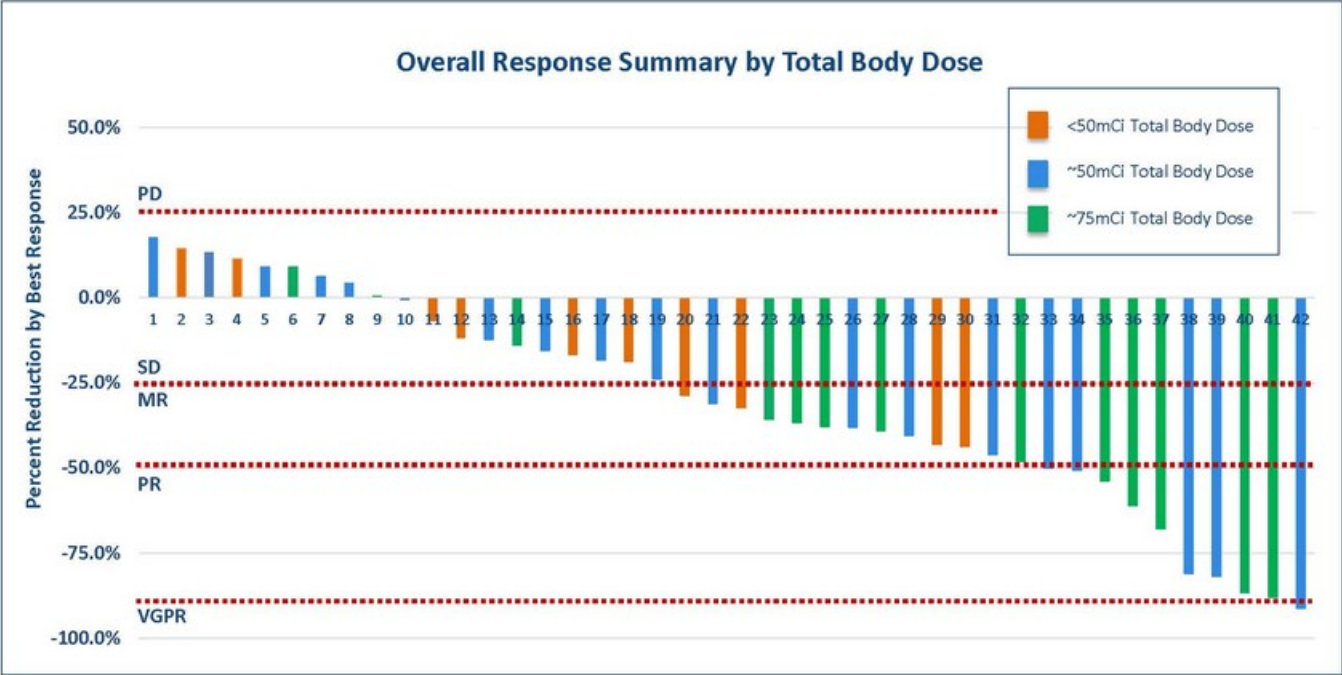
- Product profile at 50mCi and 75mCi TBD demonstrates efficacy
 - Median of 5 prior lines of therapy
 - Greater than 30% of patients are high risk
 - 95% of patients exposed to 3 classes of drugs were triple class refractory
 - Combined ORR for ~50mCi and ~75mCi TBD = 34.5% (95% CI: 24 – 45%)

~75mCi Total Body Dose Achieves 42.8% ORR

1. 95% Confidence Interval (13 – 40%) 2. 95% Confidence Interval (30 – 57%)

CLR 131 r/r Multiple Myeloma

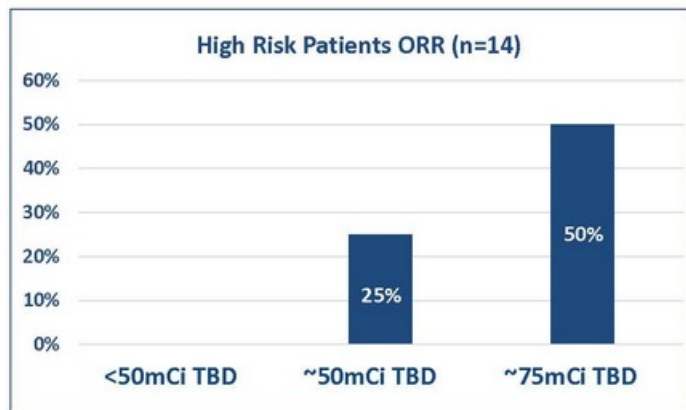
Fifth Line Median Treatment



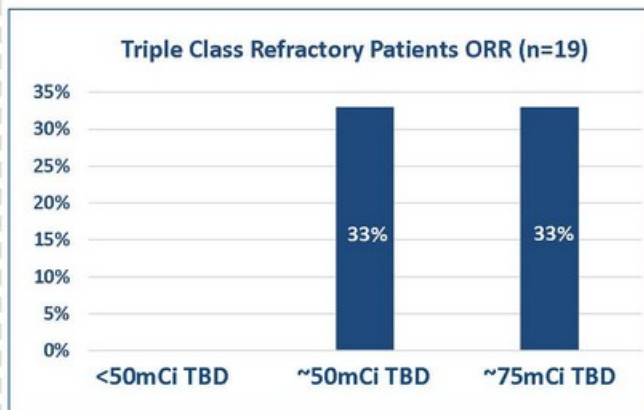
CLR 131 Demonstrates a Clear Dose Response in r/r MM

CLR 131 r/r Multiple Myeloma

Patient Subsets with High Unmet Need



- 30% of patients are high risk; similar to general MM population
- CLR 131 demonstrates dose response in high risk patients
 - 25% achieve PR or better ~50mCi TBD
 - 50% achieve PR or better ~75mCi TBD



- 44% of study patients triple class refractory
- CLR 131 achieves a 33% ORR at both 50mCi and 75mCi TBD

