

Visiting Professors

A case-based discussion on the management of myeloproliferative neoplasms

CME Information

TARGET AUDIENCE

This activity is intended for medical oncologists and other healthcare providers involved in the treatment of myeloproliferative neoplasms (MPNs).

OVERVIEW OF ACTIVITY

Myeloproliferative neoplasms (MPNs) largely consist of 3 disease entities, all heralding from clonal disorders in which an initial molecular event results in excessive production of blood cells. Importantly, although essential thrombocythemia (ET), polycythemia vera (PV) and myelofibrosis (MF) are clinically distinguishable based on laboratory and molecular parameters, they may represent a disease continuum whereby transformation from ET or PV to the more aggressive MF results in a homogenous pathologic entity with a similarly poor prognosis. In contrast to the rather indolent natural history of untransformed ET and PV, primary MF or post-PV/ET MF is a debilitating disease. Historically no FDA-approved therapy existed, but after the FDA approval of ruxolitinib in 2011 for intermediate- and high-risk MF, including primary MF, post-PV MF and post-ET MF, this agent has rapidly been adopted in clinical practice. Patient selection and dosing of ruxolitinib remain relevant topics of discussion and debate. Equally important, emerging research information on its use for patients with less aggressive MPNs, most notably PV, demonstrates that treatment algorithms for these patients are poised for significant change.

To provide clinicians with therapeutic strategies to address the disparate needs of patients with MPNs, the *Visiting Professors* series employs an innovative case-based approach that unites the perspectives of leading investigators and community oncologists. 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 MPNs.

LEARNING OBJECTIVES

- Review emerging clinical trial data and employ an understanding of disease biology to diagnose and communicate prognosis to patients with primary PV, ET and MF.
- Consider investigator perspectives regarding evidence-based therapeutic options in PV, ET and MF, and use this information to develop clinical algorithms intended to

enhance quality and quantity of life for patients with these distinct yet related diseases.

- Appreciate the recent FDA approval of ruxolitinib for patients with PV, and identify individuals who may be appropriate for therapeutic intervention with this agent.
- Develop an understanding of the emerging efficacy data and toxicity profiles of novel JAK inhibitors for MPNs in order to effectively prioritize clinical trial opportunities for appropriate patients.

ACCREDITATION STATEMENT

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AMERICAN BOARD OF INTERNAL MEDICINE (ABIM) — MAINTENANCE OF CERTIFICATION (MOC)

Successful completion of this CME activity enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Please note, this program has been specifically designed for the following ABIM specialty: **medical oncology**.

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This CME activity consists of a video component. To receive credit, the participant should watch the video, complete the Post-test with a score of 75% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/VPMPN116/Video/CME.

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Consulting Agreement: Novartis Pharmaceuticals Corporation; **Contracted Research:** Celgene Corporation, Genentech BioOncology.

William Harwin, MD

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No relevant conflicts of interest to disclose.

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Speakers Bureau and Ownership Interest: Celgene Corporation.

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Hardware/Software Requirements:

A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later

Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: May 2016

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Select Publications

A phase 2, open-label, translational biology study of momelotinib in transfusion-dependent subjects with primary myelofibrosis (PMF) or post-polycythemia vera or post-essential thrombocythemia myelofibrosis (post-PV/ET MF). NCT02515630

A phase 3, randomized, double-blind active-controlled study evaluating momelotinib vs ruxolitinib in subjects with primary myelofibrosis (PMF) or post-polycythemia vera or post-essential thrombocythemia myelofibrosis (post-PV/ET MF). NCT01969838

Gowin KL et al. **Final analysis of a multicenter pilot phase 2 study of ruxolitinib and danazol in patients with myelofibrosis.** *Proc ASH 2015;Abstract 1618.*

Guglielmelli P et al. **Impact of mutational status on outcomes in myelofibrosis patients treated with ruxolitinib in the COMFORT-II study.** *Blood 2014;123(14):2157-60.*

Harrison CN et al. **Long-term efficacy and safety in COMFORT-II, a phase 3 study comparing ruxolitinib with best available therapy for the treatment of myelofibrosis: 5-year final study results.** *Proc ASH 2015;Abstract 59.*

Harrison CN et al. **Health-related quality of life and symptoms in patients with myelofibrosis treated with ruxolitinib versus best available therapy.** *Br J Haematol 2013;162(2):229-39.*

Mesa RA et al. **Effects of ruxolitinib treatment on metabolic and nutritional parameters in patients with myelofibrosis from COMFORT-I.** *Clin Lymphoma Myeloma Leuk 2015;15(4):214-22.*

Mesa RA et al. **Effect of ruxolitinib therapy on myelofibrosis-related symptoms and other patient-reported outcomes in COMFORT-I: A randomized, double-blind, placebo-controlled trial.** *J Clin Oncol 2013;31(10):1285-92.*

Passamonti F et al. **Impact of ruxolitinib on the natural history of primary myelofibrosis: A comparison of the DIPSS and the COMFORT-2 cohorts.** *Blood 2014;123(12):1833-5.*

Prick J et al. **Clonal heterogeneity as a driver of disease variability in the evolution of myeloproliferative neoplasms.** *Experimental Hematology 2014;42(10):841-51.*

Vannucchi AM et al. **Ruxolitinib versus standard therapy for the treatment of polycythemia vera.** *N Engl J Med 2015;372(5):426-35.*

Verstovsek S et al. **PRM-151 in myelofibrosis: Durable efficacy and safety at 72 weeks.** *Proc ASH 2015;Abstract 56.*

Verstovsek S et al. **Phase 2 trial of PRM-151, an anti-fibrotic agent, in patients with myelofibrosis: Stage 1 results.** *Proc ASH 2014;Abstract 713.*

Verstovsek S et al. **The clinical benefit of ruxolitinib across patient subgroups: Analysis of a placebo-controlled, Phase III study in patients with myelofibrosis.** *Br J Haematol 2013;161(4):508-16.*

Verstovsek S et al. **A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis.** *N Engl J Med 2012;366(9):799-807.*