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 15, 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 15, 2018, bluebird bio, Inc. ("bluebird") will conduct an investor webcast summarizing clinical data from the Northstar (HGB-204), Northstar-2 (HGB-207) and HGB-206 clinical studies of its LentiGlobin product candidate being presented at the 23rd Congress of the European Hematology Association in Stockholm, Sweden. A copy of the presentation is furnished to this report as Exhibit 99.1.

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 15, 2018, bluebird issued two press releases announcing updated clinical data being presented at the 23rd Congress of the European Hematology Association in Stockholm, Sweden from the Northstar (HGB-204) and Northstar-2 (HGB-207) clinical studies of its LentiGlobin product candidate in patients with transfusion-dependent β-thalassemia, and the HGB-206 clinical study of its LentiGlobin product candidate in patients with severe sickle cell disease.

The full text of bluebird's press releases regarding the announcements are filed as Exhibits 99.2 and 99.3 to this Current Report on Form 8-K and are 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 15, 2018.
99.2	Press release issued by bluebird bio, Inc. on June 15, 2018.
99.3	Press release issued by bluebird bio, Inc. on June 15, 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 15, 2018

bluebird bio, Inc.

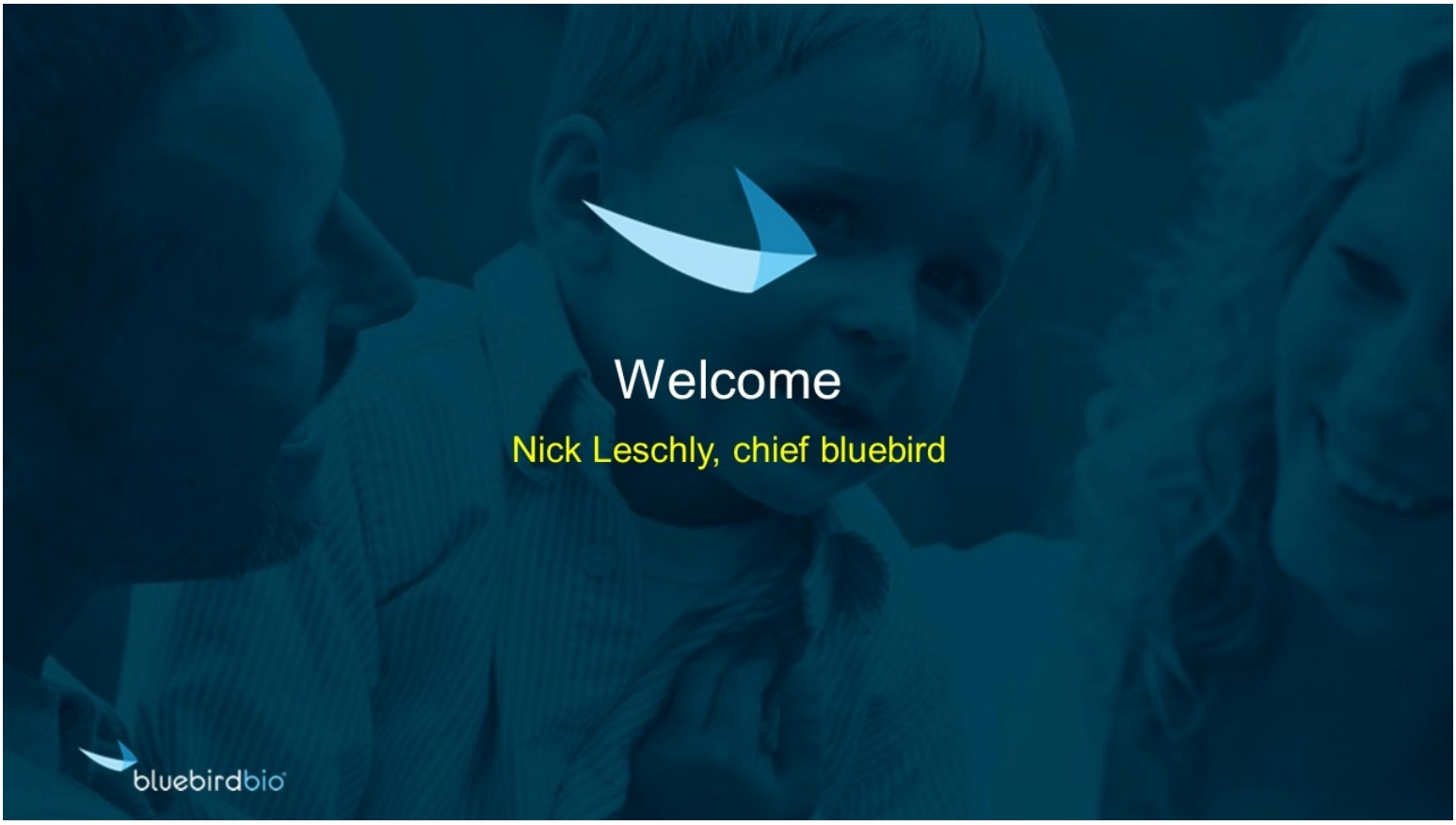
By:/s/ Jason F. Cole
Jason F. Cole
Chief Legal Officer

Exhibit 99.1


EHA Analyst & Investor Webcast
June 15, 2018
bluebirdbio
June 15, 2018
NASDAQ: BLUE

Forward-Looking Statements

These slides and the accompanying oral presentation contain forward-looking statements and information. 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


Making Hope
A Reality


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 Takeaways

LentiGlobin TDT

- Transfusion-dependent β-thalassemia (TDT) MAA filing on track for 2018
- HGB-207: 7/8 patients reaching normal/near normal total hemoglobin by 6 months
- HGB-204: 8/10 non-β^0/β^0 patients achieve and maintain TI for up to 3+ years

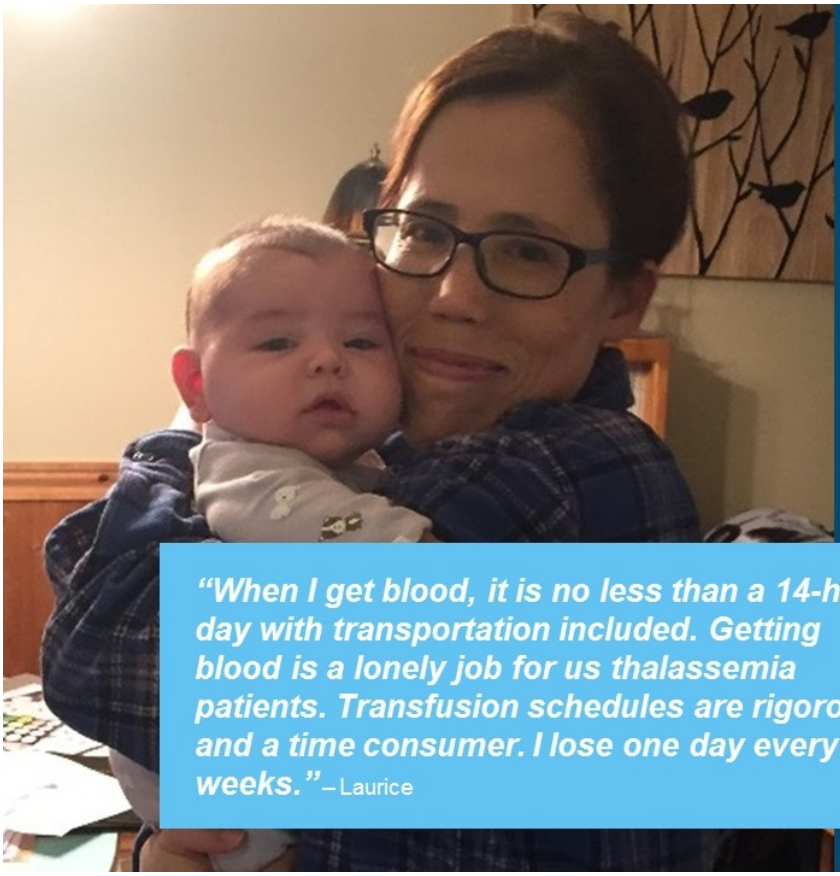
LentiGlobin SCD

- Group C (n=6) patients showing rapid and consistent anti-sickling HbA^{T87Q} expression
  - At 3 months (n=4) all patients have ≥ 30% HbA^{T87Q}
  - At 6 months (n=1) patient has 62% HbA^{T87Q}; total Hgb of 14.2 g/dL
- No new safety findings in patients treated with plerixafor

BLUE 2018 & Beyond

- Commercial readiness and implementation underway
- Early and late-stage clinical programs tracking
- Building for next phase of growth: innovation engine and commercialization


LentiGlobin TDT Data Update
David Davidson, M.D., chief medical officer
bluebirdbio



"When I get blood, it is no less than a 14-hour day with transportation included. Getting blood is a lonely job for us thalassemia patients. Transfusion schedules are rigorous and a time consumer. I lose one day every two weeks." – Laurice