CLR 131 r/r Multiple Myeloma Data Update

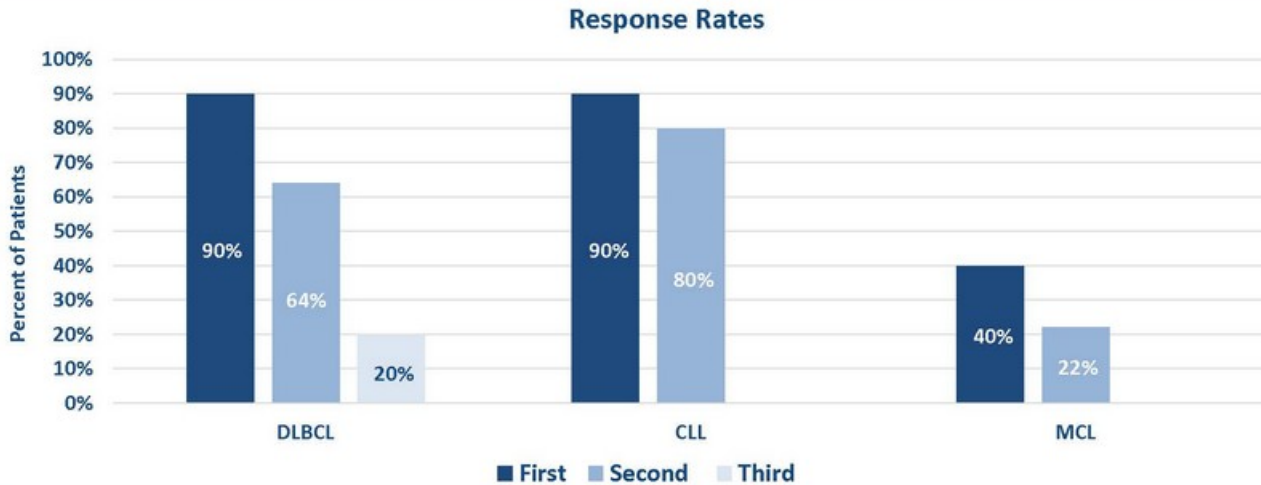
Conclusion

- Prevalence of MM is increasing in all key global markets
- High unmet medical need remains
 - Overall Response rates, durability of responses and safety/tolerability
 - 40% of eligible 3rd line plus patients decline further treatment
- CLR 131 tested in a heavily pretreated, high risk & frail patients
 - 95% of patients exposed to 3 classes of drugs were triple class refractory
 - 44% of patients studied were triple class refractory
- CLR 131 results impressive at either a 50mCi or 75mCi Total Body Dose
 - 26.3% ORR at ~50mCi Total Body Dose
 - 42.8% ORR at ~75mCi Total Body Dose
 - A safe and tolerable profile that is predictable and manageable
- CLR 131 dosing optimization may increase ORR, extend durability of response and maintain safety and tolerability profile

Presentation Topics

- 1 CLR 131 r/r Multiple Myeloma
- 2 CLR 131 r/r B-cell Non-Hodgkin's Lymphoma
- 3 CLR 131 Two Cycle Dosing Optimization
- 4 CLR 131 Clinical Development Next Steps
- 5 Conclusion

B-cell Lymphoma Epidemiology and Response Rates



- Estimated 2019 incidence: 74,200
- Median age at diagnosis: 67 years²
- Response rates and survival decrease significantly in second or third-line treatment
 - DLBCL survival in third line is $\leq 20\%$
 - MCL survival in second line is 50%

Poor Response Rates for 3rd Line DLBCL and 2nd Line MCL

CLR 131 r/r Non-Hodgkin's Lymphoma¹

Patient Characteristics²

	Total Body Dose ~50mCi (n=12)	Total Body Dose ~75mCi (n=7)	Total (n=19)
Median Age (Min-Max)	70 (52-79)	72 (65-86)	70 (52-86)
Male (%)	47.5	71	55
Median ECOG PS ³	1	1	1
Median Prior Therapies (Min-Max)	3 (1-9)	3 (2-5)	3 (1-9)
Median Days Since Last Treatment (Range)	250 (25,1212)	61 (17,2221)	135 (17,2221)
Refractory to at Least 1 Prior Treatment (%)			14 (73.7)

- Median age: 70 years
- Median prior lines of systemic therapy = 3
- Average bone marrow involvement 23% (Range 1-60%)

~74% of Patients Refractory to at Least 1 Prior Treatment

1. Non Hodgkin's Lymphoma patients include: Chronic Lymphocytic Leukemia (CLL); Lymphoplasmacytic Lymphoma (LPL)/Waldenstrom's Macroglobulinemia (WM); Marginal Zone Lymphoma (MZL); Mantle Cell Lymphoma (MCL); Diffuse Large B-cell Lymphoma (DLBCL) 2. Data as of 31Jan2020 3. Eastern Cooperative Oncology Group Performance Status

CLR 131 in r/r NHL

Well Tolerated Safety Profile

Treatment Emergent Adverse Events All Lymphoma¹ Patients² (n=19)

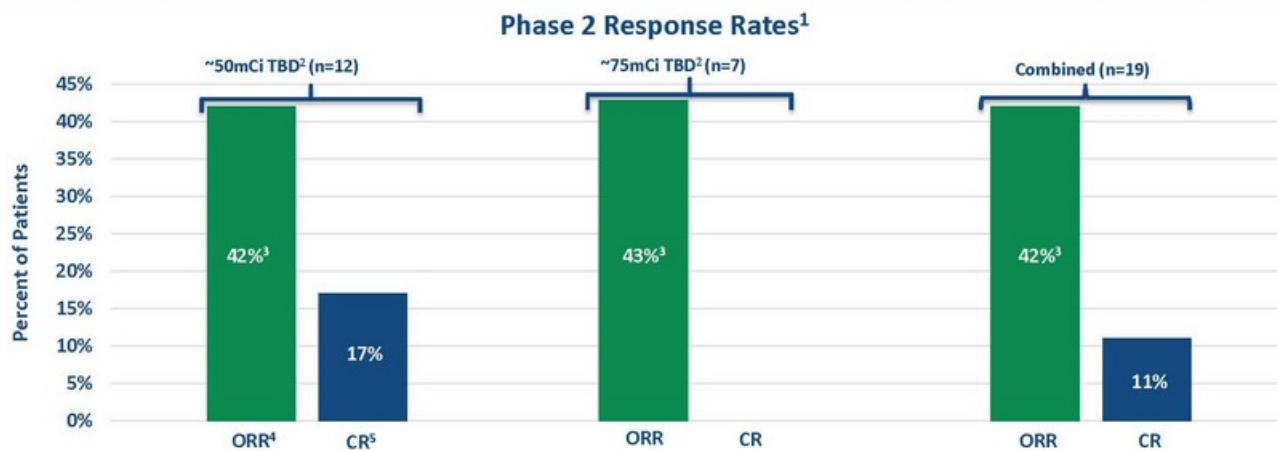
Preferred Term	All Grades		Grade 3		≥ Grade 4	
	~50mCi n=12 (%)	~75mCi n=7 (%)	~50mCi n=12 (%)	~75mCi n=7 (%)	~50mCi n=12 (%)	~75mCi n=7 (%)
Thrombocytopenia	10 (83)	6 (86)	2 (17)	2 (29)	6 (50)	4 (57)
Lymphocyte Count Decreased	3 (25)	0	2 (17)	0	0	0
Decreased White Blood Cell Count	7 (58)	3 (43)	3 (25)	2 (29)	1 (8)	1 (14)
Anemia	7 (58)	4 (57)	4 (33)	2 (29)	0	0
Neutropenia	6 (50)	6 (86)	2 (17)	2 (29)	3 (25)	3 (43)
Fatigue	9 (75)	3 (43)	4 (33)	1 (14)	0	0
Nausea	3 (25)	2 (29)	0	0	0	0
Decreased Appetite	5 (42)	3 (43)	0	0	0	0
Anxiety	3 (25)	0	0	0	0	0
Weight Decreased	3 (25)	2 (29)	0	0	0	0
Dyspnea	3 (25)	0	2 (17)	0	0	0

- Predominate TEAEs are cytopenias which are less frequent in patients without bone marrow involvement
- No cardiotoxicities, liver or renal toxicities, neurologic toxicities, keratopathy, allergic reactions, etc.

