



# A Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS) Participants Who Require Red Blood Cell Transfusions and Are ESA Naïve

**CLINICALTRIALS.GOV IDENTIFIER**  
NCT03682536

**RECRUITMENT STATUS**  
RECRUITING

**FIRST POSTED**  
SEPTEMBER 24, 2018

**LAST UPDATE POSTED**  
JULY 18, 2022

## STUDY DESCRIPTION

### Brief Summary

The purpose of this study is to determine the effectiveness of luspatercept (ACE-536) compared to epoetin alfa on red blood cell (RBC) transfusion independence (for at least 12 weeks) with a concurrent hemoglobin increase of at least 1.5 g/dL in participants with anemia due to revised international prognostic scoring system (IPSS-R) very low, low, or intermediate risk myelodysplastic syndromes (MDS) who require RBC transfusions and have never been exposed to erythropoiesis stimulating agent (ESA).

**Condition or Disease:** Myelodysplastic Syndromes

**Intervention/treatment:** Drug: Luspatercept  
Drug: Epoetin alfa

**Phase:** Phase 3

### DETAILED DESCRIPTION

N/A

## STUDY DESIGN

**Study Type:** Interventional

**Estimated Enrollment :** 350 participants

**Allocation :** Randomized

**Intervention Model :** Parallel Assignment

**Masking:** None (Open Label) ()

**Primary Purpose:** Treatment

**Official Title:** A Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS) Participants Who Require Red Blood Cell Transfusions and Are ESA Naïve

**Actual Study Start Date:** January 2019

**Estimated Primary Completion Date:** February 2023

**Estimated Study Completion Date:** June 2027

## ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Luspatercept	Drug: Luspatercept Specified dose on specified days
Active Comparator: Epoetin alfa	Drug: Epoetin alfa Specified dose on specified days

## OUTCOME MEASURES

**Primary Outcome Measures:** 1. Red blood cell transfusion independence (RBC-TI) for 12 weeks (84 days) with a mean hemoglobin increase  $\geq$  1.5 g/dL [ Time Frame: Week 1 through Week 24 ]

**Secondary Outcome Measures:** 1. RBC-TI for 24 weeks [ Time Frame: Week 1 through Week 24 ]

2. Mean hemoglobin change over 24 weeks [ Time Frame: Week 1 through Week 24 ]

3. Hematologic improvement - erythroid response (HI-E) per International Working Group (IWG) [ Time Frame: Week 1 through Week 24 ]

4. Time to HI-E [ Time Frame: Week 1 through Week 24 ]

5. RBC-TI for  $\geq$  12 weeks (84 days) [ Time Frame: Week 1 through Week 24 ]

6. Duration of RBC-TI  $\geq$  12 weeks (84 days) [ Time Frame: Week 1 through End of Treatment (EOT), up to approximately 60 months ]

7. Time to RBC-TI  $\geq$  12 weeks (84 days) [ Time Frame: Week 1 through Week 24 ]

8. Time to first red blood cell (RBC) transfusion [ Time Frame: Week 1 through EOT, up to approximately 60 months ]

9. RBC transfusion burden on treatment [ Time Frame: Week 1 through Week 24 ]

10. RBC-TI for  $\geq$  56 days (8 weeks) [ Time Frame: Week 1 through Week 24 ]

11. RBC-TI for a consecutive 24-week period [ Time Frame: Week 1 through Week 48 ]

12. The European Organization for Research and Treatment of Cancer Quality-of-Life questionnaire (EORTC QLQ-C30) [ Time Frame: Screening through Week 24 ]

13. The Functional Assessment of Cancer Therapy-Anemia Version 4 (FACT-An) questionnaire [ Time Frame: Screening through Week 24 ]
14. Number of participants with Adverse Events (AEs) [ Time Frame: Week 1 through 42 days post last dose ]
15. Pharmacokinetic - area under the concentration-time curve (AUC) [ Time Frame: Randomization through 1-year post first dose ]
16. Pharmacokinetic - maximum plasma concentration of drug (Cmax) [ Time Frame: Randomization through 1-year post first dose ]
17. Frequency of antidrug antibodies (ADA) [ Time Frame: Randomization through 1-year post first dose ]
18. Number of participants progressing to acute myeloid leukemia (AML) [ Time Frame: Randomization through up to 60 months ]
19. Percentage of participants progressing to AML [ Time Frame: Randomization through up to 60 months ]
20. Time to AML progression [ Time Frame: Randomization through up to 60 months ]
21. Overall survival [ Time Frame: Randomization through up to 60 months ]