Transfusion-Dependent β-Thalassemia (TDT)

- Inherited blood disease that requires lifelong, frequent blood transfusions and iron reduction therapy

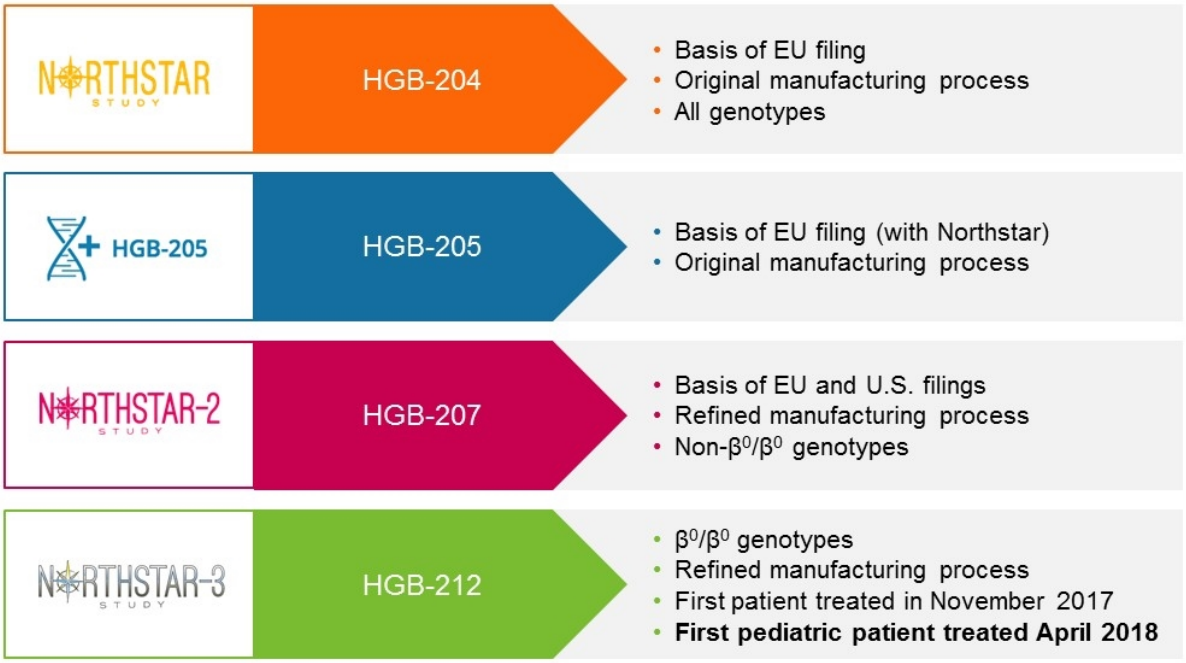
UNMET NEED

- Treatment of underlying disease limited to allo-HSCT, primarily only for pediatric patients with sibling donor matches
- Sometimes severe treatment-related risks and complications
- Requires comprehensive care throughout life

EPIDEMIOLOGY

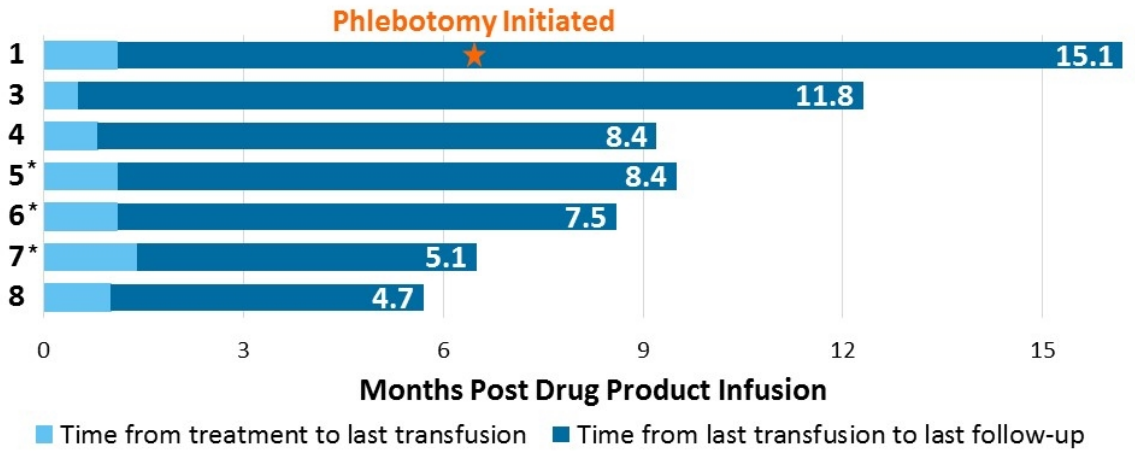
- Global prevalence ~ 288,000
- Global incidence ~ 60,000

Transfusion-Dependent β-Thalassemia



HGB-207: 7/8 Patients with ≥ 6 Months Follow-up are Transfusion Free

First treated patient achieved transfusion independence and has begun phlebotomy

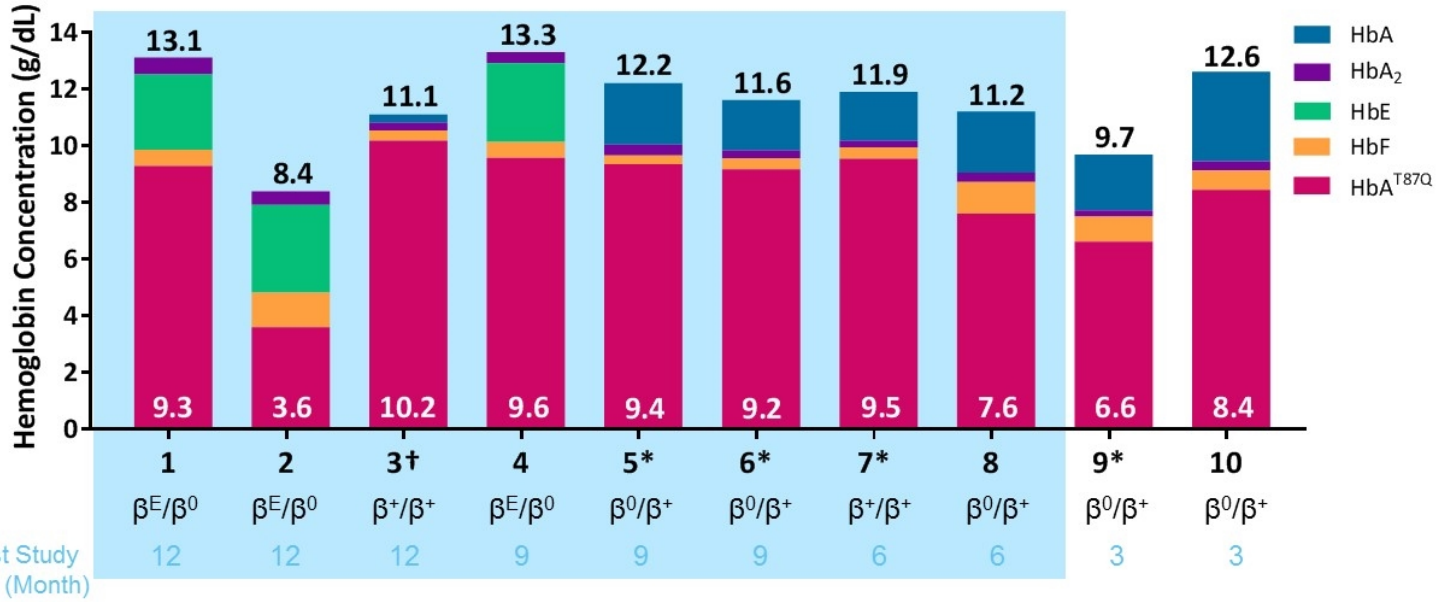


	Hb (g/dL)	Peripheral VCN
	At last study visit	
1	13.1	3.6
3	11.1	2.2
4	13.3	2.8
5*	12.2	1.5
6*	11.6	2.1
7*	11.9	5.0
8	11.2	1.1

- Patient 2 was free from chronic transfusions for 11 months, however received a transfusion following DP infusion due to low Hb; patient had a peripheral VCN of 0.2

