VOL 2 | ISSUE 1

Myeloproliferative Neoplasms™ UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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ABIM CME MOC ACCREDITED

CME Certified

Myeloproliferative Neoplasms™

UPDATE

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OVERVIEW OF ACTIVITY

Myeloproliferative neoplasms (MPNs) largely consist of 3 diseases 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 by 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 uniformly 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, post-PV 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. Not surprisingly, JAK inhibitors have been and continue to be critically evaluated for patients with both PV and ET. Most notably, in December 2014, the US FDA approved ruxolitinib as treatment for PV in patients who have experienced an inadequate response to or are intolerant of hydroxyurea. To bridge the gap between research and patient care, this issue of *Myeloproliferative Neoplasms Update* 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 MPNs.

LEARNING OBJECTIVES

- Appraise the evidence-based therapeutic options for patients with PV, ET and MF, and develop clinical algorithms intended to enhance quality and quantity of life for these individuals.
- Determine the role of ruxolitinib in the treatment of MF in patients with thrombocytopenia and anemia.
- Formulate a plan for managing the side effects associated with ruxolitinib to support quality of life and continuation of treatment.
- Recall emerging research data with the use of novel JAK inhibitors in the treatment of MF, and prepare for their potential availability in clinical practice.
- Appreciate the biologic rationale for and available efficacy and safety data with novel agents under investigation for the treatment of MPNs.

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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: **Dr Mesa** — Consulting Agreements: AOP Orphan, Novartis, Sierra Oncology; Contracted Research: AbbVie Inc, Celgene Corporation, Genentech, Incyte Corporation. **Dr Gerds** — Advisory Committee: Apexx Oncology, Celgene Corporation, CTI BioPharma Corp.

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Interview with Ruben A Mesa, MD

Tracks 1-26

Track 1 Molecular pathogenesis of myeloproliferative neoplasms (MPNs)

Track 2 Cytokine activation and its association with the distinct symptomatology of MPNs

Track 3 Targeting the JAK-STAT pathway in myelofibrosis (MF) and polycythemia vera (PV)

Track 4 **Case:** A 66-year-old man with symptomatic primary MF with a CALR mutation receives ruxolitinib

Track 5 Clinical parameters to evaluate when considering treatment with ruxolitinib

Track 6 Discussing the complexities of allogeneic transplant with patients considering this intervention

Track 7 Clinical outcomes and complication rates for younger versus older patients undergoing transplant

Track 8 Counseling patients regarding the efficacy and side-effect profile of ruxolitinib

Track 9 Symptom improvement with ruxolitinib; dosing for patients with MF

Track 10 Management of anemia associated with ruxolitinib treatment

Track 11 Approach to dosing ruxolitinib for patients with MF and cytopenias

Track 12 Consideration of ruxolitinib treatment holidays and therapy reinitiation for patients with increased splenomegaly

Track 13 Treatment options for patients with MF and disease progression on ruxolitinib

Track 14 Clonal evolution and outcomes in MF after ruxolitinib discontinuation

Track 15 Therapeutic options for patients who experience disease progression on ruxolitinib

Track 16 Activity, tolerability and ongoing investigation of novel JAK inhibitors pacritinib, momelotinib and fedratinib in MF

Track 17 FDA clinical hold on fedratinib due to possible occurrences of Wernicke encephalopathy in patients on the JAKARTA-1 trial and recent lift of the hold

Track 18 Ongoing investigation of fedratinib in MF

Track 19 Clinical experience with pacritinib, momelotinib and fedratinib

Track 20 Toward identifying molecular predictors of response to pacritinib, momelotinib and fedratinib

Track 21 **Case:** A 64-year-old woman with ruxolitinib-refractory MF receives fedratinib on the Phase II JAKARTA-2 trial

Track 22 Therapeutic approach to MF that progresses to acute myeloid leukemia

Track 23 Investigation of the novel Bcl-2 inhibitor navitoclax in combination with ruxolitinib for patients with MF

Track 24 Clinical manifestations and treatment of PV

Track 25 **Case:** A 56-year-old woman with high-risk PV and an inadequate response to hydroxyurea receives ruxolitinib

Track 26 Risk stratification and treatment for patients with essential thrombocythemia (ET)

Interview with Aaron T Gerds, MD, MS

Tracks 1-27

Track 1 Common misconceptions about MPNs

Track 2 Alterations of the JAK-STAT signaling pathway in MPNs

Track 3 **Case:** A 61-year-old woman with primary MF and mutations in JAK2, EZH2 and CALR receives ruxolitinib

Track 4 Prognostic significance of the JAK2, EZH2 and CALR mutations associated with MF

Track 5 Dosing and activity of ruxolitinib for MF

Track 6 Management of ruxolitinib-associated cytopenias and effect of ruxolitinib on disease pathogenesis

Track 7 Evolution of clinical research with the selective JAK2 inhibitor fedratinib for MF

Track 8 Association between fedratinib and thiamine levels; cytopenias associated with fedratinib

Interview with Dr Gerds (continued)