## ELIGIBILITY CRITERIA

**Ages Eligible for Study:** 18 Years and older (Adult, Older Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

### Criteria

Inclusion Criteria:

Documented diagnosis of Myelodysplastic syndromes (MDS) according to WHO 2016 classification that meets revised international prognostic scoring system (IPSS-R) classification of very low, low, or intermediate risk disease, and have < 5% blasts in bone marrow Endogenous serum erythropoietin (sEPO) level of < 500 U/L Requires Red blood cell (RBC) transfusions, as documented by the criteria: Average transfusion requirement of 2 - 6 units/8 weeks of packed red blood cells (pRBCs) confirmed for a minimum of 8 weeks immediately preceding randomization Eastern Cooperative Oncology Group (ECOG) score of 0, 1, or 2

Exclusion Criteria: Clinically significant anemia due to iron, vitamin B12, or folate deficiencies, or autoimmune or hereditary hemolytic anemia, or hypothyroidism, or any type of known clinically significant bleeding or sequestration or drug induced anemia Known history of diagnosis of Acute myeloid leukemia (AML) Uncontrolled hypertension, defined as repeated elevations of systolic blood pressure (SBP) of  $\geq 150$  mmHg and/or diastolic blood pressure (DBP)  $\geq 100$  mmHg despite adequate treatment Other protocol-defined inclusion/exclusion criteria apply

## CONTACTS AND LOCATIONS

### Contacts

Contact: BMS Study Connect Contact [www.BMSStudyConnect.com](http://www.BMSStudyConnect.com) 855-907-3286 [Clinical.Trials@bms.com](mailto:Clinical.Trials@bms.com)

Contact: First line of the email MUST contain the NCT# and Site #.

### Locations

United States, Alabama	Alabama Oncology - Grandview Cancer Center	Birmingham
United States, California	Alta Bates Summit Medical Center	Berkeley
United States, California	Sharp Memorial Hospital	San Diego
United States, California	Innovative Clinical Research Institute	Whittier
United States, California	Innovative Clinical Research Institute	Whittier
United States, Connecticut	Yale Cancer Center	New Haven
United States, District of Columbia	National Association of Veterans Research and Education Foundations NAVREF	Washington
United States, Florida	Florida Cancer Institute	Hudson
United States, Florida	Florida Cancer Specialists North Region Sarah Cannon Research	Saint Petersburg
United States, Florida	SCRI Florida Cancer Specialists PAN	Tallahassee
United States, Florida	Moffitt Cancer Center	Tampa
United States, Florida	Moffitt Cancer Center	Tampa
United States, Florida	Florida Cancer Specialists	West Palm Beach
United States, Georgia	Northwest Georgia Oncology Centers, PC	Austell
United States, Kentucky	Norton Healthcare	Louisville
United States, Kentucky	Western Kentucky Hematology and Oncology Group	Paducah
United States, Maryland	Center For Cancer and Blood Disorders	Bethesda
United States, Maryland	Center For Cancer And Blood Disorders	Bethesda
United States, Missouri	HCA Midwest Health	Kansas City
United States, New Jersey	Astera Cancer Care East Brunswick	East Brunswick
United States, New Jersey	Hackensack University Medical Center	Hackensack
United States, North Carolina	East Carolina University	Greenville
United States, Oregon	Providence Portland Medical Center	Portland

