

# Novel and Emerging Therapeutic Strategies in the Management of Hematologic Disorder-Related Anemia

## **FACULTY INTERVIEWS**

Rami Komrokji, MD

Maria-Domenica Cappellini, MD

## **EDITOR**

Neil Love, MD



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<b>Contact Information</b>	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: <a href="mailto:DrNeilLove@ResearchToPractice.com">DrNeilLove@ResearchToPractice.com</a>
<b>For CME/CNE Information</b>	Email: <a href="mailto:CE@ResearchToPractice.com">CE@ResearchToPractice.com</a>

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# Novel and Emerging Therapeutic Strategies in the Management of Hematologic Disorder-Related Anemia

## A Continuing Medical Education Audio Program

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### OVERVIEW OF ACTIVITY

Several hematologic disorders are associated with anemia that can be linked to ineffective erythropoiesis. This occurs when the marrow cannot maintain adequate red blood cell production or produces defective or immature cells that are incapable of proper functioning. Myelodysplastic syndromes (MDS), myeloproliferative neoplasms and beta thalassemia are examples of disorders often associated with moderate to severe anemia. Few treatment options are available for inherited and acquired disorders of erythropoiesis, and despite significant research gains many uncertainties and clinical challenges persist in regard to the management of related anemia. Thus it is imperative that the oncology community have access to up-to-date medical education programs designed to comprehensively address current therapeutic approaches and promising research that can facilitate effective clinical decision-making.

To bridge the gap between research and patient care, this program features one-on-one discussions with leading hematology-oncology investigators. Upon completion of this CME activity, medical oncologists and hematologists should be able to formulate an up-to-date and more complete approach to the care of patients with anemia associated with hematologic disorders.

### LEARNING OBJECTIVES

- Understand the causes and consequences of blood disorder-associated anemia, and use this information to refine disease management and supportive care of patients.
- Describe the biologic rationale for and mechanism of action of erythroid maturation agents (EMAs) in the treatment of anemia secondary to select hematologic disorders, including MDS, beta thalassemia and myelofibrosis.
- Appraise emerging clinical data with the EMA luspatercept in preparation for its potential availability for the management of beta thalassemia and/or low-risk MDS.
- Recognize the importance of screening for iron overload in transfusion-dependent patients, and develop a systematic approach for initiating and delivering iron chelation therapy.
- Analyze the biologic basis for and early research data with gene-based therapies for beta thalassemia.

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## CME INFORMATION

### FACULTY AFFILIATIONS



#### **Rami Komrokji, MD**

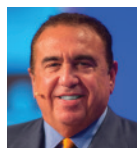
Senior Member  
Section Head, Leukemia and MDS  
Vice Chair  
Department of Malignant Hematology  
H Lee Moffitt Cancer Center  
Professor of Oncologic Sciences  
University of South Florida  
Tampa, Florida



#### **Maria-Domenica Cappellini, MD**

Professor of Internal Medicine  
University of Milan  
Fondazione IRCCS Ca' Granda  
Ospedale Policlinico  
Milan, Italy

### EDITOR



#### **Neil Love, MD**

Research To Practice  
Miami, Florida

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## Interview with Rami Komrokji, MD

### Tracks 1-22

- Track 1** Approved and emerging therapies for patients with transfusion-dependent myelodysplastic syndromes (MDS); mechanism of action of the investigational erythroid maturation agent (EMA) luspatercept
- Track 2** Design, entry criteria and outcomes of the Phase III MEDALIST trial of luspatercept for the treatment of anemia in patients with very low-, low- or intermediate-risk MDS with ring sideroblasts who require red blood cell (RBC) transfusions
- Track 3** Clinical experience with the EMAs luspatercept and sotatercept
- Track 4** Potential FDA approval of luspatercept for the management of low-risk MDS
- Track 5** Ongoing investigation of luspatercept-based strategies for MDS
- Track 6** Investigation of venetoclax in combination with a hypomethylating agent for higher-risk MDS
- Track 7** Role of luspatercept in myelofibrosis; predictors of benefit from luspatercept
- Track 8** **Case:** A man in his mid-70s presents with fatigue and dyspnea and is diagnosed with lower-risk MDS with ring sideroblasts
- Track 9** Initial workup and diagnosis for patients with MDS
- Track 10** Risk stratification in MDS and therapeutic options for patients at lower versus higher risk
- Track 11** Clinical experience with EMAs for lower-risk, RBC transfusion-dependent MDS
- Track 12** Monitoring and management of iron overload in patients with lower-risk, RBC transfusion-dependent MDS
- Track 13** **Case:** A man in his early 60s with lenalidomide-refractory, lower-risk MDS and a del(5q) mutation receives the telomerase inhibitor imetelstat on a clinical trial
- Track 14** **Case:** A man in his mid-70s with postpolycythemia vera myelofibrosis with anemia and splenomegaly receives initial ruxolitinib therapy
- Track 15** Activity and tolerability of JAK1/2 inhibitors in myelofibrosis
- Track 16** **Case:** A woman in her mid-70s with myelofibrosis and a JAK2 mutation presents with progressive splenomegaly and anemia and receives ruxolitinib
- Track 17** Novel agents and strategies under investigation for myeloproliferative neoplasms (MPNs)
- Track 18** Incidence of IDH1/2 mutations in patients with MPNs; responses to IDH1/2 inhibitors and ongoing clinical investigations
- Track 19** Activity of the antifibrotic immunomodulator PRM-151 in patients with myelofibrosis
- Track 20** Common misconceptions about the use of erythropoietin-stimulating agents
- Track 21** Perspective on the appropriate choice of therapy for patients with intermediate-2 or high-risk myelofibrosis
- Track 22** Lack of correlation between JAK2 mutation status and response to ruxolitinib

