UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): June 4, 2018 (June 1, 2018)

bluebird bio, Inc.
(Exact name of Registrant as Specified in Its Charter)

DELAWARE	001-35966	13-3680878
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
60 Binney Street, Cambridge, MA (Address of Principal Executive Offices)		02142 (Zip Code)

Registrant's Telephone Number, Including Area Code: (339) 499-9300

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 Instructions 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 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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, 2018, bluebird bio, Inc. ("bluebird") will be conducting an investor webcast summarizing updated data from the CRB-401 clinical study of the bb2121 product candidate in patients with relapsed/ refractory multiple myeloma. A copy of the presentation is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 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 (the "Exchange Act") 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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 **Other Events.**

On June 1, 2018, bluebird issued a press release announcing updated data from the CRB-401 clinical study of the bb2121 product candidate in patients with relapsed/ refractory multiple myeloma. The full text of bluebird's press release regarding the announcement is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	**Description**
99.1	Investor presentation provided by bluebird bio, Inc. on June 1, 2018.
99.2	Press release issued by bluebird bio, Inc. on June 1, 2018.

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.

Date: June 1, 2018

bluebird bio, Inc.

By:/s/ Jason F. Cole
Jason F. Cole
Chief Legal Officer

Exhibit 99.1

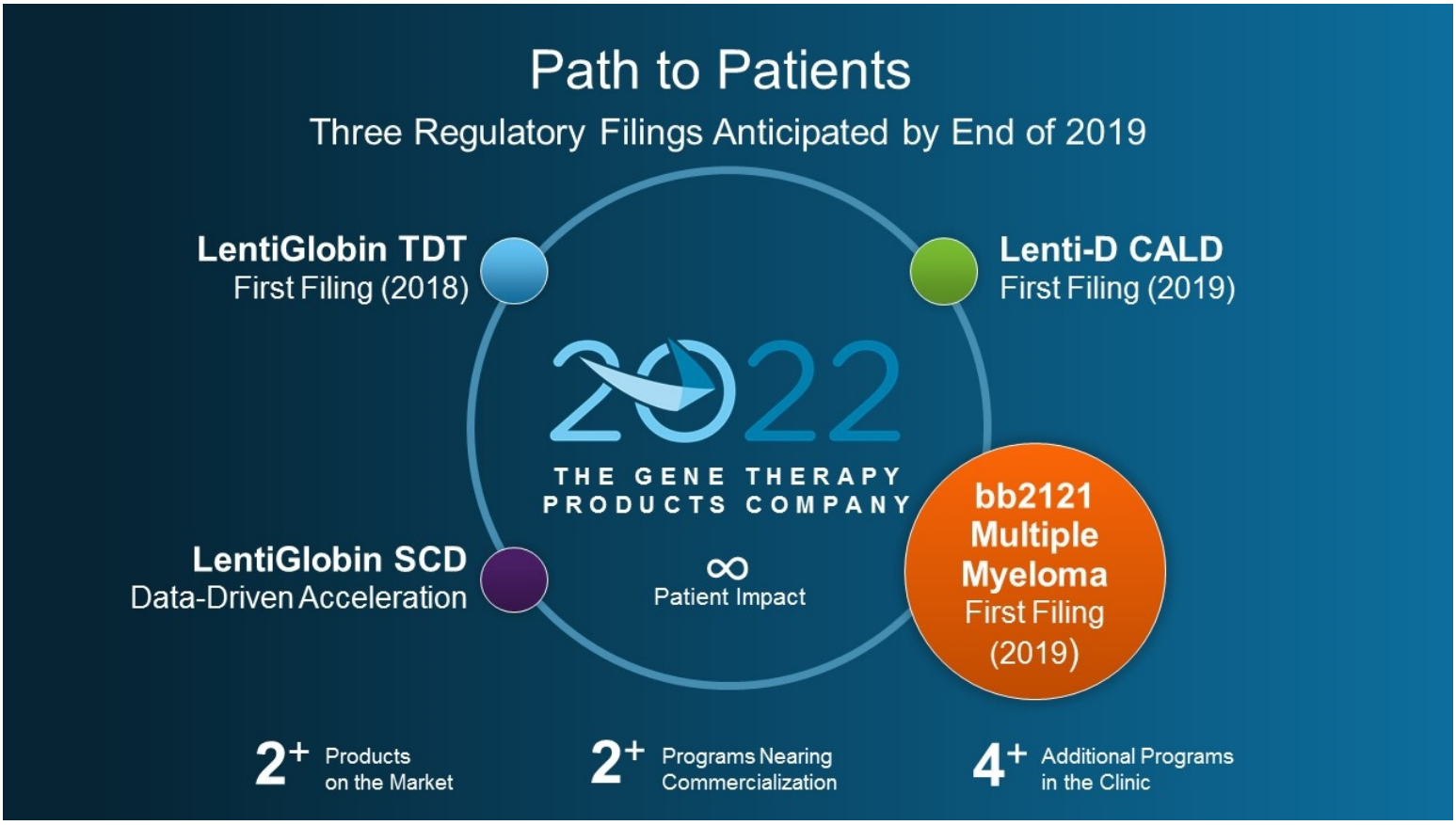

ASCO Analyst & Investor Webcast
June 1, 2018
bluebirdbio
June 1, 2018
NASDAQ: BLUE

Forward Looking Statements

These slides and the accompanying oral presentation contain forward-looking statements and information relating to bluebird bio, its product candidate bb2121 and oncology research and development plans. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. For example, all statements we make regarding the initiation, timing, progress and results of our preclinical and clinical studies and our research and development programs, our ability to advance product candidates into, and successfully complete, clinical studies, and the timing or likelihood of regulatory filings and approvals are forward looking. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. These statements are also subject to a number of material risks and uncertainties that are described in our most recent quarterly report on Form 10-Q, as well as our subsequent filings with the Securities and Exchange Commission. Any forward-looking statement 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.