United States, Oregon	Oregon Health & Science University	Portland
United States, Pennsylvania	Univ of Pittsburgh Medical Center	Pittsburgh
United States, South Carolina	Carolina Blood and Cancer Care	Rock Hill
United States, Tennessee	Tennessee Oncology	Nashville
United States, Texas	Baylor University Medical Center	Dallas
United States, Texas	UT Southwestern Simmons Cancer Center	Dallas
United States, Texas	University of Texas- MD Anderson	Houston
United States, Utah	Utah Cancer Specialists - South Salt Lake	Salt Lake City
United States, Virginia	University of Virginia Health System	Charlottesville
United States, Virginia	Peninsula Cancer Institute	Chesapeake
United States, Washington	Providence Regional Cancer Partnership	Everett
Australia, New South Wales	Border Medical Oncology - Albury Wodonga Regional Cancer Centre	Albury
Australia, New South Wales	Blacktown Hospital	Blacktown
Australia, New South Wales	Local Institution - 213	Blacktown
Australia, New South Wales	Concord Repatriation General Hospital	Concord
Australia, New South Wales	St George Hospital	Kogarah
Australia, New South Wales	Shoalhaven Cancer Care Centre	Nowra
Australia, New South Wales	Newcastle Calvary Mater Hospital	Waratah
Australia, New South Wales	Wollongong Hospital	Wollongong
Australia, Queensland	Icon Cancer Foundation	Auchenflower
Australia, South Australia	Royal Adelaide Hospital	Adelaide
Australia, Victoria	Monash Medical Centre	Clayton
Australia, Victoria	Cabrini Hospital	Malvern
Australia, Victoria	Local Institution - 203	Malvern
Australia, Victoria	The Alfred Hospital	Melbourne
Australia, Western Australia	Perth Blood Institute	West Perth
Australia	Local Institution - 212	Randwick
Australia	The Prince of Wales Hospital	Randwick
Austria	Elisabethinen Hospital Linz	Linz
Austria	Medizinische Universitat Wien	Vienna
Belgium	ZNA Middelheim	Antwerpen
Belgium	Algemeen Ziekenhuis Klina	Brasschaat
Belgium	Cliniques Universitaires St-Luc	Brussels
Belgium	Grand Hopital de Charleroi	Charleroi
Belgium	AZ Groeninge	Kortrijk
Belgium	UZ Gasthuisberg	Leuven
Belgium	H. Hartziekenhuis Roeselare-Menen vzw campus Wilgenstraat	Roeselare
Canada, Alberta	Tom Baker Cancer Centre	Calgary
Canada, Alberta	University of Alberta	Edmonton
Canada, Ontario	Juravinski Cancer Centre	Hamilton
Canada, Ontario	Local Institution - 142	Hamilton
Canada, Ontario	Ottawa General Hospital	Ottawa
Canada, Ontario	Sunnybrook Health Sciences Centre	Toronto
Canada, Quebec	Hopital Maisonneuve Rosemont dba CIUSSS de l'Est de l'le de Montreal	Montreal
Canada, Quebec	Sir Mortimer B. Davis - Jewish Genl	Montreal