## Interview with Maria-Domenica Cappellini, MD

### Tracks 1-15

- Track 1** Pathophysiology of thalassemia
- Track 2** Evolution of therapies for thalassemia
- Track 3** Prevalence and incidence of thalassemia
- Track 4** Classification and genetic inheritance of thalassemia
- Track 5** Novel treatments under investigation for thalassemia; role of gene therapy and EMAs
- Track 6** Emerging data with luspatercept and sotatercept for patients with thalassemia
- Track 7** Results of the Phase III BELIEVE trial evaluating luspatercept versus placebo for adult patients with beta thalassemia who require regular RBC transfusions
- Track 8** Tolerability and side effects associated with luspatercept

## Interview with Dr Cappellini (continued)

- Track 9** Ongoing Phase II BEYOND study evaluating the efficacy and safety of luspatercept in adults with beta thalassemia who are not transfusion dependent
- Track 10** Activity of luspatercept in patients with anemia of chronic disease and MDS
- Track 11** Effect of luspatercept on quality of life for patients with thalassemia
- Track 12** Optimal selection of patients with thalassemia who would benefit from luspatercept
- Track 13** Gene therapy for transfusion-dependent beta thalassemia
- Track 14** Gene therapy process for patients with thalassemia
- Track 15** Perspective on novel approaches to the treatment of thalassemia

## Video Program

View the corresponding video interviews with (from left) Drs Komrokji and Cappellini by Dr Love at [www.ResearchToPractice.com/Anemia19/Video](http://www.ResearchToPractice.com/Anemia19/Video)



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## SELECT PUBLICATIONS

A phase I/II study evaluating safety and efficacy of autologous hematopoietic stem cells genetically modified with GLOBE lentiviral vector encoding for the human beta-globin gene for the treatment of patients affected by transfusion dependent beta-thalassemia. [NCT02453477](#)

A phase 3, open-label, randomized study to compare the efficacy and safety of luspatercept (ACE-536) versus epoetin alpha for the treatment of anemia due to IPSS-R very low, low or intermediate risk due to myelodysplastic syndrome (MDS) ESA in native subjects who require red blood cell transfusions. [NCT03682536](#)

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Shammo JM, Komrokji RS. Clinical consequences of iron overload in patients with myelodysplastic syndromes: The case for iron chelation therapy. *Expert Rev Hematol* 2018;11(7):577-86.

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Verstovsek S et al. Long-term survival in patients treated with ruxolitinib for myelofibrosis: COMFORT-I and -II pooled analyses. *J Hematol Oncol* 2017;10(1):156.

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*Novel and Emerging Therapeutic Strategies in the Management of Hematologic Disorder-Related Anemia*

**QUESTIONS (PLEASE CIRCLE ANSWER):**

1. Which of the following statements is true regarding the Phase III MEDALIST study investigating luspatercept in the treatment of anemia?
  - a. Eligible patients included those with high-risk MDS
  - b. No new safety signals were identified in the luspatercept arm
  - c. About 40% of patients who received luspatercept attained RBC transfusion independence
  - d. All of the above
  - e. Both b and c
  - f. Both a and c
  
2. Sotatercept has demonstrated activity in the treatment of anemia associated with which of the following diseases?
  - a. Myelofibrosis
  - b. Thalassemia
  - c. MDS
  - d. All of the above
  
3. The ongoing Phase II BEYOND study is evaluating the efficacy and safety of luspatercept in adult patients with beta thalassemia who \_\_\_\_\_ transfusion dependent.
  - a. Are
  - b. Are not
  