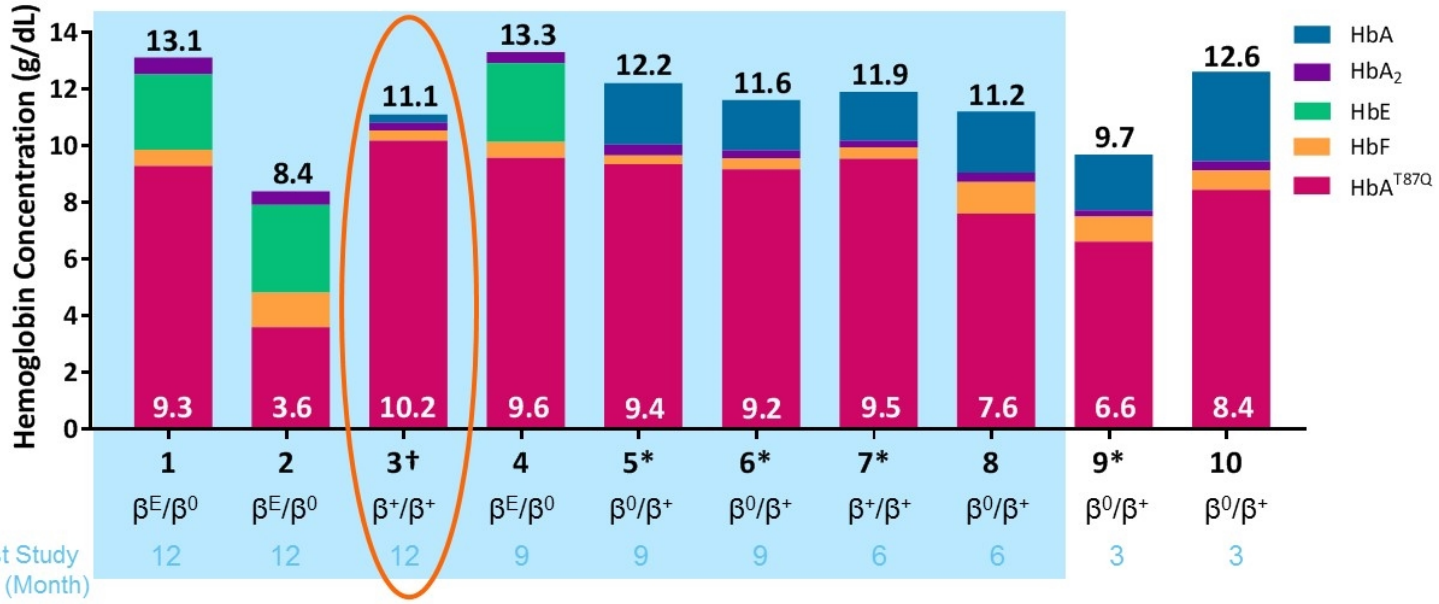
*Indicates male patients; Transfusion independence is defined as the weighted average Hb ≥9 g/dL without any RBC transfusions for ≥12 months; Hb, hemoglobin; VCN, vector copy number

HGB-207: 7/8 patients are producing ≥ 7.6 g/dL of HbA^{T87Q} by 6 months



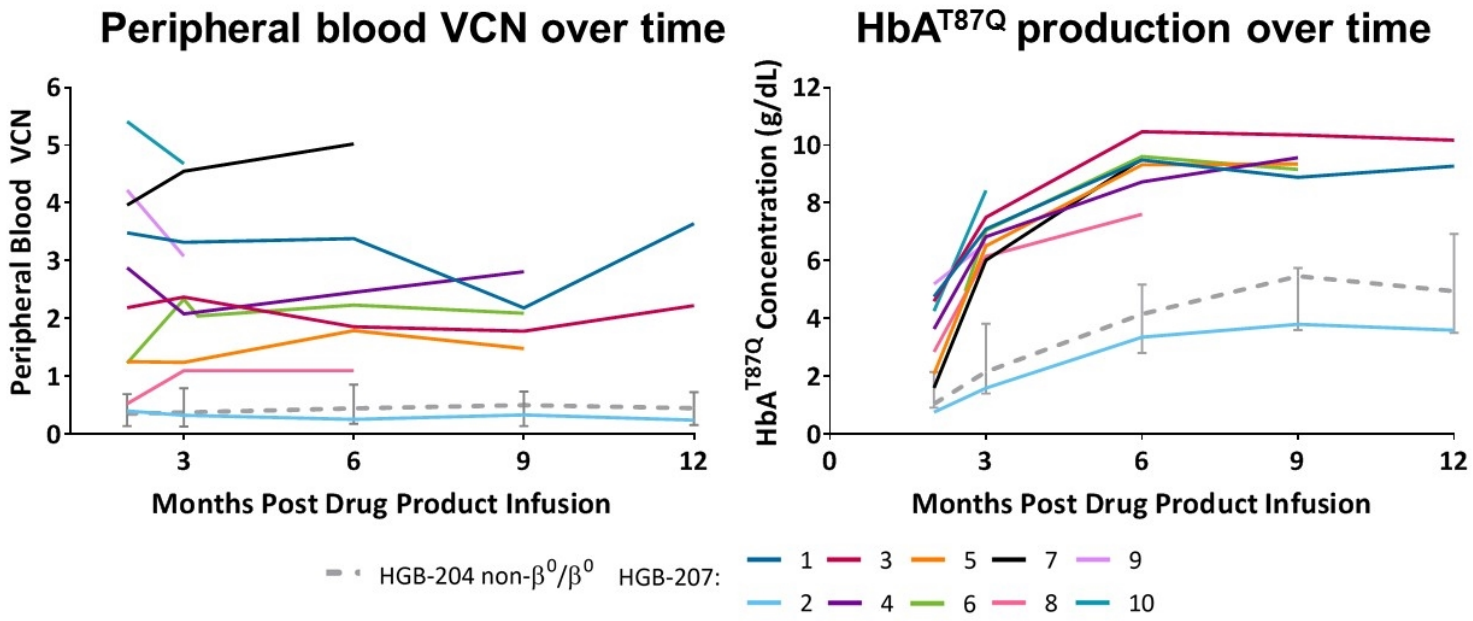
* Indicates male patients; †Patient is homozygous for severe IVS-1-5 β-globin mutation

HGB-207: 7/8 patients are producing ≥ 7.6 g/dL of HbA^{T87Q} by 6 months



†Patient is homozygous for severe IVS-1-5 β-globin mutation

Peripheral Blood VCN and HbA^{T87Q} Production Over Time

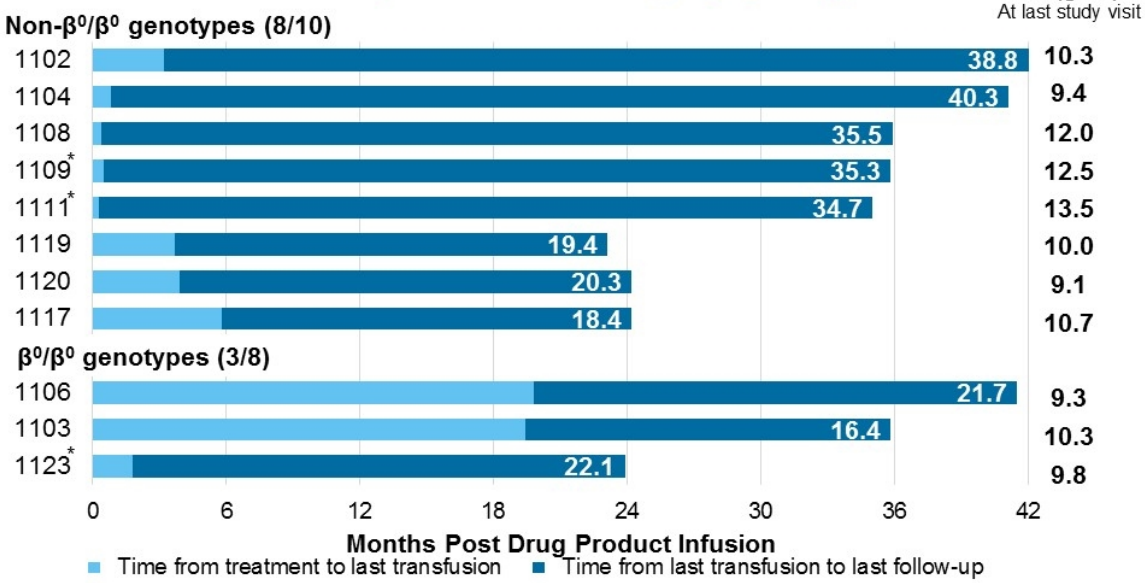


For 204 non-β^0/β^0 patients, medians (Q1, Q3) depicted

Data as of 15 May 2018 (HGB-207) and 7 Mar 2018 (HGB-204)

HGB-204: 8/10 Patients with Non-β^0/β^0 Genotypes Achieve and Maintain Transfusion Independence

Median duration of transfusion independence to date of 33 months in 8/10 patients with non-β^0/β^0 genotypes



Transfusion Independence

Non-β^0/β^0 genotypes (8/10)
80% achieved TI for 16+ to 38+ months

β^0/β^0 genotypes (2/8)
25% achieved TI for 14+ and 16+ months

Reduction in Transfusion Volume

Non-β^0/β^0 genotypes (2/10)
27% and 82%

β^0/β^0 genotypes (5/8)
Median 53%
(min – max: 8% – 74%)

NASDAQ: BLUE *Indicates male patients; Transfusion independence is defined as the weighted average Hb ≥9 g/dL without any RBC transfusions for ≥12 months

LentiGlobin Safety Profile is Generally Consistent with Myeloablative Conditioning