Welcome
Nick Leschly, chief bluebird
bluebirdbio


trueblue
Making Hope
A Reality
bluemojo


Path to Patients
Three Regulatory Filings Anticipated by End of 2019
LentiGlobin TDT
First Filing (2018)
Lenti-D CALD
First Filing (2019)
2022
THE GENE THERAPY PRODUCTS COMPANY
LentiGlobin SCD
Data-Driven Acceleration
∞
Patient Impact
bb2121
Multiple
Myeloma
First Filing
(2019)
2+ Products on the Market
2+ Programs Nearing Commercialization
4+ Additional Programs in the Clinic

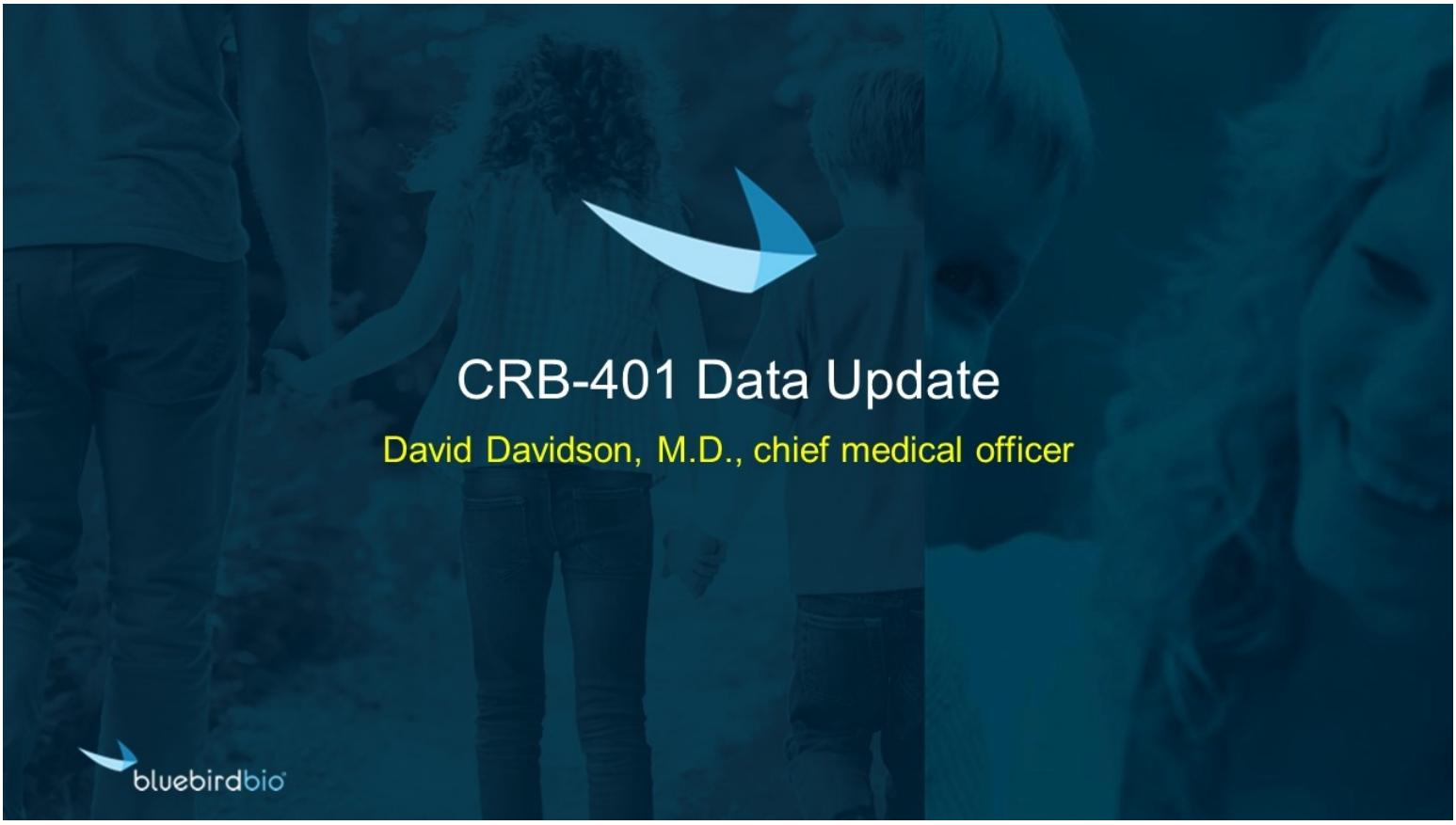
Key Questions for Today

What more have we learned about efficacy and durability of bb2121 in this heavily pretreated patient population?

What are the new learnings? BCMA expression? Dose response?

Is the safety profile still manageable?

Is the path to earlier lines progressing?


CRB-401 Data Update
David Davidson, M.D., chief medical officer
bluebirdbio

Baseline Demographics and Clinical Characteristics

Parameter	Escalation (N=21)	Expansion (N=22)
Median (min, max) follow-up, d	345 (46, 638)	87 (29, 184)
Median (min, max) age, y	58 (37, 74)	65 (44, 75)
Male, n (%)	13 (62)	16 (73)
Median (min, max) time since diagnosis, y	4 (1, 16)	6 (1, 36)
ECOG PS,[1] n (%)		
0	10 (48)	6 (27)
1	11 (52)	16 (72)
High-risk cytogenetics, n (%)		
del(17p), t(4;14), t(14;16)	8 (38)	9 (41)

ECOG, Eastern Cooperative Oncology Groups performance status; ISS, international staging system; NA, not available. [1]Data at screening presented.