1. Lymphoma patients include: Chronic Lymphocytic Leukemia (CLL); Lymphoplasmacytic Lymphoma (LPL); Marginal Zone Lymphoma (MZL); Mantle Cell Lymphoma (MCL); Diffuse Large B-cell Lymphoma (DLBCL) 2. Data as of 31Jan2020

CLR 131 r/r NHL

Efficacy in Heavily Pretreated Patients



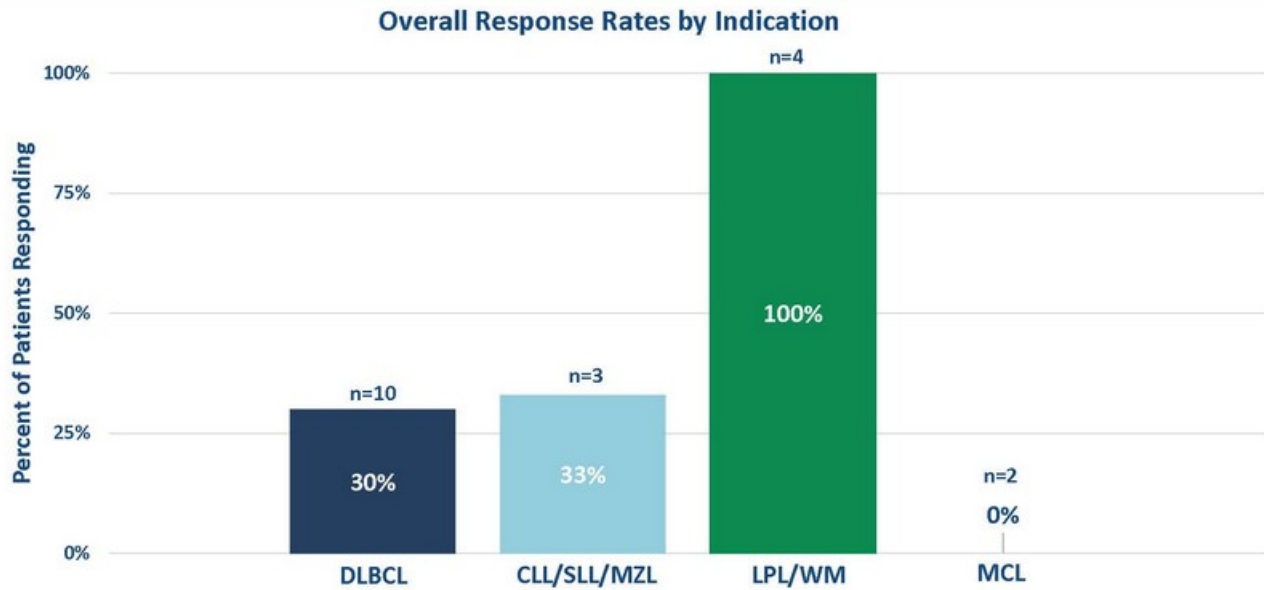
- Diverse, advanced and heavily pretreated patient population
 - Multiple r/r B-cell lymphoma histologies: DLBCL, transformed DLBCL, CLL/SLL, MZL, MCL, LPL/WM
 - Median 3 prior lines of systemic therapy
 - ~47% of patients were refractory to prior therapy
 - ~53% of patients were refractory to rituximab
- Differentiated safety profile

Both ~50mCi & ~75mCi Doses Demonstrate Efficacy in r/r non-Hodgkin's Lymphoma

1. To date 2. Total Body Dose 3. 95% confidence interval (10 – 60%), (19 – 62%), (29 – 55%) respectively. 4. (Overall Response Rate 5. Complete Response

CLR 131 r/r NHL

Efficacy by Sub-indications

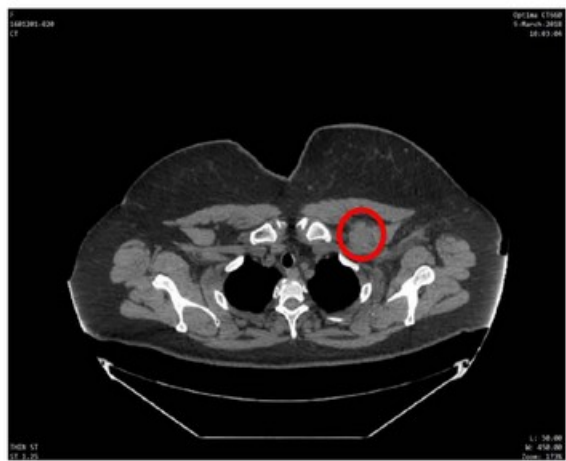


- Activity demonstrated in both aggressive and indolent NHL disease
- 75% of LPL/WM patients were refractory to rituximab or ibrutinib
- 70% of DLBCL patients were refractory; 60% to rituximab
- 100% of CLL/SLL/MZL patients were refractory to at least one drug; 100% to rituximab
- 50% of MCL patients were refractory to at least one drug

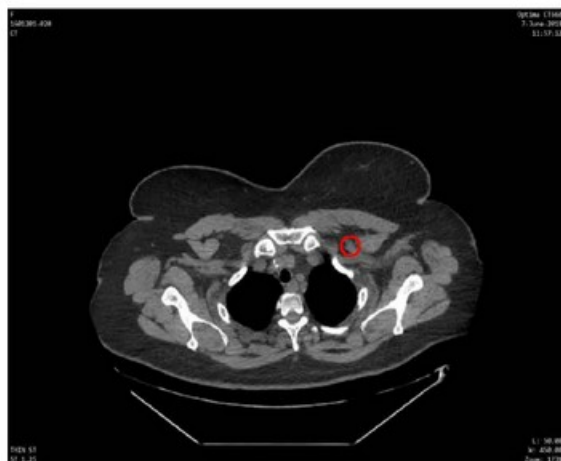
CLR 131 r/r DLBCL

Patient Case Study - Complete Response

- Female, 52 years old with subpectoral lymph node mass
 - Germinal cell DLBCL
 - Single hit: MYC positive; BCL-2 negative
- 3 prior lines of treatment - R-CHOP, RICE and chemotherapeutic combination
- Relapse within 10 months of 1st line treatment, refractory to 2nd and 3rd line TRX
- Patient continues to be a complete responder; 570+ days post treatment