HGB-204

- No grade ≥ 3 DP-related AEs
- One SAE of asymptomatic wild-type HIV infection was reported 23 months after DP infusion and was considered not related to LentiGlobin
- Two SAEs of VOD

HGB-207

- One grade 1 abdominal pain event was considered possibly related to LentiGlobin
- Two SAEs of VOD extended hospitalization following DP infusion
  - Events occurred on Day +23 and Day +34
  - Both patients were treated with defibrotide
  - Both events have resolved

No graft failure | No deaths | No vector-mediated replication competent lentivirus | No early evidence of clonal dominance

AE, adverse event; DP, drug product; HIV, human immunodeficiency virus; SAE, serious adverse event, VOD, veno-occlusive liver disease


LentiGlobin SCD Data Update
bluebirdbio

"I experienced my first sickle crisis requiring hospitalization at age 5. Since then I've endured hundreds of hospitalizations, blood transfusions and surgical procedures. Despite the devastating symptoms of sickle cell, I was determined to complete my educational goals." - Lakiea

Source: Global Genes

Sickle Cell Disease (SCD)

- Severe blood disorder that causes anemia, frequent pain crises, and shortened lifespan

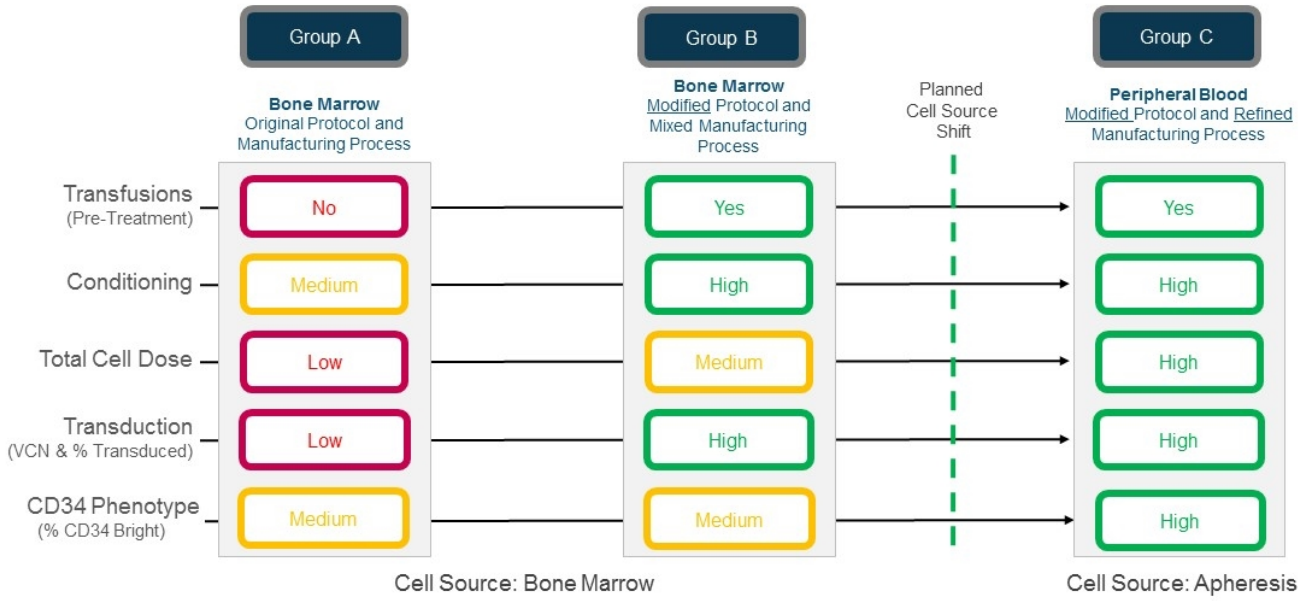
UNMET NEED

- High morbidity; early mortality; with median age of death in the 5th decade
- Treatment of underlying disease limited to allo-HSCT, primarily recommended only for pediatric patients with matched sibling donors
- 15-20% of patients with SCD may have HLA-identical sibling donor
- Substantial treatment-related risks and complications

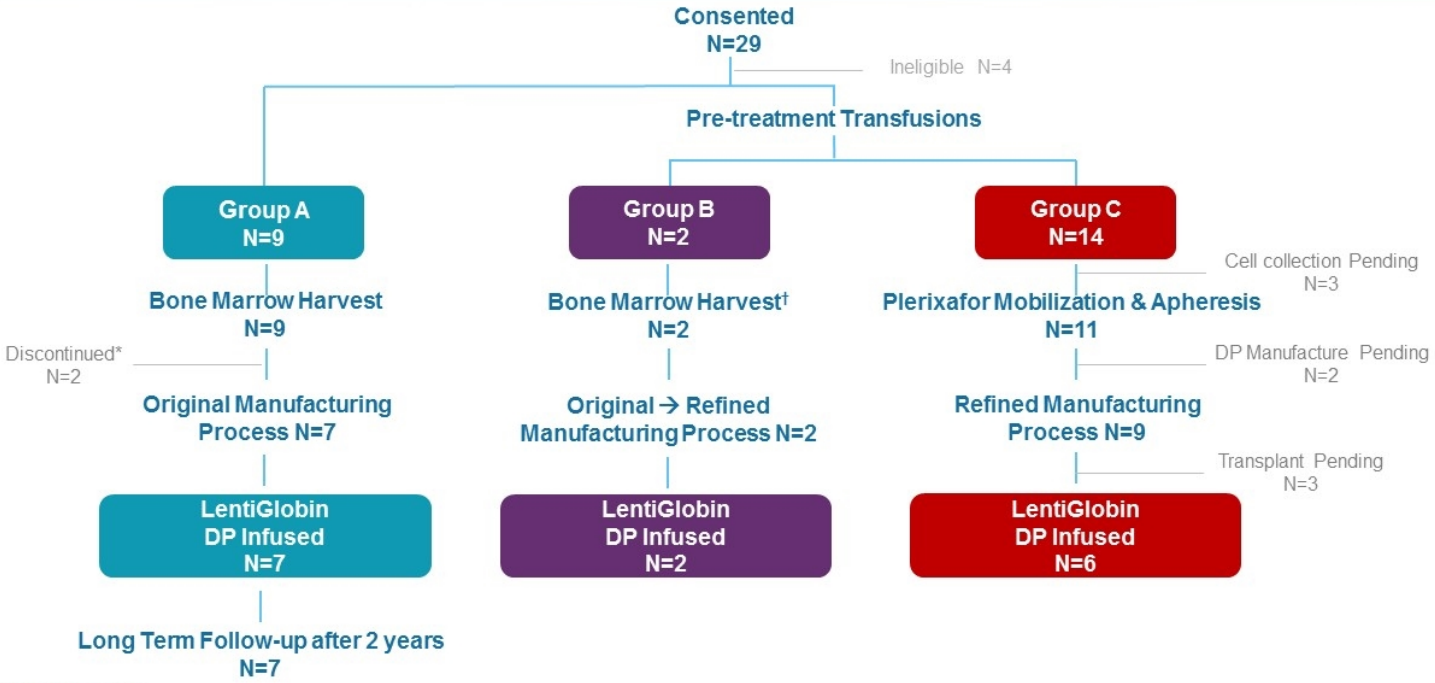
EPIDEMIOLOGY

- U.S. prevalence ~ 100,000; EU prevalence ~ 113,000
- Global annual birth incidence ~ 300,000–400,000

HGB-206: Evolution of LentiGlobin in SCD



HGB-206: Study Disposition



** 1 due to insufficient cell collection, 1 withdrew consent; †One patient also received a single mobilization cycle to collect cells for back-up*

