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Cancer Conference Update

Audio reviews of key presentations and posters from important scientific meetings

Discussion of 44 Presentations and Posters from the 2012 American Society of Hematology Annual Meeting in Atlanta, Georgia

FACULTY INTERVIEWS

Bruce D Cheson, MD
Moshe Talpaz, MD
Kenneth C Anderson, MD
Brad S Kahl, MD

EDITOR

Neil Love, MD

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OVERVIEW OF ACTIVITY

Hematologic oncology and related blood disorders are some of the most rapidly evolving fields in all of medicine. Results presented at major conferences from a plethora of ongoing clinical trials lead to the continual emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care, the practicing hematologist-oncologist must be well informed of these advances. To bridge the gap between research and patient care, this issue of *Cancer Conference Update* uses one-on-one discussions with Drs Cheson, Talpaz, Anderson and Kahl about the integration of key data sets presented at the 2012 American Society of Hematology Annual Meeting into the practical management of a number of hematologic cancers and related blood disorders.

LEARNING OBJECTIVES

- Apply emerging clinical research data to the rational selection of treatment for patients with hematologic cancers.
- Evaluate the safety profiles and response outcomes observed in studies of next-generation proteasome inhibitors, immunomodulatory agents, histone deacetylase inhibitors, elotuzumab and other novel agents alone or in combination with approved systemic treatments for relapsed/refractory multiple myeloma.
- Appropriately incorporate ruxolitinib into the treatment of JAK2 mutation-positive or mutation-negative myelofibrosis, with consideration of dosing based on platelet counts.
- Integrate new therapeutic strategies into the best-practice management of Hodgkin lymphoma.
- Recall potentially practice-changing clinical research on the care of patients with newly diagnosed, nonhigh-risk acute promyelocytic leukemia.
- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B-cell non-Hodgkin lymphomas.

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EDITOR

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CONTENT VALIDATION AND DISCLOSURES

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FACULTY — The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Cheson** — Advisory Committee: Celgene Corporation, Cephalon Inc, Gilead Sciences Inc, Mundipharma International Limited, Onyx Pharmaceuticals Inc, Pharmacyclics Inc, Sanofi; Consulting Agreements: Celgene Corporation, Cephalon Inc, Genentech BioOncology, Mundipharma International Limited. **Dr Talpaz** — Advisory Committee: Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Pfizer Inc, Sanofi; Contracted Research: Abbott Laboratories, Bristol-Myers Squibb Company, Celgene Corporation, Incyte Corporation, Millennium: The Takeda Oncology Company, Novartis Pharmaceuticals Corporation, Sanofi; Speakers Bureau: Novartis Pharmaceuticals Corporation. **Dr Anderson** — Advisory Committee: Bristol-Myers Squibb Company, Celgene Corporation, Gilead Sciences Inc, Onyx Pharmaceuticals Inc, Sanofi; Other Remunerated Activities: Acetylon Pharmaceuticals Inc. **Dr Kahl** — Advisory Committee: Celgene Corporation, Cephalon Inc, Genentech BioOncology, Millennium: The Takeda Oncology Company, Roche Laboratories Inc; Contracted Research: Abbott Laboratories, Cephalon Inc, Genentech BioOncology.

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INDOLENT B-CELL LYMPHOMAS, HODGKIN LYMPHOMA AND ANAPLASTIC LARGE CELL LYMPHOMA — Bruce D Cheson, MD

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1 Abstract 901: Final results of a Phase II study of lenalidomide and rituximab (R^2) for treatment-naïve indolent lymphoma

2 Results of CALGB-50401: A randomized Phase II study of lenalidomide with or without rituximab for recurrent follicular lymphoma (FL)

3 Abstract 793: Safety and efficacy of pidilizumab (CT-011), a humanized anti-PD-1 monoclonal antibody, in combination with rituximab in relapsed FL

4 Abstract 191: Activity and tolerability of the selective phosphatidylinositol 3-kinase-delta inhibitor idelalisib (GS-1101) with rituximab and/or bendamustine in relapsed or refractory chronic lymphocytic leukemia (CLL)

5 Abstract 717: Chimeric antigen receptor T cells directed against CD19 induce durable responses and transient cytokine release syndrome in relapsed/refractory CLL and acute lymphoblastic leukemia (ALL)