Scan Day 1

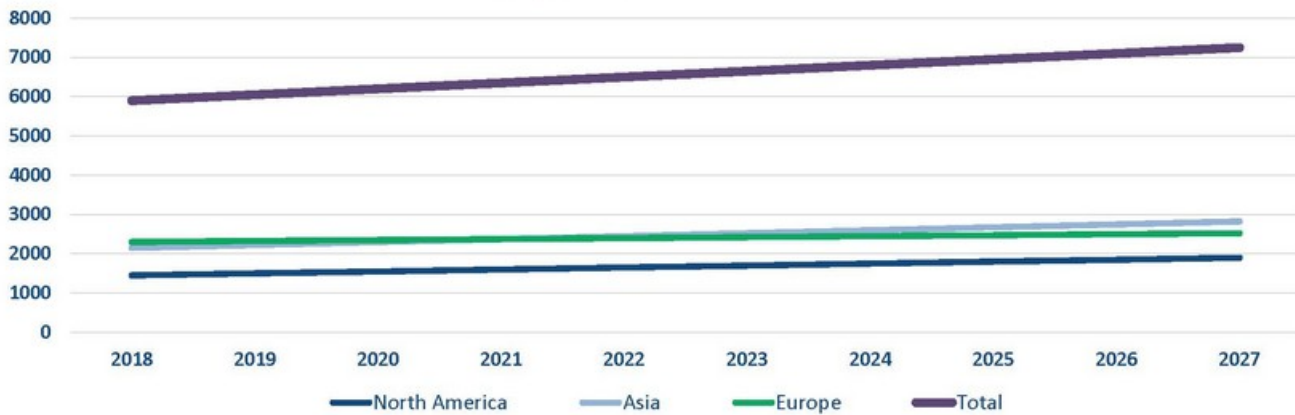


Scan Day 90

LPL/WM Epidemiology

U.S., Top 5 EU and Asia Prevalence

LPL/WM Annual Incidence

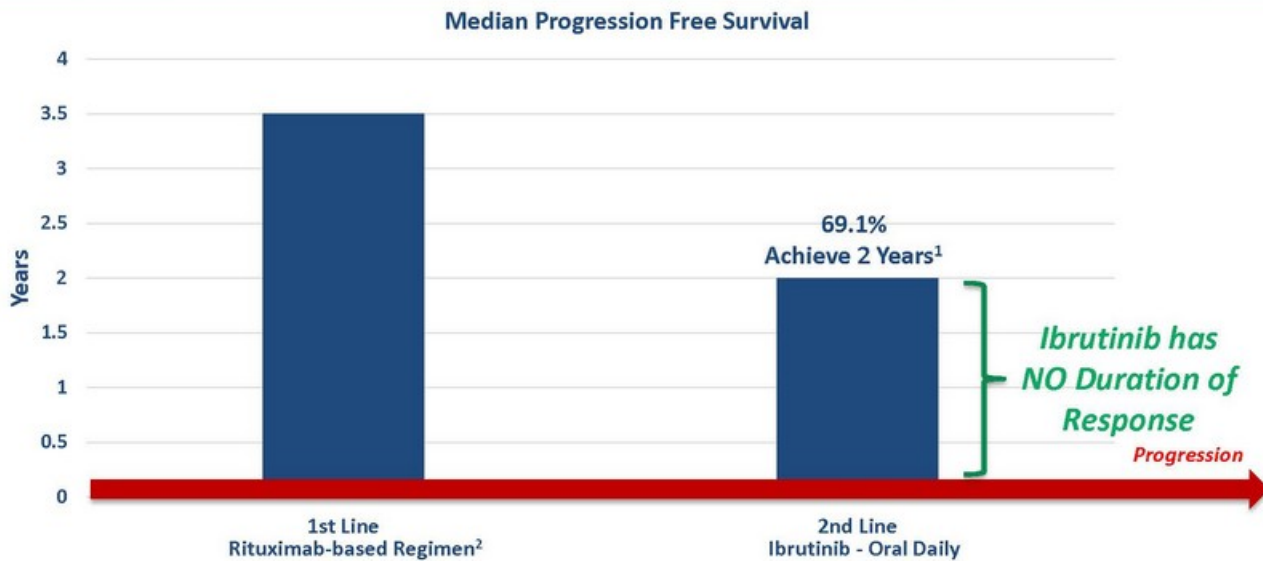


- LPL/WM is an ultra-orphan disease
- 2018 incidence ~5,900 worldwide¹
- Annual growth rate projected @ 2.29%
- Prevalence forecast to 7,250 by 2027
- Global r/r population estimated to be ~5,250

1. Datamonitor Healthcare; Centers for Disease Control and Prevention, 2017; Ferlay et al., 2018; National Cancer Institute, 2017; Steingrímsson et al., 2017; United Nations, 2017 2. Leukemia & Lymphoma Society (2018). Waldenström Macroglobulinemia Factsheet. https://www.lls.org/sites/default/files/file_assets/waldenströmmacroglobulinemia.pdf

LPL/WM Market

Significant Unmet Treatment Need Remains



- Similar to Multiple Myeloma, LPL/WM is an incurable disease
- There are limited early-line and no late-line treatment options for these patients
- Significant adverse events occur with long term use of ibrutinib - discontinuation rate ~30%³

Early CLR 131 ORR, DOR and Safety Data Exceed Current SOC⁴

¹ Treon, Steven P., et al. "Ibrutinib in Previously Treated Waldenström's Macroglobulinemia." *New England Journal of Medicine*, vol. 372, no. 15, 2015, pp. 1430-1440, doi:10.1056/nejmoa1501548. ² Dimopoulos, M. A., Gardia-Sanz, R., Gavriliadou, M., Morel, P., Kyttonis, M.-C., Michalis, E., ... *Survivance*, P. (2013). Primary therapy of Waldenström macroglobulinemia (WM) with weekly bortezomib, low-dose dexamethasone, and rituximab (BDR): long-term results of a phase 2 study of the European Myeloma Network (ENM). *Blood*, 122(19), 3276-3282. doi:10.1182/blood-2013-05-509862. ³ Naranjo, R. (2020, January 8). Zanolitinib Faces Off Against Ibrutinib in CLL Trial. Retrieved January 30, 2020, from <https://www.oncive.com/publications/Oncology-live/2020/vol-21-no-1/zanolitinib-faces-off-against-ibrutinib-in-cll-trial>. ⁴ Second-line Standard of Care