HGB-206: Patient Characteristics

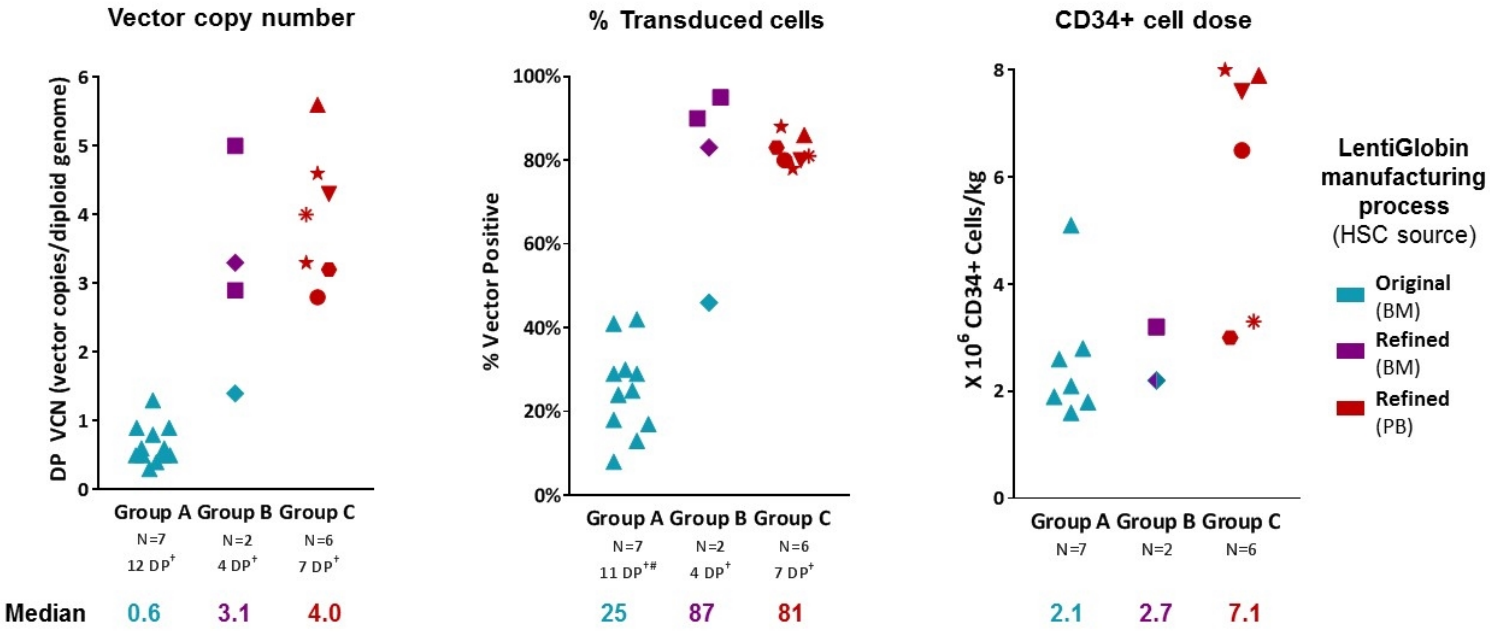
N=22 Patients Who Started Cell Collection

Parameter	Group A N=9	Group B N=2	Group C N=11
Age at consent median (min – max), years	**26** (18 – 43)	**24.5** (22 – 27)	**25** (18 – 35)
Gender	**2 Female**	**0 Female**	**5 Female**
Genotype β^S/β^S	**9**	**2**	**11**
Prior SCD History **No. of patients** **No. of events**, median (min – max)			
Hydroxyurea use	**5**	**2**	**6**
Recurrent VOCs[*,†]	**7** **4.5** (2.0 – 27.5)	**2** **10.0** (2.5 – 17.5)	**6** **7.5** (4.0 – 14.0)
Acute chest syndrome[*,†]	**1** **1**	**1** **1**	**2** **1** (1 – 1)
Any history of stroke	**2**	**0**	**3**
Regular pRBC transfusions before study entry	**1**	**0**	**7**
TRJV >2.5 m/s[*]	**1**	**0**	**0**

*Within 2 years prior to informed consent, or initiation of regular transfusions in case of VOCs; †Median Annualized values in patients with ≥2 events/year (for VOCs), or ≥1 events/year with at least one episode in the year before informed consent or initiation of regular transfusions (for ACS)

ACS, acute chest syndrome; VOC, vaso-occlusive crisis, TRJV, Tricuspid regurgitant jet velocity

Refinements to Manufacturing and Cell Harvest Lead to Improved Drug Product Characteristics

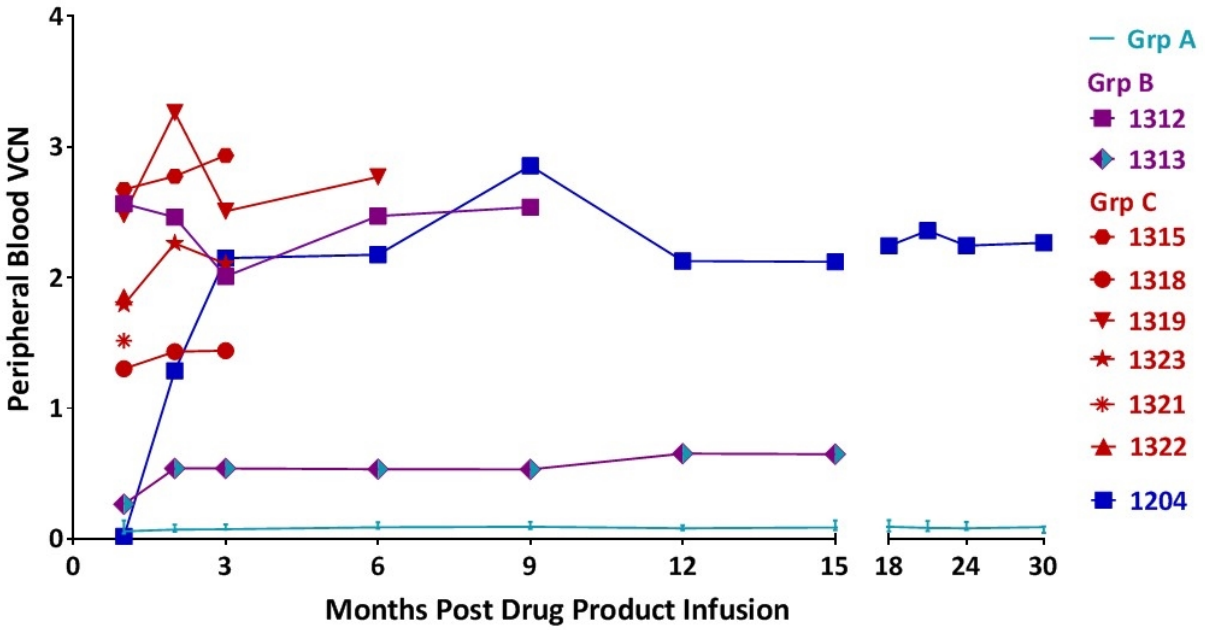


Median	0.6	3.1	4.0	25	87	81	2.1	2.7	7.1

†Number of DP exceeds number of patients since some patients were harvested or mobilized more than once; # % Transduced cells not available for 1 DP at time of analyses; Grey line indicates median

BM, bone marrow; HSC, hematopoietic stem cell; Med, median; PB, peripheral blood.

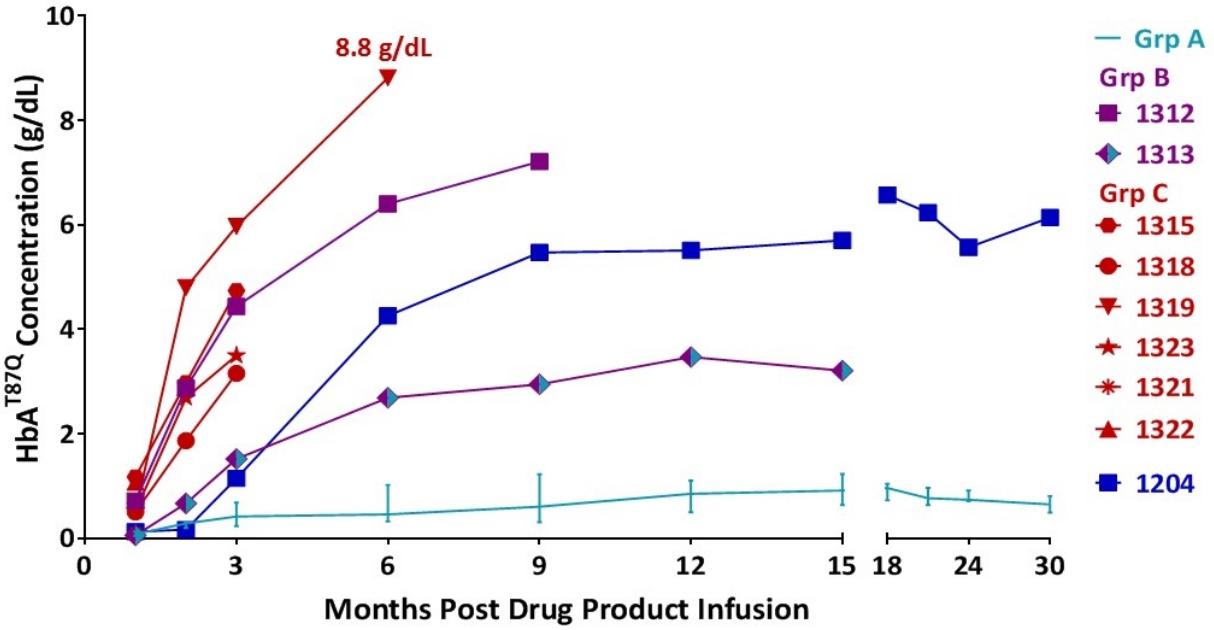
Peripheral Blood VCN is Higher in Patients in Group B and C



For Group A patients, medians (min, max) depicted; Group A patients with month 30 study visit (N=3)