Canada, Saskatchewan	Saskatoon Cancer Center	Saskatoon
Canada	Centre Hospitalier Universitaire de Sherbrooke CHUS	Sherbrooke
Czechia	Fakultni nemocnice Hradec Kralove	Hradec Kralove
Czechia	Local Institution - 560	Hradec Kralove
Czechia	Fakultni Nemocnice Ostrava	Ostrava-Poruba
Czechia	Local Institution - 564	Ostrava-Poruba
Czechia	Fakultni nemocnice Kralovske Vinohrady	Prague 10
Czechia	Local Institution - 562	Praha 2
Czechia	Vseobecna Fakultni Nemocnice v Praze	Praha 2
Czechia	Ustav hematologie a krevni transfuze	Praha
France	CHU Angers	Angers
France	Local Institution - 317	Angers
France	Centre Hospitalier de la cote basque	Bayonne
France	CHU de Caen	Caen Cedex 9
France	Centre Hospitalier Universitaire de Grenoble Hopital Albert Michallon	La Tronche
France	Centre Hospitalier Le Mans	Le Mans
France	CHRU de Lille France	Lille
France	Local Institution - 309	Lille
France	CHU Limoges	Limoges Cedex
France	Hotel Dieu CHU Nantes	Nantes Cedex 01
France	CHU Nice Hopital de L'Archet 2	Nice Cedex 3
France	Assistance Publique - Hopitaux de Paris - Hopitaux Saint-Louis	Paris
France	Local Institution - 302	Paris
France	Cochin, Hôpital	Paris
France	CHU Bordeaux	Pessac
France	Local Institution - 308	Pessac
France	Centre Hospitalier Lyon Sud	Pierre Bénite
France	CHU de Poitiers	Poitiers
France	Institut de Cancérologie Strasbourg Europe	Strasbourg
France	CHU Purpan	Toulouse
France	CHRU Hopital BretonneauOnco-hematologie	Tours cedex
France	CHU de Nancy-Hopital Brabois Adulte	Vandoeuvre les Nancy
Germany	Stauferklinikum Schwab. Gmund	Baden-Warttemberg
Germany	Medizinisches Versorgungszentrum (MVZ) Onkologischer Schwerpunkt am Oskar-Helene-Heim	Berlin
Germany	Local Institution - 426	Dresden
Germany	Universitaetsklinikum Carl Gustav Carus	Dresden
Germany	St. Johannes Krankenhaus Duisburg	Duisburg
Germany	Marien Hospital	Dusseldorf
Germany	OncoResearch Lerchenfeld GmbH	Hamburg
Germany	Universitaetsklinikum Schleswig-Holstein	Keil
Germany	Praxis fuer Haematologie und Onkologie Koblenz	Koblenz
Germany	Ärzte f. Innere Medizin Gemeinschaftspraxis f. Hamatologie u. Onkologie	Köln
Germany	Local Institution - 430	Leipzig
Germany	Universitaetsklinikum Leipzig	Leipzig

Germany	Universitaetsklinikum Mannheim	Mannheim
Germany	Klinikum rechts der Isar der Technischen Universitaet Muenchen	Munchen
Germany	University Hospital of Ulm	Ulm
Germany	Klinkum der Stadt Villingen-Schwenningen GmbH	Villingen-Schwenningen
Germany	Rems-Murr-Kliniken	Winnenden
Germany	Hamatologisch-onkologische Praxis	Würzburg
Greece	University Hospital of Alexandroupolis	Alexandroupolis
Greece	Evangelismos General Hospital of Athens	Athens
Greece	Laiko General Hospital of Athens	Athens
Greece	Laiko General Hospital of Athens	Athens
Greece	Local Institution - 391	Athens
Greece	Attikon university General Hospital	Athens
Greece	General Hospital of Athens - George Gennimatas	Athina
Greece	Local Institution - 395	Athina
Greece	University General Hospital of Heraklion	Heraklion
Greece	University of Patras	Patras
Greece	University General Hospital of Patras	Rio Patras
Greece	AHEPA University General Hospital of Thessaloniki	Thessaloniki
Greece	Georgios Papanikolaou General Hospital of Thessaloniki	Thessaloniki
Hungary	Semmelweis Egyetem	Budapest
Hungary	Del-pesti Centrumkorhaz- Orszagos Hematologiai és Infektologiai Intezet	Budapest
Hungary	Debreceni Egyetem Orvos- es Egyszegtudomanyi Centrum	Debrecen
Hungary	Somogy Megyei Kaposi Mor Oktato Korhaz	Kaposvar
Hungary	Local Institution - 536	Nyiregyhaza
Hungary	Szabolcs-Szatmar-Bereg Megyei Korhazak es Egyetemi Oktatokorhaz , Josa Andras Oktatókórház	Nyiregyhaza
Hungary	Szegedi Tudomanyegyetem Szent-Gyorgyi Albert Klinikai Kozpont	Szeged
Israel	Carmel Medical Center	Haifa
Israel	Shaare Zedek Medical Center	Jerusalem
Israel	Hadassah Medical Center	Jerusalem
Israel	Meir Medical Center	Kfar-Saba
Israel	Galilee Medical Center	Nahariya
Israel	Tel Aviv Sourasky Medical Center Department of Hematology	Tel Aviv
Israel	Shamir Medical Center - Assaf Harofeh	Zerifin
Italy	Istituto di Ematologia L. e A. Seragnoli-Azienda Ospedaliero Universitaria Policlinico S. Orsola M	Bologna
Italy	Azienda Ospedaliera Universitaria Careggi	Firenze
Italy	Istituto Scientifico Romagnolo Per Lo Studio e La Cura Dei Tumori (I.R.S.T.)	Meldola
Italy	A.O. Ospedale Ca Granda - Niguarda	Milano
Italy	Local Institution - 321	Milano
Italy	Azienda Ospedaliero - Universitaria San Luigi Gonzaga	Orbassano
Italy	Hospital of Di Padova	Padova
Italy	Azienda Ospedaliera Bianchi Melacrino Morelli	Reggio Di Calabria
Italy	Local Institution - 326	Reggio Di Calabria
Italy	Fondazione PTV Policlinico Tor Vergata	Roma