LPL/WM Competitive Landscape

2nd Line or Later Monotherapy - 1 Approved Product

	Overall Response Rate (ORR)	Complete Response Rate
Ibrutinib ¹ (n=63)	90.5%	0%
Zanubrutinib ²	80.8%	0%
Acalabrutinib ³	93%	0%
Venetoclax (n=30)	86%	0%

- Rituximab combinations are first line treatments
- Ibrutinib is the only drug approved for second line treatment
 - Oral medication taken daily until progression
- No approved or in-development monotherapy has achieved a complete response

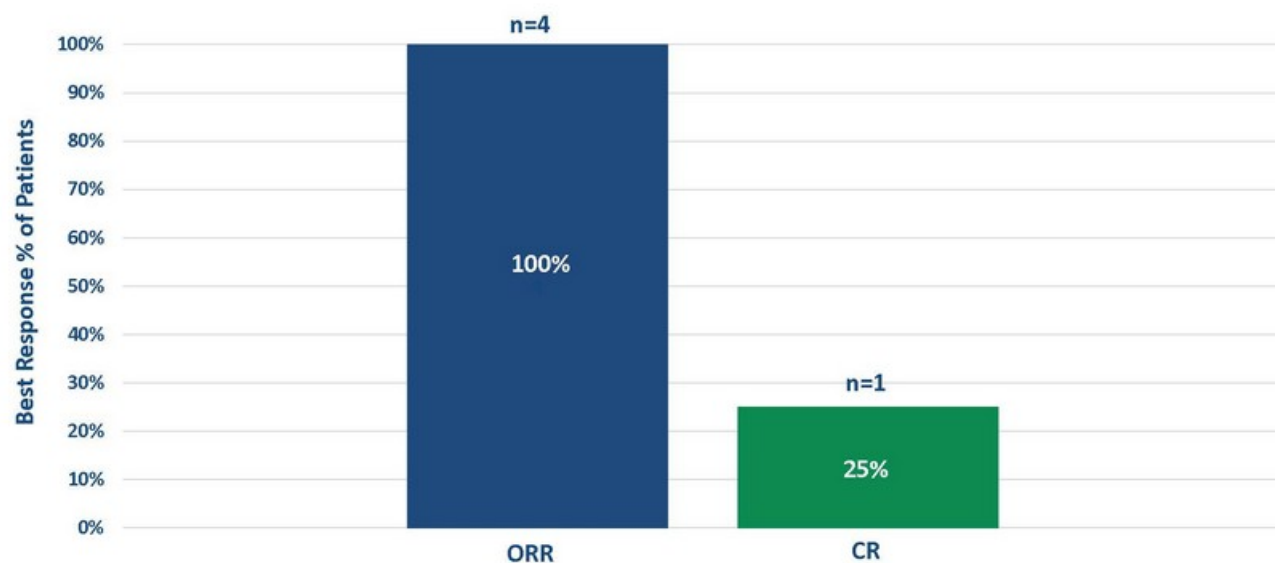
1. Treon, Steven P., et al. "Ibrutinib in Previously Treated Waldenström's Macroglobulinemia." *New England Journal of Medicine*, vol. 372, no. 15, 2015, pp. 1430–1440., doi:10.1056/nejmoa1501548

2. BioSpace. (2019, December 16). BeiGene Announces Results of Phase 3 ASPEN Trial of Zanubrutinib Compared to Ibrutinib for the Treatment of Patients with Waldenström's Macroglobulinemia. Retrieved from <https://www.biospace.com/article/releases/beigene-announces-results-of-phase-3-aspen-trial-of-zanubrutinib-compared-to-ibrutinib-for-the-treatment-of-patients-with-waldenström-s-macroglobulinemia/>

3. Owen, R. G., McCarthy, H., Rule, S., Dsa, S., Thomas, S. K., Tournilhac, O., Furman, R. R. (2020). Acalabrutinib monotherapy in patients with Waldenström macroglobulinemia: a single-arm, multicentre, phase 2 study. *The Lancet Haematology*, 7(2). doi: 10.1016/s2352-3026(19)30210-8

CLR 131 r/r LPL/WM

Response Rates



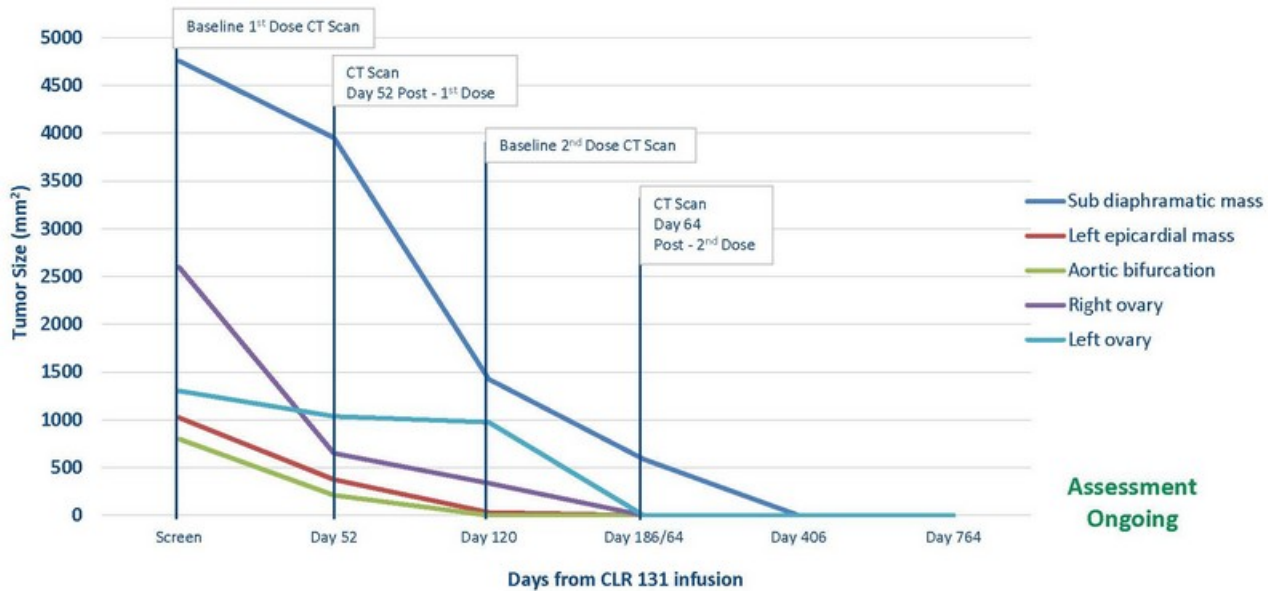
- CLR 131 demonstrates highly encouraging efficacy
 - 100% Overall Response Rate; 25% Complete Response Rate
- All patients were relapsed or intolerant to ibrutinib and rituximab combinations