Heavily Pretreated Patient Population

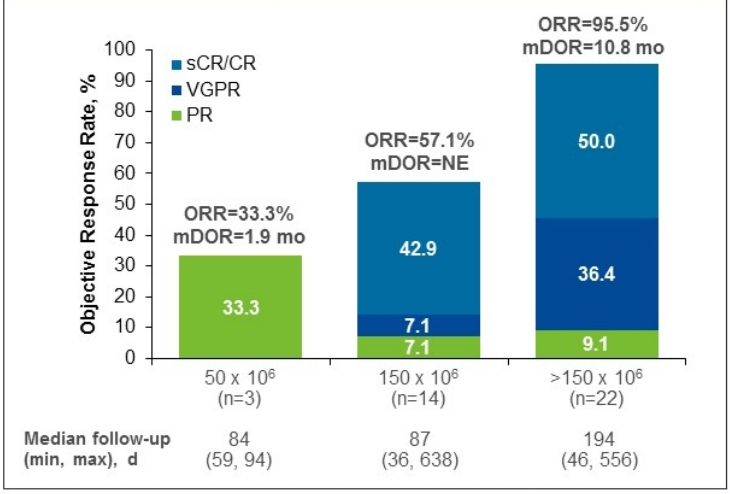
Parameter	Escalation (N=21)	Expansion (N=22)
Median (min, max) prior regimens	7 (3, 14)	8 (3, 23)
Prior autologous SCT, n (%)	21 (100)	19 (86)
0	0	3 (14)
1	15 (71)	14 (64)
>1	6 (29)	5 (23)

	Escalation (N=21)		Expansion (N=22)	
Parameter	**Exposed**	**Refractory**	**Exposed**	**Refractory**
Prior therapies, n (%)				
Bortezomib	21 (100)	14 (67)	22 (100)	16 (73)
Carfilzomib	19 (91)	12 (57)	21 (96)	14 (64)
Lenalidomide	21 (100)	19 (91)	22 (100)	18 (82)
Pomalidomide	19 (91)	15 (71)	22 (100)	21 (96)
Daratumumab	15 (71)	10 (48)	22 (100)	19 (86)
Cumulative exposure, n (%)				
Bort/Len	21 (100)	14 (67)	22 (100)	14 (64)
Bort/Len/Car/Pom/Dara	15 (71)	6 (29)	21 (96)	7 (32)

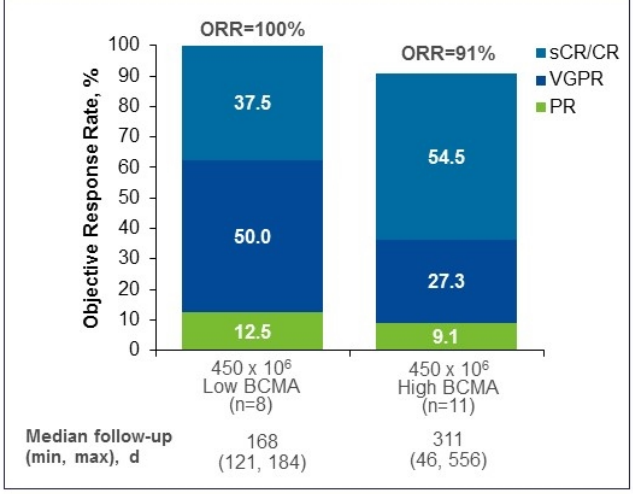
SCT, stem cell transplant. Data cut-off: March 29, 2018.

Tumor Response: Dose-related and Independent of Myeloma BCMA Expression Levels

Tumor Response By Dose[1]



Tumor Response By BCMA Expression[1]



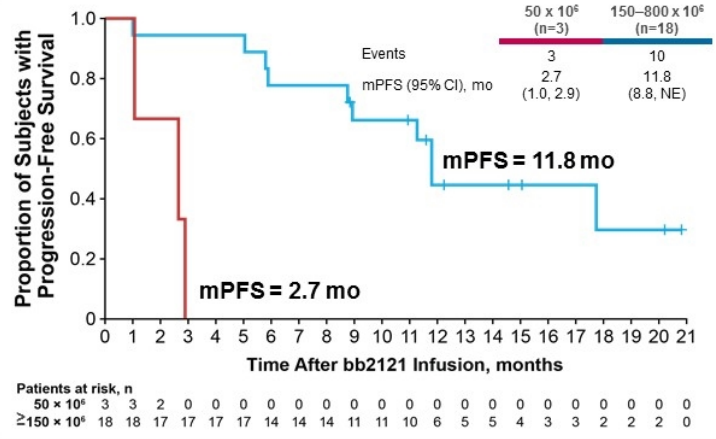
- 80.6% ORR across active dose cohorts (150-800 x 10^6)

CR, complete response; mDOR, median duration of response; ORR, objective response rate; PD, progressive disease; PR, partial response; sCR, stringent CR; VGPR, very good partial response. Data cut-off: March 29, 2018. [1]Patients with ≥2 months of response data or PD/death within <2 months. ORR is defined as attaining sCR, CR, VGPR, or PR, including confirmed and unconfirmed responses. Low BCMA is <50% bone marrow plasma cells expression of BCMA; high BCMA is defined as ≥50%.

Hitting the Mark for Progression Free Survival

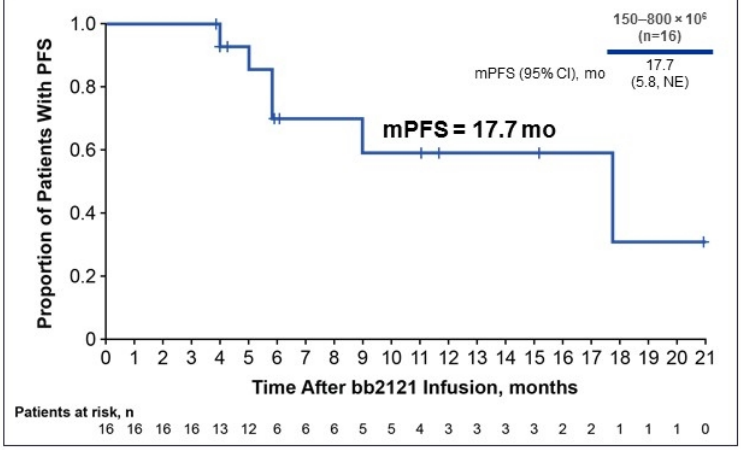
- mPFS of 11.8 months at active doses (≥150 x 10^6 CAR+ T cells) in 18 subjects in dose escalation
- mPFS of 17.7 months in 16 responding subjects from all study cohorts who are MRD-negative

PFS at Inactive (50 x 10^6) and Active (150–800 x 10^6) Dose Levels[1]



Data cut-off: March 29, 2018. Median and 95% CI from Kaplan-Meier estimate. NE, not estimable.
[1]PFS in dose escalation cohort.