Italy	Local Institution - 328	Roma
Italy	Azienda Ospedaliera Sant Andrea	Roma
Italy	La Sapienza, University of Rome	Rome
Italy	Istituto Clinico Humanitas	Rozzano
Italy	Azienda Ospedaliero-Universitaria Santa Maria della Misericordia die Udine	Udine
Japan	Hyogo Prefectural Amagasaki General Medical Center	Amagasaki-Shi
Japan	Fujisawa City Hospital	Fujisawa-Shi
Japan	National Hospital Organization Kyushu Medical Center	Fukuoka
Japan	Hitachi General Hospital	Hitachi, Ibaraki
Japan	Kameda General Hospital	Kamogawa
Japan	JCHO Kyushu Hospital	Kitakyushu-Shi
Japan	Matsuyama Red Cross Hospital	Matsuyama
Japan	Nagaoka Red Cross Hospital	Nagaoka-Shi
Japan	The Japanese Red Cross Nagasaki Genbaku Hospital	Nagasaki
Japan	National Hospital Organization - Nagoya Medical Center	Nagoya-shi
Japan	Ogaki Municipal Hospital	Ogaki
Japan	Okayama City General Medical Center	Okayama
Japan	Kindai University Hospital	Osaka-Sayama
Japan	Osaka City University Hospital	Osaka
Japan	Kitasato University Hospital	Sagamihara
Japan	Aiiku Hospital	Sapporo-shi
Japan	Tohoku University Hospital	Sendai
Japan	Japan Red Cross Medical Center	Shibuya-ku
Japan	Dokkyo Medical University Hospital	Shimotsuga-gun
Japan	NTT Medical Center Tokyo	Shinagawa-ku, Tokyo
Korea, Republic of	Pusan National University Hospital	Busan
Korea, Republic of	Kyungpook National University Hospital	Daegu
Korea, Republic of	Chonnam National University Hwasun Hospital	Hwasun-Gun
Korea, Republic of	Seoul National University Bundang Hospital	Seongnam-si
Korea, Republic of	Local Institution - 256	Seoul
Korea, Republic of	The Catholic University of Korea Seoul - Saint Mary's Hospital	Seoul
Korea, Republic of	Samsung Medical Center	Seoul
Korea, Republic of	Seoul National University Hospital	Seoul
Korea, Republic of	Asan Medical Center	Seoul
Korea, Republic of	Local Institution - 254	Seoul
Lithuania	Hospital of Lithuanian University Health and Sciences	Kaunas
Lithuania	Vilnius University Hospital Santariskiu Klinikos	Vilnius
Netherlands	VU University Medical Center	Amsterdam
Netherlands	HagaZiekenhuis	Den Haag
Netherlands	Radboudumc	Nijmegen
Netherlands	Erasmus Universitair Medisch Centrum	Rotterdam
Netherlands	Zuyderland Medisch Centrum	Sittard-Geleen
Poland, Łódzkie	Local Institution - 570	Lodz
Poland	Local Institution - 575	Gdansk
Poland	Uniwersyteckie Centrum Kliniczne	Gdansk