Data as of May 15, 2018 for HGB-206 and Sep 20, 2017 for pt 1204

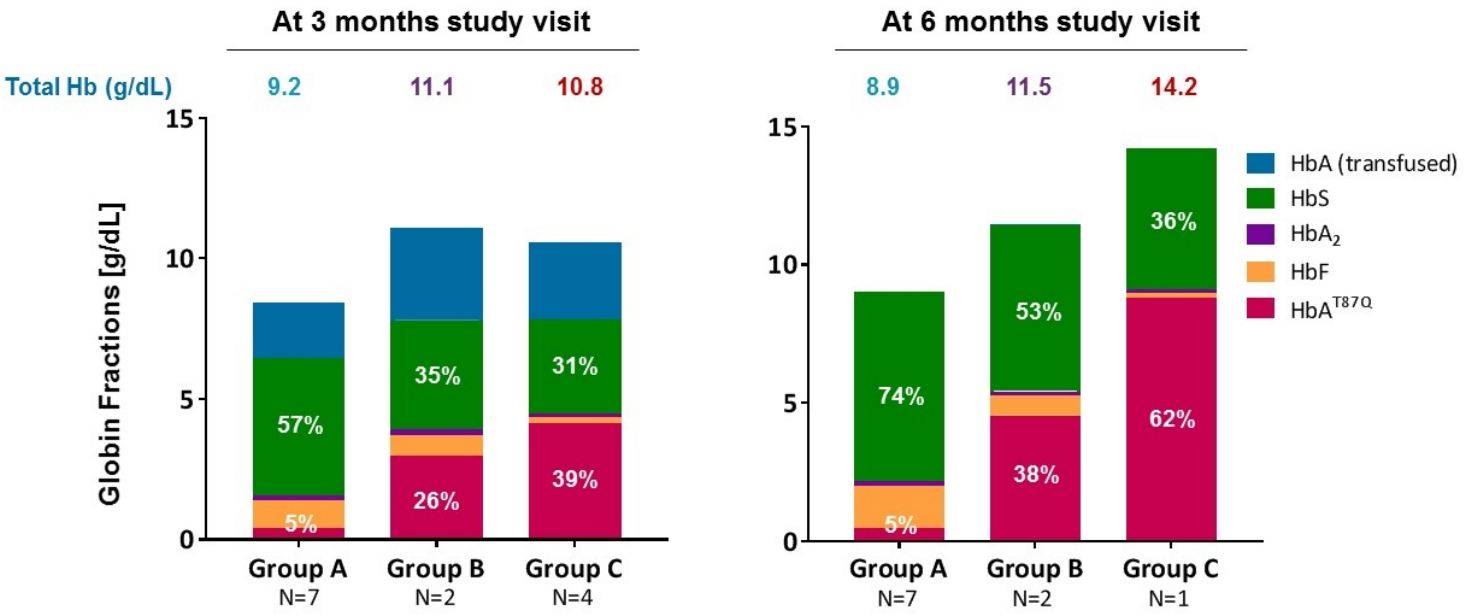
Patients in Group B and C Demonstrate Higher HbA^{T87Q} Production



NASDAQ: BLUE For Group A patients, medians (min, max) depicted; Group A patients with month 30 study visit (N=2)

Data as of May 15, 2018 for HGB-206 and Sep 20, 2017 for pt 1204

All Group C Patients Above 30% Anti-Sickling Hemoglobin by 3 Months



- 5 incremental patients since data presented at ASH; no clinically significant new safety events

Median for DP-infused patients depicted, except for Group C at 6 months given N=1

Data as of May 15, 2018 for HGB-206 and Sep 20, 2017 for pt 1204

Key Takeaways

LentiGlobin TDT

- Transfusion-dependent β-thalassemia (TDT) MAA filing on track for 2018
- HGB-207: 7/8 patients reaching normal/near normal total hemoglobin by 6 months
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LentiGlobin SCD

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  - At 3 months (n=4) all patients have ≥ 30% HbA^{T87Q}
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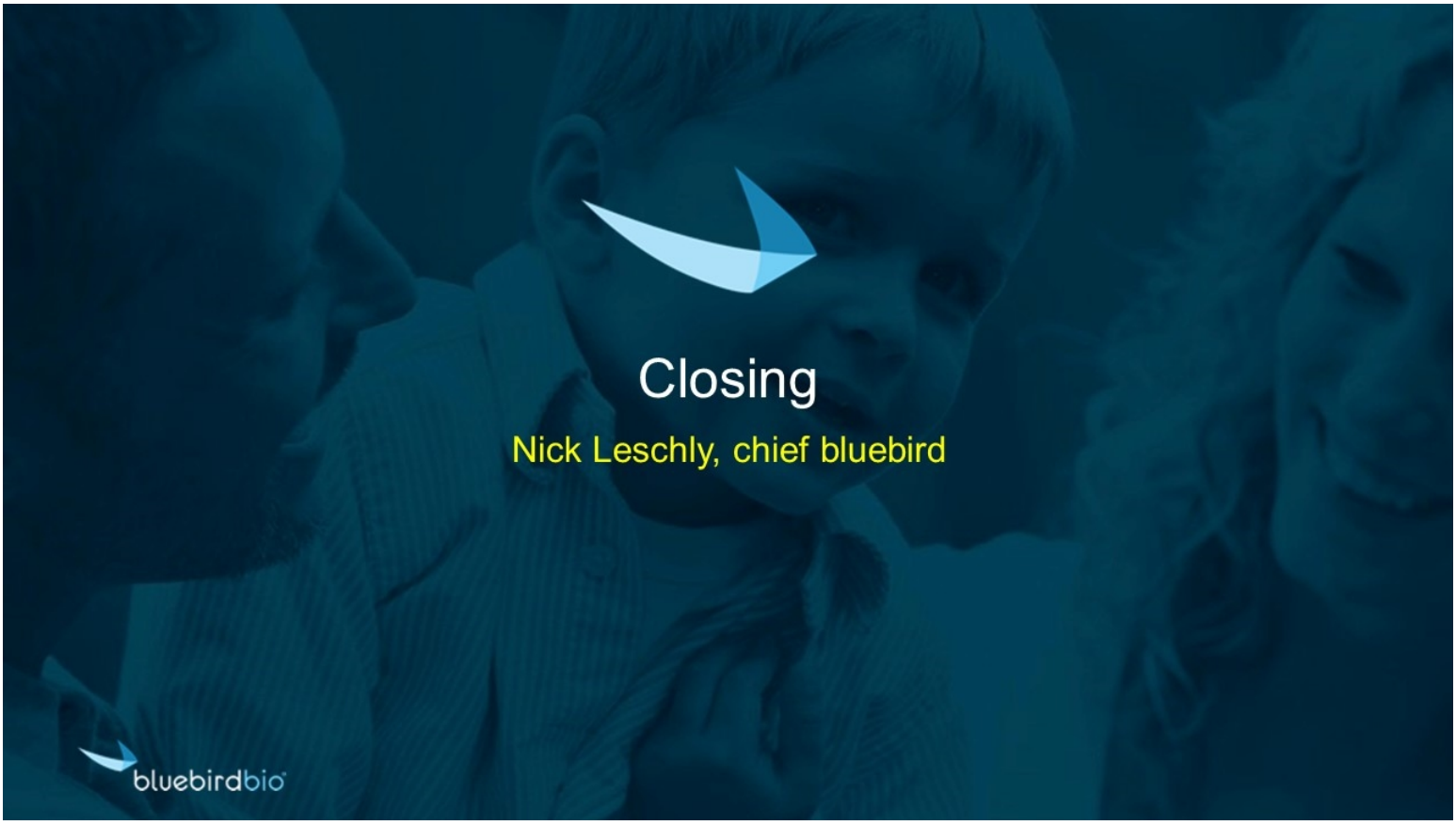
- No new safety findings in patients treated with plerixafor


Closing
Nick Leschly, chief bluebird
bluebirdbio

Leaders in Gene & Cell Therapy

Our Integrated Platforms

Gene Therapy · Cell Therapy · Gene Editing

Our Clinical Programs

Lenti-D™
LentiGlobin®

bb2121
bb21217

500+ bluebirds

Cambridge | Seattle | Durham | Zug

Regulatory Designations

RMAT *Regenerative Medicine Advanced Therapy*

ODD *Orphan Drug Designation*

BTD *Breakthrough Therapy Designation*

PRIME *PRIority MEdicines*

3 Regulatory filings planned by end of 2019

Strategic Partnerships

Boston Children's Hospital · medigene · TC BIOPHARM · Celgene

Manufacturing

apceth · novasep · brammer · Lonza · MilliporeSigma

Toolbox

Lentiviral Gene Delivery
- Reproducible
- Scalable

Genome Editing Platform
- megaTALs
- homing endonucleases

9 Active Treatment Studies

Starbeam STUDY

CRB-401 · KarMMa™* · CRB-402

HGB-205 · HGB-206 · BCL11a**

NORTHSTAR-2 STUDY · NORTHSTAR-3 STUDY

*Led by Celgene, **Led by BCH

Stay Tuned…

TDT

- ✓ Northstar-2 (HGB-207) Updated Data
- ✓ Northstar (HGB-204) Updated Data
- • MAA Filing in non-β^0/β^0 Genotypes
- • Northstar-3 (HGB-212) Early Data
- • Northstar-2 Updated Data