CLR 131 Only Reported Monotherapy Achieving a Complete Response

CLR 131 r/r LPL/WM

Patient Case Study - Complete Response

- Baseline pleural effusion & multiple large tumor nodules; third line treatment
 - Patient was refractory to all previous treatments
- Day 187 CT: 100% overall tumor burden reduction & complete resolution of 5/5 tumors
- Day 406 CT: Confirmed Complete Response ongoing as of day 764 (DOR >25 months)



CLR 131 r/r NHL Data Update

Conclusion

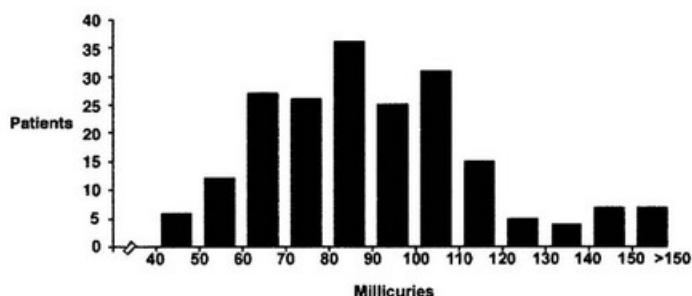
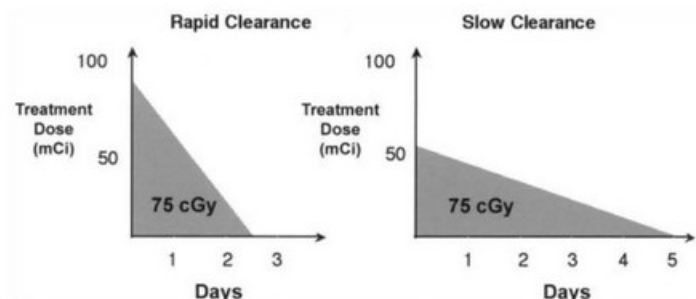
- CLR 131 tested in heavily pretreated and extremely challenging patients
 - Median 3 prior lines of systemic therapy
 - ~47% of patients were refractory to prior therapy
 - ~53% of patients were refractory to rituximab
- Both the ~50mCi and ~75mCi doses demonstrate efficacy in r/r NHL
 - ~50mCi achieved a 42% ORR in 12 patients
 - ~75mCi achieved a 43% ORR in 7 patients
 - Durable, Complete Response(s) achieved in 2 distinct indications
- High unmet medical need in r/r sub-indications such as LPL/WM
 - No approved or in-development monotherapy has achieved a CR
 - Ibrutinib is the only drug approved for second line treatment
- CLR 131 dosing optimization may increase ORR, extend durability of response and maintain safety and tolerability profile

Presentation Topics

- 1 CLR 131 r/r Multiple Myeloma
- 2 CLR 131 r/r B-cell Non-Hodgkin's Lymphoma
- 3 CLR 131 Two Cycle Dosing Optimization
- 4 CLR 131 Clinical Development Next Steps
- 5 Conclusion

CLR 131 Two Cycle Dosing Optimization

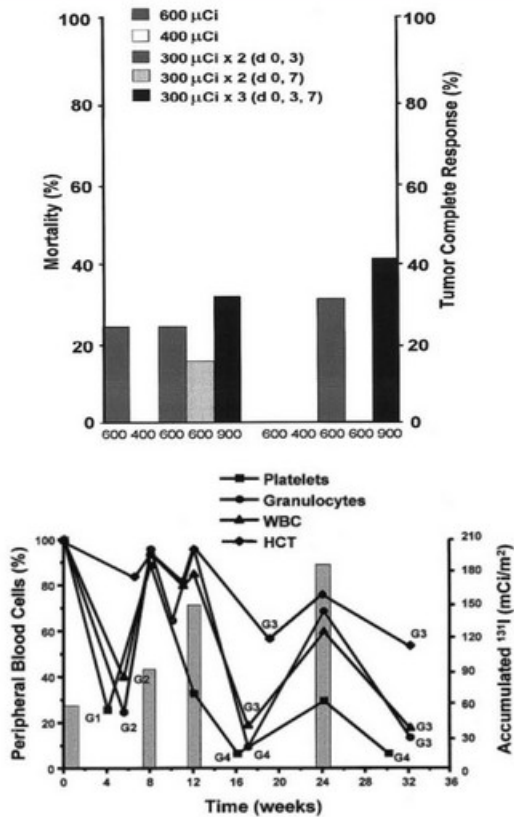
Analysis of Bexxar and DeNardo Data



- To achieve optimal efficacy with iodine-131 (Bexxar), 75cGy identified as target absorbed dose
- To attain the absorbed dose of 75cGy, patients with rapid clearance require higher doses to achieve necessary AUC¹
- To achieve 75cGy absorbed dose, the majority of patients require 90mCi or greater
 - 70% response rate when 75cGy achieved

CLR 131 Two Cycle Dosing Optimization

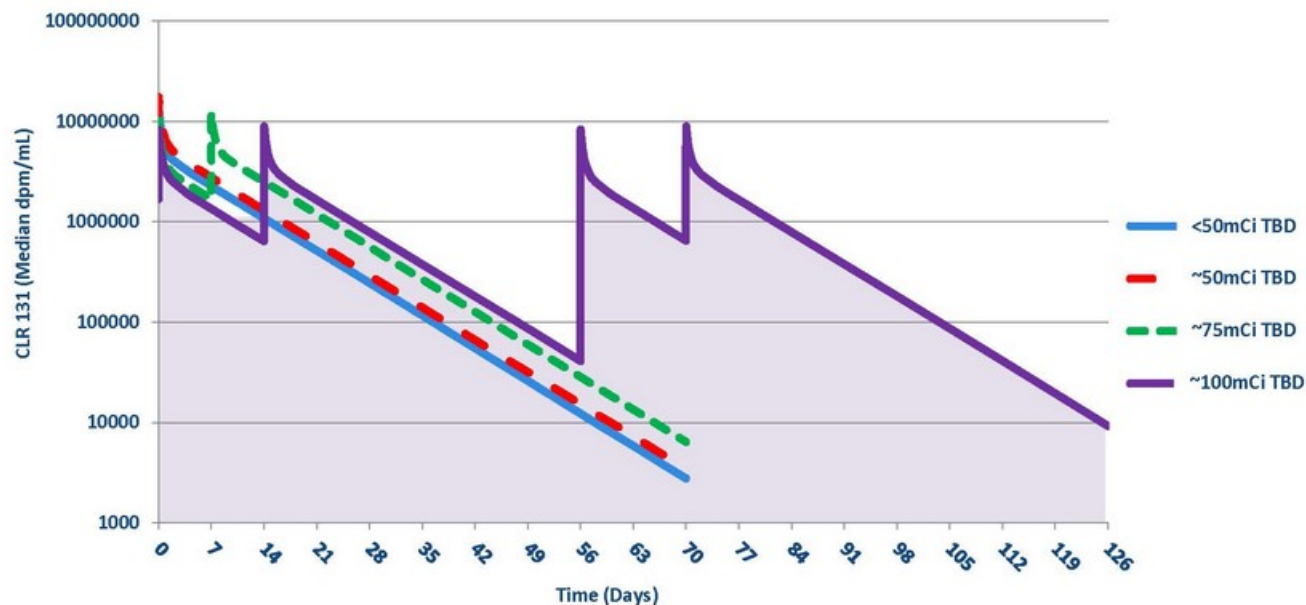
Analysis of Bexxar and DeNardo Data Cont.