Poland	Wojewodzkie Wielospecjalistyczne Centrum Onkologii i Traumatologii im. M. Kopernika w Lodzi	Lodz
Poland	Samodzielny Publiczny Szpital Kliniczny nr 1 Klinika Hematoonkologii i Transplantacji Szpiku	Lubin
Poland	Local Institution - 576	Poznan
Poland	Szpital Kliniczny im. H.Swieckiego Uniwersytetu Medycznego im. Karola Marcinkowskiego w Poznaniu	Poznan
Poland	Kliniczny Szpital Wojewodzki nr 1 im. Fryderyka Chopina w Rzeszowie	Rzyszów
Poland	Wojewodzki Szpital Specjalistyczny im Korczaka w Supsku	Slupsk
Poland	Local Institution - 578	Walbrzych
Poland	Specjalistyczny Szpital im. dra Alfreda Sokolowskiego	Walbrzych
Poland	Wojskowy Instytut Medyczny	Warsaw
Poland	Samodzielny Publiczny Szpital Kliniczny Nr 1 we Wrocławiu	Wroclaw
Poland	Akademicki Szpital Kliniczny Klinika Reumatologii i Chorob Wewnętrznych	Wroclaw
Portugal	Hospital José Joaquim Fernandes	Beja
Portugal	Hospital de Braga	Braga
Portugal	Instituto Portugues de Oncologia de Lisboa, Francisco Gentil	Lisboa
Portugal	Ipo Instituto Portugues De Oncologia Porto	Porto
Portugal	Centro Hospitalar de Setubal EPE	Setubal
Russian Federation	Kaluga Regional Hospital	Kaluga
Russian Federation	Kaluga Regional Hospital	Kaluga
Russian Federation	Federal State Institute Kirov Research Inst. of Hematology and Blood Transfusion of Rosmedtec	Kirov
Russian Federation	Federal State Institute Kirov Research Inst. of Hematology and Blood Transfusion of Rosmedtec	Kirov
Russian Federation	Krasnoyarsk Regional Clinical Hospital	Krasnoyarsk
Russian Federation	Krasnoyarsk Regional Clinical Hospital	Krasnoyarsk
Russian Federation	Moscow Clinical Scientific Center	Moscow
Russian Federation	Moscow Clinical Scientific Center	Moscow
Russian Federation	City Clinical Hospital 52	Moscow
Russian Federation	Moscow State Healthcare Institution City clinical hospital n.a. S.P.Botkin	Moscow
Russian Federation	Moscow State Healthcare Institution City clinical hospital n.a. S.P.Botkin	Moscow
Russian Federation	City Clinical Hospital 40	Moscow
Russian Federation	Saratov State Medical University	Saratov
Russian Federation	Saratov State Medical University	Saratov
Russian Federation	Federal Centre of Heart, Blood and Endocrinology of Rosmed technologies V.A. Almazov	St Petersburg
Russian Federation	Federal Centre of Heart, Blood and Endocrinology of Rosmed technologies V.A. Almazov	St Petersburg
Russian Federation	First Pavlov State Medical University of St. Petersburg	St. Petersburg
Russian Federation	First Pavlov State Medical University of St. Petersburg	St. Petersburg
Russian Federation	Tula Regional Oncology Center	Tula
Russian Federation	Tula Regional Oncology Center	Tula
Spain	Hospital Universitari Vall d'Hebron	Barcelona
Spain	Instituto Catalan de Oncologia-Hospital Duran i Reynals	Barcelona
Spain	Hospital Virgenes de las Nieves	Granada
Spain	Hospital General Universitario Gregorio Maranon	Madrid
Spain	Hospital Universitario 12 de Octubre	Madrid
Spain	Hospital Universitario Virgen De La Victoria	Malaga