PFS in MRD-Negative Responders
Escalation and Expansion Cohorts



PFS progression-free survival; MRD, minimal residual disease.
Includes patients treated with <50 x 10^6 CAR T cells who were MRD-negative at >1 postbaseline time point

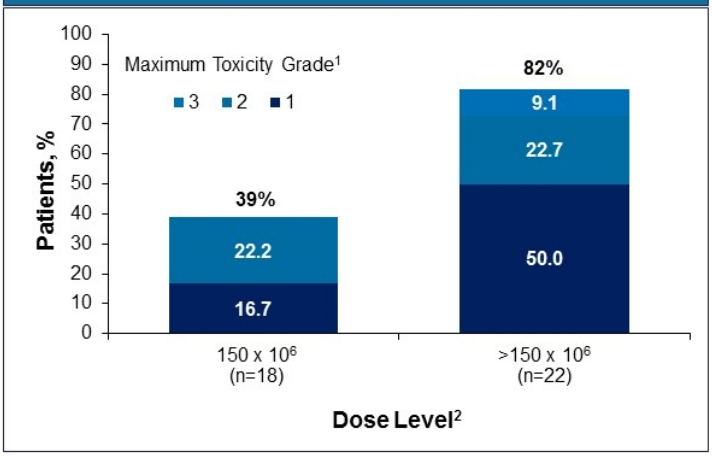
bb2121 Continues to be Generally Well-Tolerated; No New Safety Signals

CAR T Treatment-Emergent Adverse Events All Infused Patients (N=43)

TEAE, n (%)	Overall	Grade ≥3
Cytokine release syndrome[1]	27 (63)	2 (5)
Neurotoxicity[2]	14 (33)	1 (2)
Neutropenia	35 (81)	34 (79)
Thrombocytopenia	26 (61)	22 (51)
Anemia	24 (56)	19 (44)
Infection[3]		
Overall	26 (61)	9 (21)
First Month	10 (23)	2 (5)

- No grade 4 CRS events
- No fatal CRS or neurotoxicity events

Cytokine Release Syndrome By Dose Level



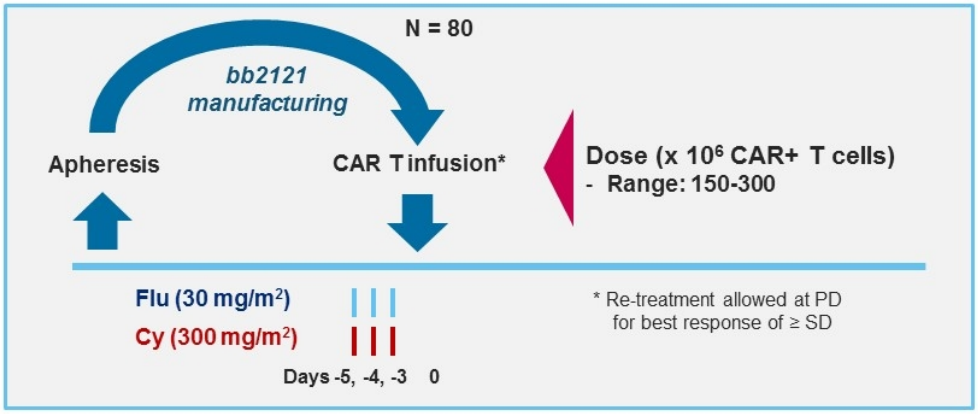
- Patients with a CRS event, 63%

Data cut-off: March 29, 2018. NE, not estimable.[1]CRS uniformly graded per Lee et al., *Blood* 2014;124:188-195.[2]Events occurring in first 28 d and including dizziness, bradyphrenia, somnolence, confusional state, nystagnmus, insomnia, memory impairment, depressed level of consciousness, neurotoxicity, lethargy, tremor and hallucination. [3]Includes the SOC Infections and Infestations. Events observed in >10% include upper respiratory tract infection and pneumonia. [4]Includes patients treated with active doses (150–800 × 10^6 CAR+ T cells; N=40). Median and 95% CI from Kaplan-Meier estimate. [5]Time from first bb2121 infusion to the first grade ≤2 event after day 32.

bb2121-MM-001: bb2121 Registration-Enabling Trial (KarMMa)

Relapsed and refractory MM

- ≥3 prior treatment regimens with ≥ 2 consecutive cycles each (unless PD was best response)
- Received prior IMiD®, PI and anti-CD38
- Refractory (per IMWG) to last treatment regimen