- Animal studies demonstrated fractionation allowed for a higher rate of complete tumor response
 - Corroborated by CLR 131 data
- In NHL patients, fractionation also demonstrated an ability to increase the TBD and efficacy without increasing the toxicity
 - Tumor absorbed dose was increased
 - Bone marrow absorbed dose was decreased
- It was determined
 - 2nd fraction administered ~2 weeks post-dose 1
 - 3rd & 4th fraction administered within 8-12 weeks
- This dosing strategy allowed for treatment of patients with significant bone marrow involvement

CLR 131 Two Cycle Dosing Optimization

Pharmacokinetics - ~200% Increase of Area Under the Curve

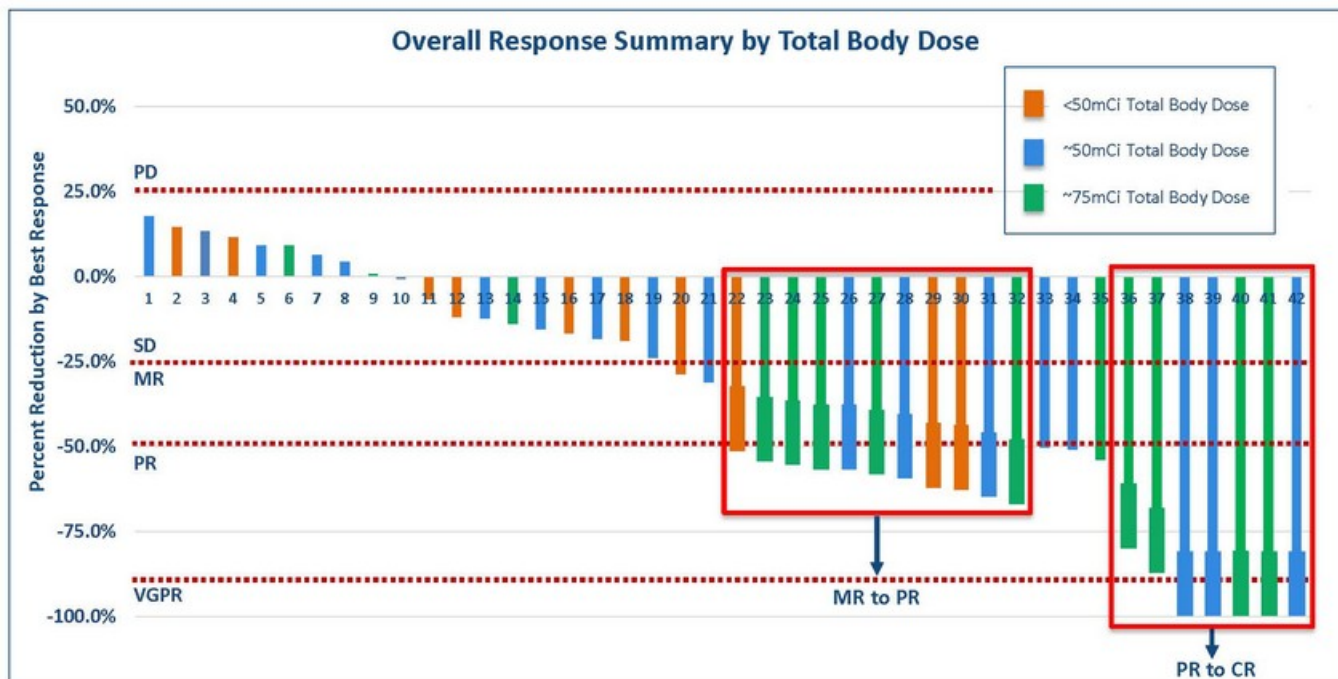


- Increased plasma exposure demonstrates increased tumor uptake and responses¹
- Fractions separated by 14 days increases the plasma exposure of first cycle

Second Cycle More Than Doubles Plasma Exposure, Further Increasing Tumor Uptake

CLR 131 r/r Multiple Myeloma

Fifth Line Median Treatment



Patients Receiving a Second Cycle Achieved an Average Additional Reduction of 18% in Efficacy Marker; Opportunity for an Increased Overall Response

CLR 131 r/r Multiple Myeloma

Dosing Optimization with Two Cycles¹

	~50mCi Total Body Dose	~75mCi Total Body Dose	Two Cycle Fractionated
Overall Response Rate	26.5%	Ongoing: 42.8%	Ongoing
Minimal Response Rate	21.1%	Ongoing: 35.7%	Ongoing
Progression Free Survival	Ongoing	Ongoing	Ongoing: >10 months
Duration of Response	Ongoing	Ongoing	Ongoing: >291 days

- Two cycle fractionated treatment further increases total body dose which may:
 - Improve response rates, the depth and durability of response and PFS
 - Maintain safety and tolerability profile
- Patients that progress remain responsive to a second cycle

***Two Cycle Fractionated Dosing Optimization Could Result
in Outcomes Similar to or Better than CAR-Ts & BCMA***

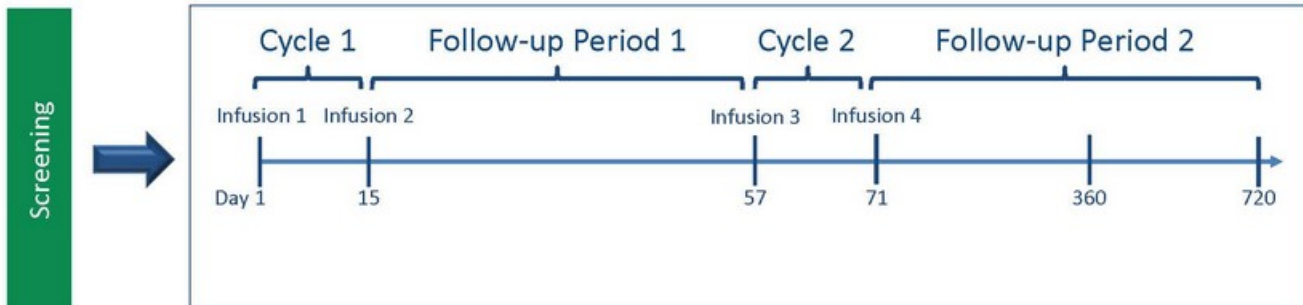
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CLR 131 r/r Hematologic Malignancies