Spain	Hospital General Universitario Morales Meseguer	Murcia
Spain	C. H. de Orense	Ourense
Spain	Hospital Universitario Central de Asturias	Oviedo
Spain	Hospital Son Espases	Palma de Mallorca
Spain	Hospital Universitario de Salamanca	Salamanca
Spain	Hospital Universitario Virgen del Rocio	Seville
Spain	Hospital Clinico Universitario de Valencia	Valencia
Spain	Hospital Universitari i Politecnic La Fe de Valencia	Valencia
Sweden	Sahlgrenska Universitetssjukhuset	Goteborg
Sweden	Skanes Universitetssjukhus Lund	Lund
Sweden	Karolinska Universitetssjukhuset - Huddinge	Stockholm
Switzerland	Inselspital Bern	Bern
Switzerland	Local Institution - 450	Bern
Switzerland	Luzerner Kantonsspital	Luzern 16
Switzerland	Kantonsspital Winterthur	Winterthur
Taiwan	Changhua Christian Hospital	Changhua City, Changhua
Taiwan	Kaohsiung Chang Gung Memorial Hospital	Niaosong District Kaohsiung City
Taiwan	China Medical University Hospital	Taichung City
Taiwan	Taichung Veterans General Hospital	Taichung
Taiwan	National Taiwan University Hospital	Taipei, Zhongzheng Dist.
Turkey	Ankara University Medical Faculty	Ankara
Turkey	Celal Bayar University Medical Faculty	Manisa
Turkey	Karadeniz Technical University Medical Faculty	Trabzon
Ukraine	Cherkassy Regional Oncology Center	Cherkassy
Ukraine	Cherkassy Regional Oncology Center	Cherkassy
Ukraine	Dnipropetrovsk City Multidisciplinary Clinical Hospital No 4, Hematological Center	Dnipro
Ukraine	Dnipropetrovsk City Multidisciplinary Clinical Hospital No 4, Hematological Center	Dnipro
Ukraine	State Institution National Research Centre for Radiation Medicine of NAMS of Ukraine	Kyiv
Ukraine	Institute of Blood Pathology and Transfusion Medicine of the UAMS	Lvov
Ukraine	Institute of Blood Pathology and Transfusion Medicine of the UAMS	Lvov
Ukraine	Mykolaiv Regional Clinical Hospital	Mykolaiv
Ukraine	Mykolaiv Regional Clinical Hospital	Mykolaiv
Ukraine	CI of TRC Ternopil University Hospital	Ternopil
Ukraine	CI of TRC Ternopil University Hospital	Ternopil
United Kingdom	Aberdeen Royal Infirmary	Aberdeen
United Kingdom	Royal Bournemouth Hospital	Bournemouth
United Kingdom	University of Oxford	Headington, Oxford
United Kingdom	Lincoln County Hospital	Lincoln
United Kingdom	Kings College Hospital	London
United Kingdom	Hammersmith Hospital	London
United Kingdom	Christie Hospital NHS Trust	Manchester

#### Sponsors and Collaborators

Celgene

Acceleron Pharma Inc.



**Investigator**

Study Director : Bristol-Myers Squibb Bristol-Myers Squibb

---

**MORE INFORMATION**

**Responsible Party :** Celgene  
**ClinicalTrials.gov Identifier :** NCT03682536  
**Other Study ID Numbers :** ACE-536-MDS-002, U1111-1218-1810, 2017-003190-34  
**First Posted :** September 24, 2018  
**Last Update Posted :** July 18, 2022  
**Last Verified :** July 2022  
**Studies a U.S. FDA-regulated Drug Product:** Yes  
**Studies a U.S. FDA-regulated Device Product:** No  
**Keywords provided by Celgene:** *Luspatercept*  
*ACE-536*  
*Anemia*  
*Myelodysplastic Syndromes*  
*Blood Transfusion RBC Transfusion*  
*Erythropoiesis-stimulating agents*  
*Erythropoietin*  
*Myelodysplasia*  
*Anemia*  
*Disease*  
**Additional relevant MeSH terms :** *Hematologic Diseases* *Pathologic Processes*  
*Preleukemia* *Bone Marrow Diseases*  
*Myelodysplastic Syndromes* *Precancerous Conditions*  
*Syndrome* *Neoplasms*