Endpoints

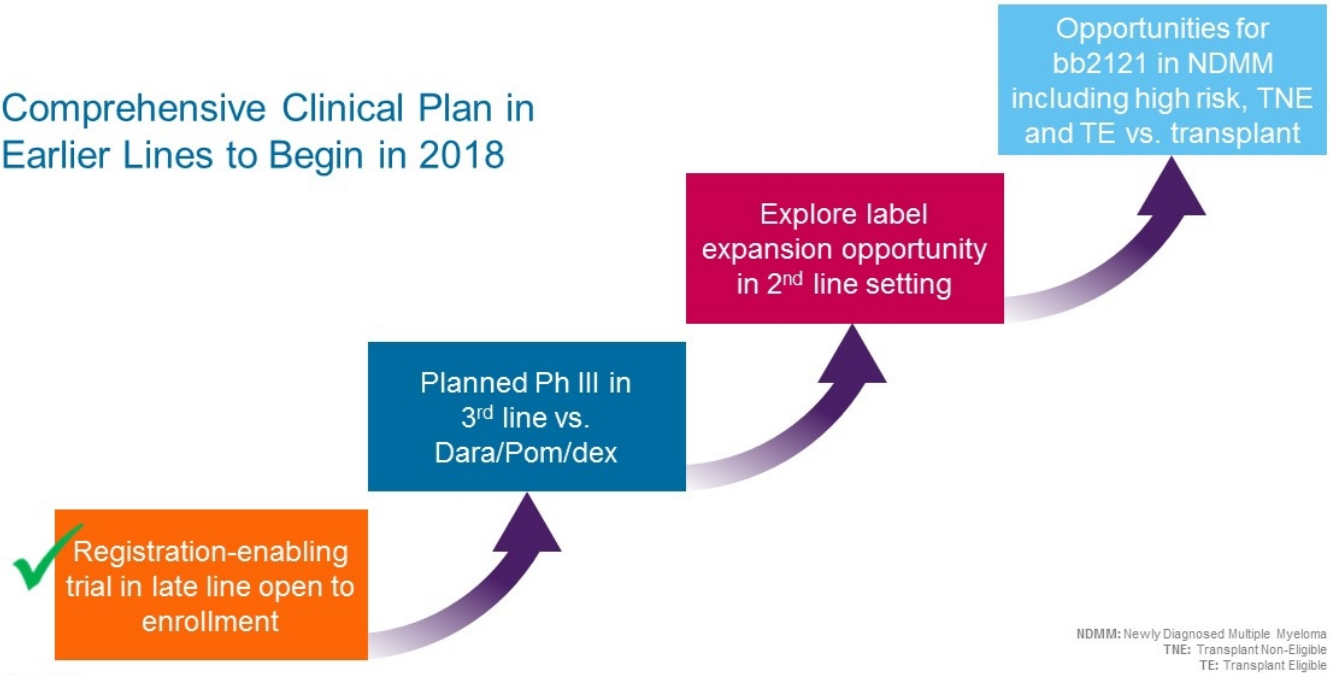
Primary: ORR

Key Secondary: CR, TTR, DOR, PFS, TTP, OS, Safety, bb2121 expansion and persistence, MRD (genomic and flow assays)

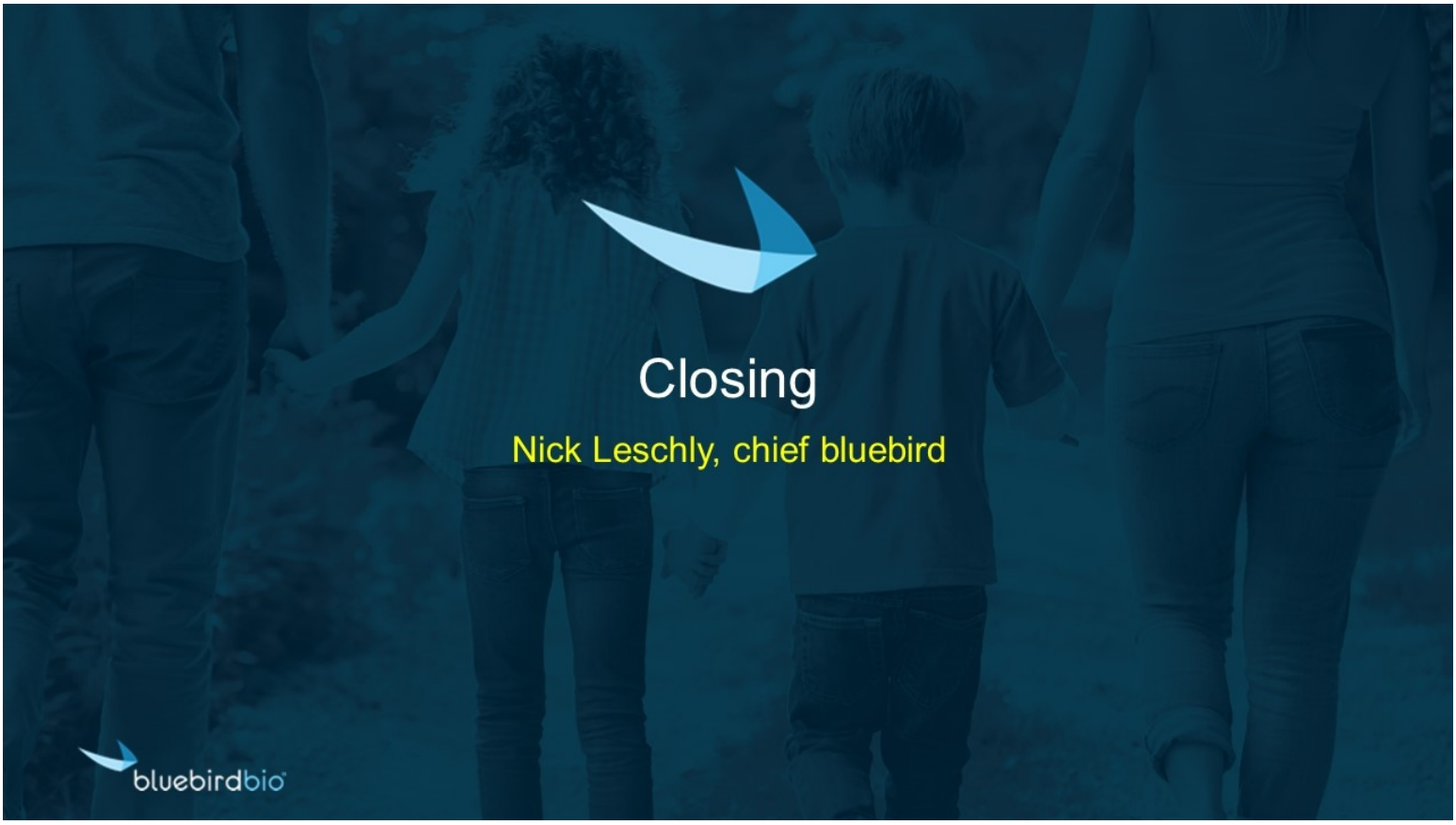
Exploratory: BCMA expression/loss, T cell immunophenotype, GEP in BM, HEOR