Track 9	Efficacy of fedratinib as second-line treatment for patients with disease progression on ruxolitinib
Track 10	Risks and benefits associated with pacritinib therapy
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Track 15	Hepcidin suppression and improvement of anemia in patients with MF; effect of novel JAK inhibitors, including fedratinib and momelotinib
Track 16	Results of the SIMPLIFY 2 study evaluating momelotinib versus best available therapy for patients with MF previously treated with ruxolitinib
Track 17	Use of JAK inhibitors for rheumatoid arthritis
Track 18	Novel agents and approaches under investigation for MPNs
Track 19	Perspective on the potential role of venetoclax for patients with MPNs
Track 20	**Case:** A 75-year-old woman previously diagnosed with ET and a JAK2 V617F mutation is found to have disease transformation to PV on reassessment 12 years later
Track 21	Efficacy and side effects of the MDM2 antagonist idasanutlin in the treatment of PV
Track 22	Importance of maintaining hematocrit control in patients with PV
Track 23	Role of ruxolitinib for patients with PV
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Track 25	Therapeutic options for patients with ET
Track 26	Perspective on the need for aspirin for ET
Track 27	Role of interferon and PI3-kinase inhibitors in the treatment of MPNs

Video Program

View the corresponding video interviews with (from left) Drs Mesa and Gerds by Dr Love at www.ResearchToPractice.com/MPNUpdate119/Video

SELECT PUBLICATIONS

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **A pooled analysis of 5-year data from the COMFORT-I and COMFORT-II studies demonstrated that ruxolitinib _____ prolong overall survival for patients with intermediate-2 or high-risk MF compared to those who received best available therapy or placebo.**
   a. Did
   b. Did not

2. **The SIMPLIFY-2 study investigating momelotinib versus best available therapy for patients with MF previously treated with ruxolitinib _____ demonstrate a significant reduction in spleen size with momelotinib.**
   a. Did
   b. Did not

3. **Which of the following best describes the mechanism of action of idasanutlin?**
   a. Hypomethylating agent
   b. JAK1/2 inhibitor
   c. MDM2 antagonist

4. **Which of the following statements is true about ruxolitinib in the treatment of MF?**
   a. It is associated with an increased risk of infection
   b. It improves anemia
   c. It is associated with thrombocytopenia
   d. All of the above
   e. Both b and c
   f. Both a and c

5. **The JAKARTA-2 study investigated the JAK2 inhibitor fedratinib in the _____ setting for patients with MF.**
   a. First-line
   b. Second-line

6. **The CYTO-PV study evaluating the intensity of cytoreductive therapy to prevent cardiovascular events in patients with PV demonstrated a significantly lower rate of cardiovascular death and major thrombosis with a hematocrit target of _____ compared to the arm with a hematocrit target of _____.**
   a. Less than 45%; 45% to 50%
   b. 45% to 50%; less than 45%

7. **Results from the MPD-RC 112 study comparing front-line pegylated interferon alpha-2a to hydroxyurea for patients with high-risk PV or ET demonstrated higher response rates in the interferon arm.**
   a. True
   b. False

8. **Patients experiencing benefit with JAK inhibitor therapy should immediately discontinue treatment when the response to therapy begins to diminish.**
   a. True
   b. False

9. **In a retrospective analysis, an improvement in overall survival was not reported after allogeneic hematopoietic stem cell transplant among patients with MF and an intermediate-1 risk score.**
   a. True
   b. False

10. **Which of the following drug types best describes the mechanism of action of PRM-151?**
    a. Antifibrotic immunomodulator
    b. JAK2 inhibitor
    c. PI3-kinase inhibitor

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Myeloproliferative Neoplasms Update — Volume 2, Issue 1

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
Management of cytopenias in patients with MF receiving ruxolitinib	4 3 2 1	4 3 2 1
Risks and benefits of pacritinib for patients with MF	4 3 2 1	4 3 2 1
Efficacy and tolerability of the JAK2 inhibitor fedratinib for MF	4 3 2 1	4 3 2 1
Role of the MDM2 antagonist idasanutlin in the treatment of PV	4 3 2 1	4 3 2 1
Survival advantage with allogeneic transplant for patients with MF and an intermediate-1 or a higher DIPSS score	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice

☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with the following do you see per year? MF..... PV..... ET.....

Was the activity evidence based, fair, balanced and free from commercial bias?

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

.....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain): .....

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.

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

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

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

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

- Appraise the evidence-based therapeutic options for patients with PV, ET and MF, and develop clinical algorithms intended to enhance quality and quantity of life for these individuals..... 4 3 2 1 N/M N/A
- Determine the role of ruxolitinib in the treatment of MF in patients with thrombocytopenia and anemia..... 4 3 2 1 N/M N/A
- Formulate a plan for managing the side effects associated with ruxolitinib to support quality of life and continuation of treatment..... 4 3 2 1 N/M N/A
- Recall emerging research data with the use of novel JAK inhibitors in the treatment of MF, and prepare for their potential availability in clinical practice..... 4 3 2 1 N/M N/A
- Appreciate the biologic rationale for and available efficacy and safety data with novel agents under investigation for the treatment of MPNs..... 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: .....

.....

.....

PART 2 — Please tell us about the faculty and editor for this educational activity

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

Faculty	Knowledge of subject matter	Effectiveness as an educator
Ruben A Mesa, MD	4 3 2 1	4 3 2 1
Aaron T Gerds, MD, MS	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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