Phase 2 Study Extension

Two Cycle Dosing Optimization



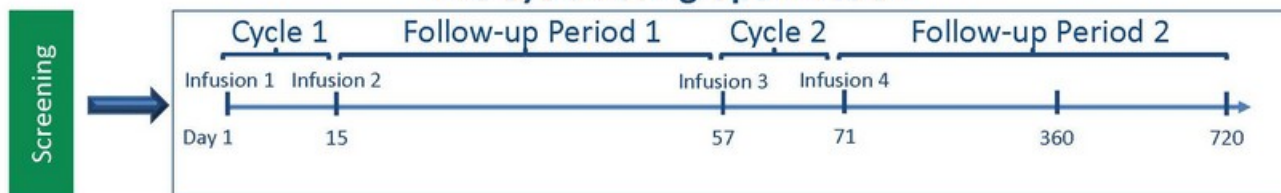
- Protocol extension approved by FDA and investigator sites
- Target enrollment of ~10 additional two cycle patients
- Anticipate 3Q20 two cycle study update

Pivotal Study Initiation Remains on Target for 4Q20

CLR 131 Pivotal Study Designs

Traditional Study Designs

Two Cycle Dosing Optimization



Relapsed/Refractory Multiple Myeloma

Proposed Pivotal Study Design

- Granted U.S. ODD¹, Fast Track and EU ODD
- Relapsed/refractory 5th line Multiple Myeloma
- **Pivotal, single-arm (n=75-100)**
 - Primary endpoint: Overall Response Rate (ORR)

Program Timing²

- Pursuing traditional & innovative regulatory strategies
- Pivotal study initiation/start-up activities 4Q20
- **Estimate 4 years to complete**

Clinical Costs²

- **Pivotal study = \$30 million**
- Eligible for pivotal study SBIR Grant up to \$4M³

Relapsed/Refractory LPL/WM

Proposed Pivotal Study Design

- Granted U.S. ODD for LPL/WM
- Relapsed/refractory $\geq 2^{\text{nd}}$ line LPL/WM
- **Pivotal, single-arm (n=30-60)**
 - Primary endpoint: Overall Response Rate (ORR)

Program Timing²

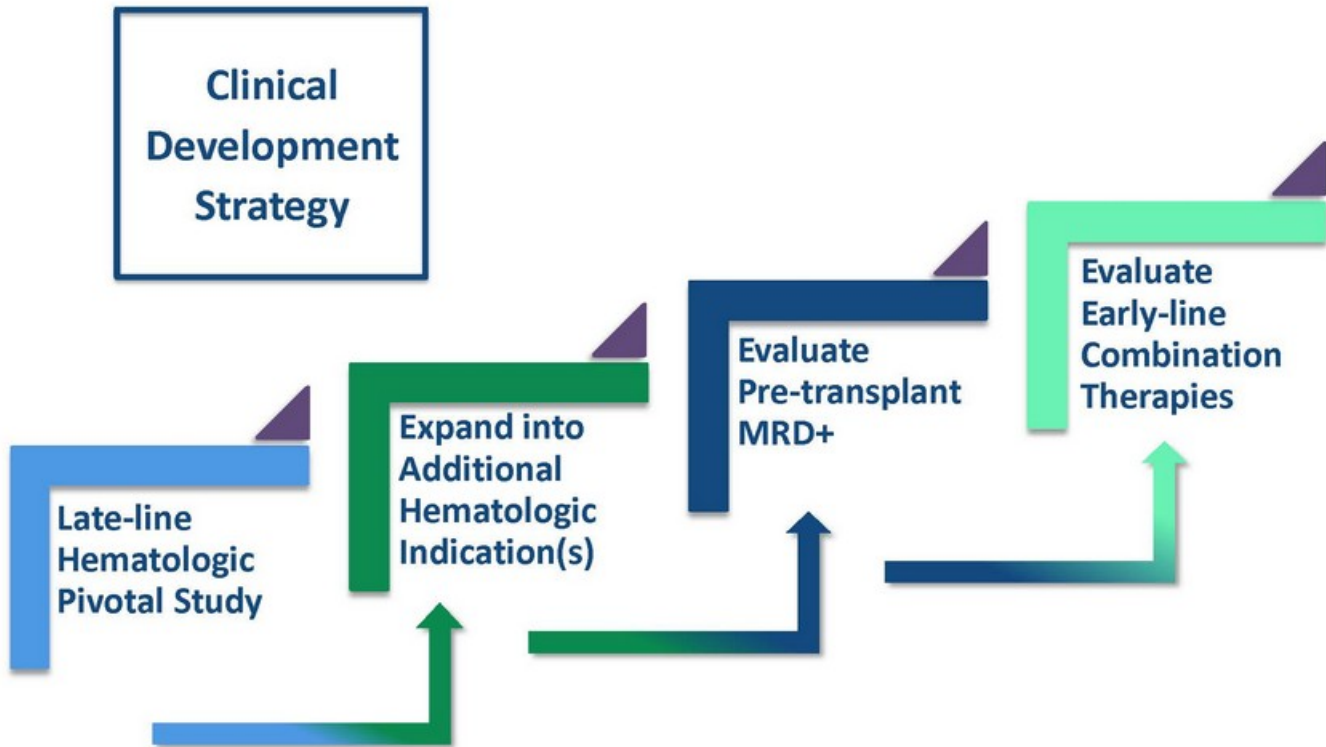
- Pursuing traditional & innovative regulatory strategies
- Pivotal study initiation/start-up activities 4Q20
- **Estimate 3 years to complete**

Clinical Costs²

- **Pivotal study = \$20 million**
- Eligible for pivotal study SBIR Grant up to \$4M³

CLR 131 Adult Hematology

Additional Market Opportunities



CLR 131 r/r Multiple Myeloma and NHL Data Update

Conclusion

- Prevalence of MM and NHL increasing in all key global markets
- High unmet medical need remains in r/r MM and NHL
- CLR 131 r/r MM and NHL efficacy impressive and consistent in heavily pretreated patients at either a ~50mCi or ~75mCi Total Body Dose
 - MM: 26.3% ORR at ~50mCi and 42.8% ORR at ~75mCi
 - NHL: 42% ORR at ~50mCi and 43% ORR at ~75mCi
 - LPL/WM: 100% ORR
- CLR 131 profile is safe and tolerable, predictable and manageable
- CLR 131 two cycle dosing optimization may increase ORR, extend durability of response and maintain safety and tolerability profile
- Near-term Pivotal Study considerations include r/r MM & LPL/WM
- Future CLR 131 adult hematology development considerations include additional indications, pre-transplant MRD+ and combination therapies

Initiation of Selected Indication for Pivotal Study Remains on Target for 4Q20