Advancing bb2121 into Earlier Lines of Multiple Myeloma

Comprehensive Clinical Plan in Earlier Lines to Begin in 2018



NDMM: Newly Diagnosed Multiple Myeloma
TNE: Transplant Non-Eligible
TE: Transplant Eligible

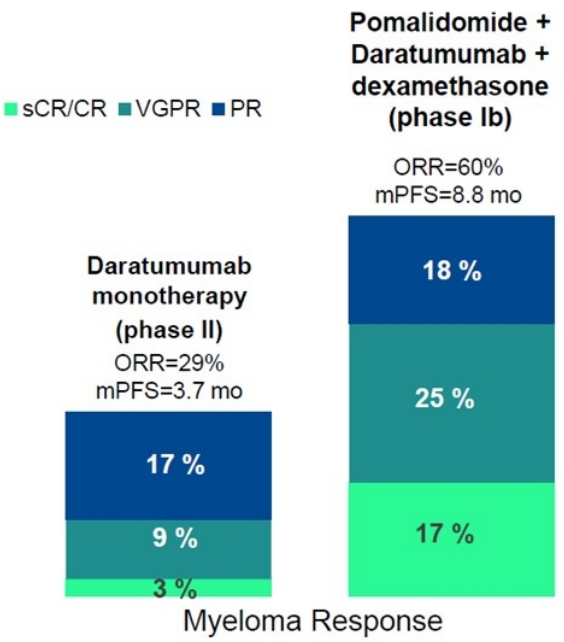

Closing
Nick Leschly, chief bluebird
bluebirdbio

Response to Current Standard of Care in Late Line RRMM

Current standard of care in RRMM after two or more lines of therapy:

	Dara	PDd	bb2121
Phase	II	I	I
N	106	103	43
Eligibility	≥ 3 prior lines Pom allowed Dara-naive	≥ 2 prior lines Pom-naïve Dara-naive	≥ 3 prior lines Pom allowed Dara allowed
Median prior lines	5	4	7

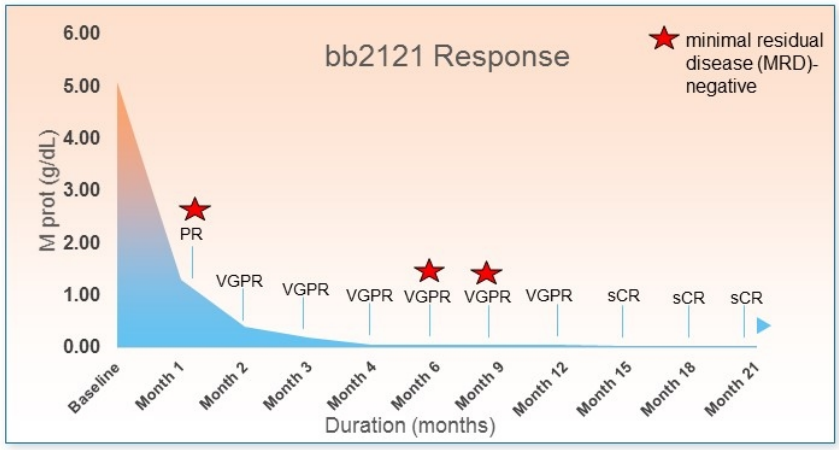
PDd=Pomalidomide + Daratumumab +dexamethasone.
Pom=Pomalidomide; Dara=Daratumumab



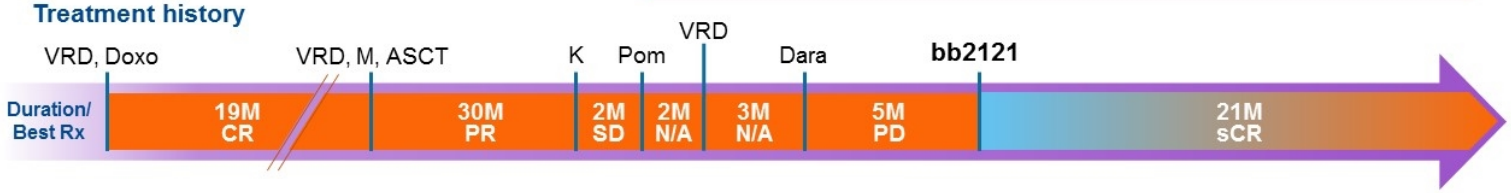
Chari, A. Blood 2017

bb2121 Patient Case: 21 Months in sCR

General Information	
Age & Gender	52 year old Male
Dose group	150x10^6
Tumor Burden	High
High Risk Cytogenetics (based on FISH)	No
Number of prior regimens	6
Initial diagnosis	May, 2010
BCMA% (prescreen, baseline)	60, 75