SCD

- ✓ HGB-206 Data
- • Registration Strategy Update

MM

- ✓ CRB-401 bb2121 ASCO Data
- • Initiate 3rd Line Study*
- • CRB-402 bb21217 Early Data
- • CRB-401 Updated Data

CALD

- • Starbeam (ALD-102) Updated Data

*Conducted by Celgene


Q&A
bluebirdbio

bluebird bio Announces New Interim Data from Phase 1 (HGB-206) Study of LentiGlobin™ Gene Therapy in Patients with Severe Sickle Cell Disease at Annual Congress of the European Hematology Association

– *All patients (n=4) in Group C with ≥ 3 months follow-up consistently producing ≥ 30% anti-sickling HbA^{T87Q}* –

– *First Group C patient generating a normal total hemoglobin of 14.2 g/dL with over 60% anti-sickling HbA^{T87Q} at 6 months* –

– *Company to hold conference call and webcast today, June 15, 8:00 a.m. EDT* –

CAMBRIDGE, Mass., June 15, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) today announced new interim data from the ongoing HGB-206 Phase 1 multicenter clinical study of LentiGlobin investigational gene therapy in patients with severe sickle cell disease (SCD) will be presented in an oral presentation on Saturday, June 16 at the 23rd Congress of the European Hematology Association (EHA) by Julie Kanter, M.D., Medical University of South Carolina, Charleston, South Carolina.

"The consistent production of increased amounts of anti-sickling HbA^{T87Q} in the Group C patients reflects the substantial positive impact of the changes introduced with the amended HGB-206 study protocol and refined manufacturing process. All four Group C patients with greater than or equal to three months follow-up are making over 30 percent anti-sickling HbA^{T87Q}. The first patient treated, now with six months of follow-up, is producing over 60 percent anti-sickling HbA^{T87Q} with a normal total hemoglobin level of 14.2 g/dL," said David Davidson, M.D., chief medical officer, bluebird bio. "The upward trajectory in Group C at these early time points suggests the potential for these patients to exceed the initially proposed therapeutic target of 30 percent anti-sickling HbA^{T87Q}. We continue to define the development plan with regulatory authorities, and with further follow-up, we hope to see even higher levels of HbA^{T87Q}, as well as sustained clinical benefit for patients."

SCD is a genetic disease that causes the protein in red blood cells, called hemoglobin, to be misshapen. As a result of this abnormal hemoglobin, many affected individuals live with severe anemia and vaso-occlusive events which include severe, recurrent pain crises that lead to organ damage and shortened life span.

"The early data from Group C patients are very exciting and provide increasing confidence that LentiGlobin has the potential to deliver transformative benefit to patients. The longer-term data from patients treated earlier in the study show that levels of anti-sickling HbA^{T87Q} in patients with SCD treated with LentiGlobin remain stable for at least

two years," said Dr. Kanter, a lead investigator of the HGB-206 study. "Treatment options that can address the underlying cause of sickle cell disease are limited and LentiGlobin gene therapy has the potential to prevent or substantially reduce damaging symptoms associated with this debilitating disease."

Recent Progress in Gene Therapy for Severe Sickle Cell Disease: Updated Interim Results from a Phase 1 Clinical Study of LentiGlobin Gene Therapy (Abstract S836)

Presenter: Julie Kanter, M.D., Medical University of South Carolina, Charleston, SC
Date & Time: Saturday, June 16, 2018, 12:30 – 12:45 p.m. CEST (6:30 a.m. EDT)
Location: Room A8

HGB-206 is an ongoing, open-label study designed to evaluate the safety and efficacy of LentiGlobin gene therapy for the treatment of adults with severe SCD. Patients in this study are divided into three cohorts: A, B and C. Patients in Group A were treated under the original study protocol. Patients in Group B were treated under an amended study protocol that included a refined Drug Product (DP) manufacturing process intended to increase DP vector copy number (VCN) as well as changes to improve engraftment of gene-modified stem cells. Patients in both Group A and B had DP made from stem cells collected using bone marrow harvest. Patients in Group C were also treated under the amended study protocol, but received LentiGlobin gene therapy made from stem cells collected from peripheral blood after mobilization with plerixafor rather than via bone marrow harvest. Results, as of May 15, 2018, include:

- **Group C:** 6 patients treated under the amended study protocol and with DP manufactured using the refined process, median (range) follow-up 3 (1.2 – 6.0) months:
  - 4 of 6 patients had ≥ 3 months follow up, and were producing 3 – 6 g/dL of HbA^{T87Q} by 3 months
  - 1 patient was producing 8.8 g/dL of HbA^{T87Q} and a total hemoglobin level of 14.2 g/dL at 6 months
  - Median transduced CD34+ cells: 81%
  - Median DP cell dose: 7.1 x 10^6 CD34+ cells
  - Median DP VCN (copies per diploid genome): 4
  - Overall safety profile remains generally consistent with myeloablative conditioning
  - Continued feasibility of plerixafor mobilization and apheresis observed
- **Group B:** 2 patients treated under the amended study protocol and with DP manufactured using stem cells from bone marrow harvest with ≥ 9 months follow up:
  - Patient 1312, who received LentiGlobin manufactured entirely using a refined manufacturing process, was producing 7.2 g/dL HbA^{T87Q} and 12.8 g/dL of total hemoglobin (56% HbA^{T87Q}) at 9 months of follow-up
  - Patient 1313, who received LentiGlobin manufactured using a combination of the original and the refined manufacturing processes, was

producing 3.2 g/dL HbA^{T87Q} and 11.0 g/dL of total hemoglobin (29% HbA^{T87Q}) at 15 months of follow-up

- **Group A:** Long-term data on 7 patients in the initial study cohort with ≥ 2 years follow-up:
  - Steady levels of LentiGlobin vector and HbA^{T87Q} were maintained through 2 years (median follow-up: 24.2 months; range: 22.8-32.9)
  - Median transduced CD34+ cells: 25%
  - Media DP cell dose: 2.1 x 10^6 CD34+ cells
  - Median DP VCN: 0.6
  - Median (range) total hemoglobin at last study visit was 9.1 (7.1 - 11.4) g/dL

Conference Call & Webcast Information
bluebird bio will host a conference call and live webcast at 8:00 a.m. EDT on Friday, June 15, 2018. To access the live webcast, please visit the “Events & Presentations” page within the Investors and Media section of the bluebird bio website at http://investor.bluebirdbio.com. Alternatively, investors may listen to the call by dialing (844) 825-4408 from locations in the United States or +1 (315) 625-3227 from outside the United States. Please refer to conference ID number 4678706. A replay of the webcast will be available on the bluebird bio website for 90 days following the call.

About SCD
Sickle cell disease (SCD) is a serious, progressively debilitating, and life-threatening genetic disease. SCD results from production of abnormal sickle hemoglobin (HbS), which leads to sickled red blood cells (RBCs) and hemolysis. As a result of this abnormal hemoglobin, many affected individuals live with severe anemia and vaso-occlusive events which include severe, recurrent pain crises that lead to organ damage and shortened life span.

Where adequate medical care is available, common treatments for patients with SCD largely revolve around prevention of infection, and management and prevention of acute sickling episodes. Chronic management includes a limited number of pharmaceutical treatment options and, in certain cases, chronic transfusions. Allogeneic hematopoietic stem cell transplant (HSCT) is currently the only available option with the potential to correct the genetic deficiency in SCD. However, its use is limited to certain pediatric patients with severe disease who have an unaffected matched sibling donor. Complications of allogeneic HSCT include a risk of treatment-related mortality, graft failure, graft-versus-host disease (GvHD) and opportunistic infections, particularly in patients who undergo non-sibling-matched allogeneic HSCT.

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

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's research, development, manufacturing and regulatory approval plans for its LentiGlobin product candidate to treat severe sickle cell disease. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risks that the preliminary positive efficacy and safety results from our prior and ongoing clinical trials of LentiGlobin will not continue or be repeated in our ongoing, planned or expanded clinical trials of LentiGlobin, the risks that the changes we have made in the LentiGlobin manufacturing process or the HGB-206 clinical trial protocol will not result in improved patient outcomes, risks that the current or planned clinical trials of LentiGlobin will be insufficient to support regulatory submissions or marketing approval in the US and EU, the risk of a delay in the enrollment of patients in our clinical studies, and the risk that any one or more of our product candidates will not be successfully developed, approved or commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

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bluebird bio Presents New Data from Northstar (HGB-204) and Northstar-2 (HGB-207) Studies of LentiGlobin™ Gene Therapy in Patients with Transfusion-Dependent β-Thalassemia at Annual Congress of the European Hematology Association

– 7/8 non-β^0/β^0 patients with ≥ 6 months follow-up producing normal or near-normal amounts of total hemoglobin (11.1 – 13.3 g/dL) and are transfusion free in Northstar-2 Study –

– 8/10 of non-β^0/β^0 patients achieving and maintaining transfusion independence for up to 3 years in Northstar (HB-204) Study –

– On track to file Marketing Authorization Application in the European Union in second half of 2018 –

– Company to hold conference call and webcast today, June 15, at 8:00 a.m. EDT –

CAMBRIDGE, Mass. - June 15, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) announced that new data from the completed Phase 1/2 Northstar (HGB-204) study in adolescents and adults with transfusion-dependent β-thalassemia (TDT) and any genotype, and its ongoing, Phase 3 Northstar-2 (HGB-207) multicenter clinical study of LentiGlobin™ investigational gene therapy in patients with TDT and non-β^0/β^0 genotypes, will be presented in an oral session on June 16 at the 23rd Annual Congress of the European Hematology Association by Franco Locatelli, M.D., Ph.D., of the IRCCS Ospedale Pediatrico Bambino Gesù of Rome, Italy.