4. The BELIEVE trial demonstrated significant reductions in RBC transfusion burden with luspatercept in comparison to placebo for adult patients with transfusion-dependent beta thalassemia.
  - a. True
  - b. False
  
5. Which of the following statements most accurately describes the mechanism of action of luspatercept?
  - a. It inhibits VEGF receptors
  - b. It inhibits several ligands in the TGF-beta superfamily
  - c. It is an inhibitor of JAK1/2
  
6. The TELESTO trial evaluating deferasirox versus placebo for patients with low- or intermediate-1-risk MDS \_\_\_\_\_ its composite primary endpoint of time to death or first nonfatal event associated with cardiac or liver function or transformation to acute myeloid leukemia.
  - a. Met
  - b. Did not meet
  
7. Which of the following statements is true regarding the splicing factor SF3B1 gene mutation?
  - a. It is associated with benefit from luspatercept
  - b. It occurs with high frequency in patients with anemia with ring sideroblasts
  - c. It is associated with adverse outcomes among patients with MDS
  - d. All of the above
  - e. Both a and b
  
8. The ongoing Phase III COMMANDS trial is comparing \_\_\_\_\_ to an erythropoietin-stimulating agent for the treatment of anemia associated with MDS.
  - a. Luspatercept
  - b. Sotatercept
  - c. Aflibercept
  
9. Which of the following drug types best reflects the mechanism of action of PRM-151?
  - a. Antifibrotic immunomodulator
  - b. JAK2 inhibitor
  - c. PI3-kinase inhibitor
  
10. The JAK2/FLT3 inhibitor pacritinib does not confer significant benefit in terms of reduction in spleen volume and improvement in constitutional symptoms for patients with myelofibrosis and thrombocytopenia.
  - a. True
  - b. False



**EDUCATIONAL ASSESSMENT AND CREDIT FORM**

*Novel and Emerging Therapeutic Strategies in the Management of Hematologic Disorder-Related Anemia*

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

**PART 1 — Please tell us about your experience with this educational activity**

**How would you characterize your level of knowledge on the following topics?**

4 = Excellent    3 = Good    2 = Adequate    1 = Suboptimal

	BEFORE	AFTER
Biologic rationale for the investigation of luspatercept in the treatment of anemia associated with hematologic disorders	4 3 2 1	4 3 2 1
Results from the MEDALIST study evaluating luspatercept for the treatment of anemia in patients with MDS	4 3 2 1	4 3 2 1
Pathophysiology of beta thalassemia and emerging data with gene therapy	4 3 2 1	4 3 2 1
Key efficacy findings from the BELIEVE trial investigating luspatercept for beta thalassemia	4 3 2 1	4 3 2 1
Novel agents and strategies under investigation for myelofibrosis	4 3 2 1	4 3 2 1

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- Yes     No    If no, please explain: .....

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- This activity validated my current practice  
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**If you intend to implement any changes in your practice, please provide 1 or more examples:**

.....

.....

.....

**The content of this activity matched my current (or potential) scope of practice.**

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**Please respond to the following learning objectives (LOs) by circling the appropriate selection:**

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**As a result of this activity, I will be able to:**

- Understand the causes and consequences of blood disorder-associated anemia, and use this information to refine disease management and supportive care of patients. .... 4 3 2 1 N/M N/A
- Describe the biologic rationale for and mechanism of action of erythroid maturation agents (EMAs) in the treatment of anemia secondary to select hematologic disorders, including MDS, beta thalassemia and myelofibrosis.....4 3 2 1 N/M N/A
- Appraise emerging clinical data with the EMA luspatercept in preparation for its potential availability for the management of beta thalassemia and/or low-risk MDS. .... 4 3 2 1 N/M N/A

**EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)**

**As a result of this activity, I will be able to:**

- Recognize the importance of screening for iron overload in transfusion-dependent patients, and develop a systematic approach for initiating and delivering iron chelation therapy. . . . . 4 3 2 1 N/M N/A
- Analyze the biologic basis for and early research data with gene-based therapies for beta thalassemia. . . . . 4 3 2 1 N/M N/A

**Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:**

.....  
 .....  
 .....

**Would you recommend this activity to a colleague?**

Yes       No

If no, please explain: .....

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<b>Faculty</b>	<b>Knowledge of subject matter</b>				<b>Effectiveness as an educator</b>			
Rami Komrokji, MD	4	3	2	1	4	3	2	1
Maria-Domenica Cappellini, MD	4	3	2	1	4	3	2	1
<b>Editor</b>	<b>Knowledge of subject matter</b>				<b>Effectiveness as an educator</b>			
Neil Love, MD	4	3	2	1	4	3	2	1

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