Treatment history

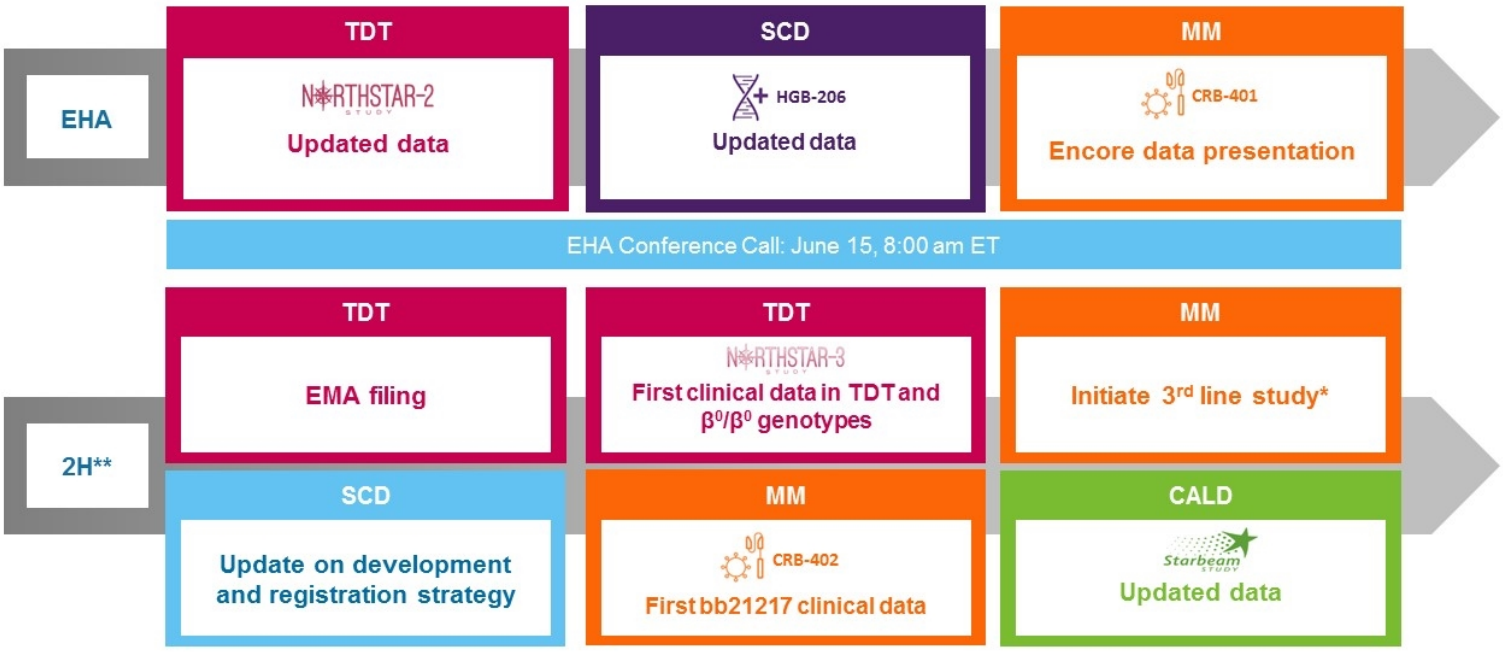


KEY: ASCT: autologous stem cell transplant, R: Revlimid, M: melphalan, d: dexamethasone, V: Velcade, K: Kyprolis, P/Pom: Pomalyst, Vor: vorinostat, Dara: daratumumab, Doxo:Doxorubicin

Key Takeaways

Efficacy?	• 95.5% ORR in doses above 150M cells. • 50% CR rate at doses above 150M cells.
Durability?	• 11.8 months median PFS in dose-escalation active doses. • 17.7 months median PFS in MRD(-) patients with response (escalation and expansion).
BCMA? MRD?	• Consistent responses across BCMA expression levels. • 16/16 responding, MRD-evaluable patients were MRD negative.
Safety?	• No new safety signals (G3/G4 CRS or Neurotox).
Path forward?	• KarMMa on track. Earlier line development plan advancing.

Stay Tuned…



*Celgene Responsibility, **Anticipated Clinical Data Updates


Q&A
bluebirdbio

Exhibit 99.2

UPDATED RESULTS OF ONGOING MULTICENTER PHASE I STUDY OF BB2121 ANTI- BCMA CAR T CELL THERAPY CONTINUE TO DEMONSTRATE DEEP AND DURABLE RESPONSES IN PATIENTS WITH LATE-STAGE RELAPSED/REFRACTORY MULTIPLE MYELOMA AT ASCO ANNUAL MEETING

High rates of response that were both deep and durable were seen at the highest dose levels

Median PFS of approximately one year achieved in heavily pre-treated patients in the active doses of the dose escalation cohort

Consistent response observed for both low and high BCMA expression levels

Adverse events have been manageable across doses

Summit, N.J. and Cambridge, Mass., June 1, 2018 – Celgene Corporation (NASDAQ: CELG) and bluebird bio, Inc. (NASDAQ: BLUE) today announced updated results from the ongoing CRB-401 phase I clinical study of bb2121, an investigational anti-B-cell maturation antigen (BCMA) CAR T cell therapy, in 43 patients with late-stage relapsed/refractory multiple myeloma. These data were the subject of an oral presentation by Noopur Raje, M.D. at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

“We are encouraged by the continuing deep and durable responses seen in this study and look forward to the results of our pivotal study, KarMMa, which is currently enrolling,” said Jay Backstrom, Chief Medical Officer for Celgene. “We continue to see BCMA as an excellent target in multiple myeloma and we believe bb2121 has the potential to have a significant impact on the treatment approach and outcomes for these patients. We and our partners at bluebird bio are fully committed to the continued rapid clinical development of bb2121 and the evaluation of its potential in the treatment of patients with relapsed and refractory multiple myeloma.”

“To see a median PFS of 11.8 months in this heavily pretreated patient population is very encouraging,” said David Davidson, M.D., Chief Medical Officer, bluebird bio. “As the data from this program continue to mature, bb2121 has set a high bar as the leading investigational anti-BCMA CAR T cell candidate for relapsed and refractory multiple myeloma. In addition, the deep MRD-negative responses, the activity seen across myeloma with high and low levels of BCMA expression, as well as adverse events observed support the evaluation of bb2121 in earlier lines of multiple myeloma, where patients may experience more durable outcomes.”