“The maturing data from HGB-204 and HGB-207 suggest that one-time treatment with LentiGlobin may address the underlying genetic cause of TDT. With our refined manufacturing process, the majority of patients with TDT and non-β^0/β^0 genotypes are transfusion-free and producing total hemoglobin at normal or near-normal levels,” said David Davidson, M.D., chief medical officer, bluebird bio. “We are on track to submit a marketing authorization application in the European Union later this year, and we continue to work closely with clinical investigators and regulatory authorities to complete our ongoing clinical trials and bring this important treatment option to patients as soon as possible.”

People with TDT need regular blood transfusions to survive, but chronic transfusions carry risks, including unavoidable iron overload that can result in multi-organ damage and shortened life expectancy. Eliminating or reducing the need for transfusions may reduce the long-term complications associated with TDT and current standards of care.

“Consistently higher *in vivo* vector copy numbers and HbA^{T87Q} hemoglobin levels in patients indicate that LentiGlobin manufacturing refinements have resulted in improved gene therapy characteristics and may enable sustained transfusion independence for a great majority of patients,” said Professor Locatelli, the lead investigator of the Northstar-2 study. “Further, we are now seeing more than three years of data from the Northstar study indicating that LentiGlobin

therapy may enable long-term transfusion independence in the majority of patients with non-β^0/β^0 genotypes. These results hold the promise to change the natural history of many patients with this severe genetic disorder of hemoglobin production."

LentiGlobin Gene Therapy for Transfusion-Dependent β-Thalassemia (TDT) in Patients with Non-β^0/β^0 Genotypes: Updated Results from Northstar-2 (Abstract #1510)

Presenter: Franco Locatelli, M.D., Ph.D., Professor of Pediatrics, University of Pavia, Italy and Director, Department of Pediatric Hematology and Oncology, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy
Oral Session: Cell and Gene Therapy: Clinical Results
Date & Time: Saturday, June 16, 2018, 11:45 a.m. – 12:00 p.m. CEST (5:45 a.m. EDT)
Location: Room A8

The safety and efficacy of LentiGlobin in patients with TDT were evaluated in the Phase 1/2 Northstar study (HGB-204). To further improve clinical results, a refined manufacturing process was used to produce LentiGlobin drug product (DP). The aim of the ongoing Phase 3 Northstar-2 study (HGB-207) is to evaluate the efficacy and safety of LentiGlobin DP with manufacturing refinements in patients with TDT and non-β^0/β^0 genotypes. Data from Northstar and Northstar-2 will be included in the oral presentation.

Northstar-2 (HGB-207) results include (as of May 15, 2018):

- 11 patients had been infused with LentiGlobin and the median follow-up was 8.5 months (range: 0.3-16.2 months).
- 7 of 8 patients are producing ≥ 7.6 g/dL of HbA^{T87Q} and are maintaining total hemoglobin levels of 11.1 – 13.3 g/dL by 6 months.
- These 7 patients with ≥ 6 months follow-up remain transfusion free for 4.7 – 15.1 months.
- For the 11 study participants, the median DP vector copy number (VCN) was 3.4 (range: 2.4-5.6) copies/diploid genome, and the median proportion of transduced $CD34^+$ cells was 82% (range: 53-90%).
- The safety profile of LentiGlobin to date is similar to that observed in the Northstar study, and consistent with myeloablative conditioning with single-agent busulfan. No grade 3 or higher DP-related adverse events (AE) have been observed.
- All study participants remain enrolled in the trial, and there have been no reports of graft- versus-host disease (GvHD).

Northstar (HGB-204) results include (as of March 7, 2018):

- All 18 patients have completed the primary two-year study and are continuing into the long-term follow-up study LTF-303.
- 8 of 10 patients with non-β^0/β^0 genotypes were transfusion independent for a median of 33 months as of last follow-up.

- For the 18 study participants, the median DP VCN was 0.7 (range: 0.3-1.5) copies/diploid genome, and the median proportion of transduced CD34+ cells was 32% (range: 17-58%).
- The safety profile of LentiGlobin DP continues to be consistent with myeloablative conditioning with single-agent busulfan. There have been no reports of GvHD and no deaths on the study.
- One serious AE of HIV infection was reported 23 months after infusion. HIV was contracted from typical exposure and is not related to treatment with LentiGlobin. This was confirmed by two laboratory tests that differentiate between HIV and the lentivirus used in LentiGlobin.

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About the Northstar (HGB-204) Study
The completed Phase 1/2 Northstar study was an open-label, single-dose, non-randomized, multi-center study conducted in the United States, Australia and Thailand. It was designed to evaluate the safety and efficacy of LentiGlobin in increasing hemoglobin production and eliminating or reducing transfusion dependence in subjects with transfusion-dependent beta-thalassemia. The study treated 18 adults and adolescents who are being followed to evaluate safety and efficacy post-LentiGlobin infusion. For more information on the Northstar study, please visit www.northstarclinicalstudies.com or clinicaltrials.gov using identifier NCT01745120.

About the Northstar-2 (HGB-207) Study
Northstar-2 is a Phase 3 global, multi-center study being conducted in the United States, Thailand, Germany, Italy, the United Kingdom, and France designed to evaluate the safety and efficacy of LentiGlobin drug product in patients with transfusion-dependent beta-thalassemia and non-β^0/β^0 genotypes. For this study, the manufacturing process by which the patient's cells are transduced with the LentiGlobin viral vector has been improved, with the intent of increasing vector copy number and the percentage of cells successfully transduced.

The target enrollment of the study is 15 adult and adolescent patients and 8 pediatric patients. The study's primary endpoint is the proportion of treated subjects who meet the definition of "transfusion independence," defined as total hemoglobin levels of at least 9 g/dL without any red blood cell transfusions for a continuous period of at least 12 months at any time during the study. For more information on the Northstar-2 study, please visit www.northstarclinicalstudies.com or clinicaltrials.gov using identifier NCT02906202.

About LentiGlobin
bluebird bio is developing LentiGlobin with a goal of filing for regulatory approval in the United States and the EU for TDT and for severe sickle cell disease (SCD). The company is currently conducting four ongoing clinical studies of LentiGlobin with a fifth that has recently completed. Studies currently ongoing include HGB-205, a single center Phase 1/2 study in both TDT and SCD; Northstar-2 (HGB-207) and Northstar-3 (HGB-212), both multi-center, international Phase 3 studies for the treatment of patients with both non-β^0/β^0 and β^0/β^0 TDT genotypes, respectively; and HGB-206, a multicenter Phase 1 study in the United States for the treatment of patients with severe SCD. In addition, bluebird is conducting a long-term safety and efficacy follow-up study (LTF-303) for subjects with hemoglobinopathies (TDT or severe SCD) who have been treated with LentiGlobin in bluebird bio-sponsored clinical studies.

LentiGlobin was granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of β-thalassemia and SCD. The FDA granted Breakthrough Therapy designation to LentiGlobin for the treatment of transfusion-dependent patients with β-thalassemia major and Fast-Track Designation for the treatment of beta-thalassemia major and for the treatment of certain patients with severe SCD. bluebird bio is participating in the EMA's Adaptive Pathways pilot program, which is part of the EMA's effort to improve timely access for patients to new medicines. The EMA granted Priority Medicines (PRIME) eligibility to LentiGlobin for the treatment of TDT.

About TDT
Transfusion-dependent β-thalassemia (TDT) is a severe genetic disease characterized by reduced or absent hemoglobin levels that results in severe anemia and ineffective red blood cell production. Supportive care for people with TDT consists of a lifelong regimen of chronic blood transfusions to enable survival and suppress symptoms of the disease, and iron chelation therapy to manage iron overload that results from the transfusions. Despite the availability of supportive care, many people with TDT experience serious complications and organ damage due to underlying disease and iron overload.

Allogeneic hematopoietic stem cell transplantation (HSCT) is currently the only available option with the potential to correct the genetic deficiency in TDT. Complications of allogeneic HSCT include a risk of treatment-related mortality, graft failure, graft-versus-host disease (GvHD) and opportunistic infections, particularly in patients who undergo non-sibling matched allogeneic HSCT.

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