The open-label phase I CRB-401 study (NCT02658929) is evaluating the preliminary safety and efficacy of bb2121 anti-BCMA CAR T cell therapy in patients with relapsed/refractory multiple myeloma.

Patients in the study were heavily pre-treated, with a median of seven prior myeloma treatment regimens (min, max: 3,14) in the dose escalation cohort (n=21) and eight prior regimens (min, max: 3, 23) in the dose expansion cohort (n=22). More than 90% of patients had received prior treatment with two IMiD® therapies, two proteasome inhibitors, daratumumab and an autologous stem cell transplant.

Exhibit 99.2

As of the March 29, 2018 data cut-off, 43 patients had been enrolled and dosed in either the dose-escalation cohort of the study, at four dose levels (50 x 10^6, 150 x 10^6, 450 x 10^6 and 800 x 10^6 CAR+ T cells), or in the dose expansion cohort in a dose range between 150-450 x 10^6 CAR+ T cells.

Patients received a lymphodepleting conditioning regimen of fludarabine and cyclophosphamide, followed by an infusion of bb2121 anti-BCMA CAR T cells. The CAR T cells were produced from each patient's own blood cells, which were modified using a proprietary lentiviral vector encoding the anti-BCMA CAR.

Response outcomes in efficacy evaluable patients* in the study were as follows:

Measure	50 x 10^6 (n=3), median follow-up 84 days (59,94)	150 x 10^6 (n=14), median follow-up 87 days (36,638)	>150 x 10^6 (n=22), median follow-up 194 days (46, 556)
Overall response (ORR)	33.3%	57.1%	95.5%
Complete response (CR)	0%	42.9%	50%
Very good partial response (VGPR)	0%	7.1%	36.4%
Median duration of response mDOR	1.9 months	Not estimable	10.8 months

*Patients with ≥2 months of response data or PD/death within <2 months

Responses were dose-related and observed for both low and high BCMA expression levels. In patients treated with 450 x 10^6 CAR+ T cells whose myeloma cells expressed low levels of BCMA (0 to 50% of cells BCMA positive), 8 of 8 had a response. In those expressing high BCMA (≥50% BCMA positive), 10 of 11 had a response.

The median progression-free survival (PFS) estimate for patients in the dose-escalation phase treated at active doses (≥150 x 10^6 CAR+ T cells) was 11.8 months (95% CI 8.8, NE), while patients receiving 50 x 10^6 CAR+ T cells had a median PFS of 2.7 months (95% CI 1.0, 2.9).

In the dose-escalation and expansion phase of the study, all patients who responded and were evaluable for minimal residual disease (MRD as measured by adaptive next-generation sequencing assay) (n=16) were MRD negative at one or more time points. Additionally, two patients who did not have a response and were evaluated for MRD were MRD positive at month one. The median PFS estimate in MRD negative responders was 17.7 months (95% CI: 5.8, NE).

Among all infused patients (n=43), 63% had cytokine release syndrome (CRS), mostly Grade 1 & 2, with 2 patients experiencing Grade 3 CRS (5%). Nine patients (21%) received tocilizumab, including 4 patients (9%) who also received steroids and the median duration of CRS was 6 days (1,32). For patients receiving 150 x 10^6 CAR+ T cells (n=18), the rate of CRS was 39% with no grade 3 cases. For patients receiving ≥150 x 10^6 CAR+ T cells (n=22), the rate of CRS was 82% with 9.1% of patients experiencing grade 3 events. Also among all infused patients, there were 14 patients (33%) who experienced neurotoxicity, with one patient experiencing a grade 3 or higher

Exhibit 99.2

event. Other frequent Grade 3/4 AEs included cytopenias commonly associated with lymphodepleting chemotherapy such as neutropenia (79%), thrombocytopenia (51%) and anemia (44%), as well as infection (any grade) with a frequency of 61% overall and 23% in the first month. Grade 3 or higher infection occurred with a frequency of 21% overall and 5% in the first month.

“The continuing high, durable response rates and MRD-negative results in this heavily pre-treated population of multiple myeloma patients further illustrates BCMA as a promising target in this incurable disease and bb2121 as an investigational therapy of great potential in patients with relapsed and refractory multiple myeloma with both high and low BCMA expression,” said Dr. Raje., Professor of Medicine at Harvard Medical School and Director of the Multiple Myeloma Center at Massachusetts General Hospital. “We will continue to evaluate the long-term effect of bb2121 as we learn more about the potential for this investigational therapy.”

bb2121 is an investigational compound that is not approved for any use in any country. bb2121 received Breakthrough Therapy Designation from the U.S. FDA and PRIME eligibility from the EMA. Celgene has also sponsored an open-label, single-arm, pivotal, phase 2 study (KarMMa), which is recruiting in North America and Europe, to evaluate bb2121 further in patients with relapsed and refractory multiple myeloma (NCT03361748).

About Celgene
Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

About bluebird bio, Inc.
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and cancer. bluebird bio's gene therapy clinical programs include Lenti-D™ for the treatment of cerebral adrenoleukodystrophy, and LentiGlobin™ for the treatment of transfusion-dependent β-thalassemia, also known as β-thalassemia major, and severe sickle cell disease. bluebird bio's oncology pipeline is built upon the company's leadership in lentiviral gene delivery and T cell engineering, with a focus on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR T) and T cell receptor (TCR) therapies. bluebird bio's lead oncology programs, bb2121 and bb21217, are anti-BCMA CAR T programs partnered with Celgene. bluebird bio also has discovery research programs utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, Durham, North Carolina and Zug, Switzerland.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

Forward-Looking Statements

Exhibit 99.2

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between bluebird bio and Celgene; the potential of bb2121 as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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