6 Abstract 189: Profound activity of the Bruton tyrosine kinase (BTK) inhibitor ibrutinib in treatment-naïve and relapsed or refractory CLL or small lymphocytic lymphoma (SLL)

7 Abstract 187: Activity and tolerability of ibrutinib/rituximab in high-risk CLL

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9 Abstract 798: Front-line therapy with brentuximab vedotin combined with ABVD or AVD in newly diagnosed advanced-stage Hodgkin lymphoma (HL)

10 Brentuximab vedotin in the treatment of HL and anaplastic large cell lymphoma (ALCL)

11 Abstract 547: Results of the UK NCRI RAPID trial of involved field radiation therapy versus no further treatment in patients with clinical Stages IA and IIA HL and a "negative" PET scan after 3 cycles of ABVD

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MYELOFIBROSIS, ACUTE MYELOID LEUKEMIA, CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA AND ACUTE PROMYELOCYTIC LEUKEMIA — Moshe Talpaz, MD

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2 Lack of correlation between JAK2 mutation status and response and survival outcomes with ruxolitinib

3 Abstract 801: Long-term safety, efficacy and survival findings from the COMFORT-II study comparing ruxolitinib to best available therapy for the treatment of MF

4 Abstracts 176, 177: Efficacy, hematologic effects and dose of ruxolitinib in patients with MF who have low initial platelet counts (50 to 100 x 10^9/L)

5 Ruxolitinib treatment for patients with MF who have platelet counts lower than 50 x 10^9/L

6 Abstract 45: Homoharringtonine (omacetaxine mepesuccinate)-based induction regimens for de novo acute myeloid leukemia (AML) — Results of a Phase III study

7 Abstracts 48, 673: Final results of a Phase II study of quizartinib in patients with FLT3-ITD-positive or negative relapsed/refractory AML

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MYELOFIBROSIS, ACUTE MYELOID LEUKEMIA, CHRONIC MYELOGENOUS LEUKEMIA, ACUTE LYMPHOBLASTIC LEUKEMIA AND ACUTE PROMYELOCYTIC LEUKEMIA — Dr Talpaz

CONTINUED

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11 Abstract 670: Anti-CD19 BiTE blinatumomab induces high complete remission rates and prolongs overall survival in patients with relapsed/refractory B-precursor ALL

12 Abstract 2612: Weekly inotuzumab ozogamicin in patients with relapsed or refractory CD22-positive ALL

13 Abstract 6: ATRA and arsenic trioxide versus ATRA and idarubicin for newly diagnosed, nonhigh-risk acute promyelocytic leukemia (APL) — Results of the Phase III Intergroup APL0406 study

MULTIPLE MYELOMA — Kenneth C Anderson, MD

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11 Abstract 73: Results of a Phase I/II dose-escalation study of daratumumab, a CD38 monoclonal antibody, in relapsed/refractory MM

12 Abstract 202: Updated results of a Phase II study of elotuzumab, lenalidomide and low-dose dexamethasone in relapsed/refractory MM

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2 Proposed ECOG study of R^2-CHOP versus R-CHOP in untreated diffuse large B-cell lymphoma (DLBCL) with correlational analyses of cell of origin and response

3 Abstract 903: The Phase II REAL07 study of R^2-CHOP versus R-CHOP in elderly patients with untreated DLBCL

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4 Abstract 686: Preferential activity of the oral BTK inhibitor ibrutinib in the ABC subtype of relapsed/refractory de novo DLBCL — Interim results of a Phase II study

5 Durability of response and toxicity of ibrutinib in mantle-cell lymphoma (MCL) and CLL/SLL

6 Abstract 902: Results of the randomized BRIGHT study evaluating BR, R-CVP and R-CHOP as first-line treatment in advanced indolent non-Hodgkin lymphoma or MCL

7 Abstract 153: Mature results of the ECOG-E1405 study evaluating bortezomib/rituximab-CVAD with maintenance rituximab in previously untreated MCL

8 Optimal duration of maintenance rituximab in MCL

9 Abstract 904: Interim Phase II study results of ibrutinib in relapsed or refractory MCL

10 Abstract 60: Concurrent multiagent chemotherapy and brentuximab vedotin as front-line treatment for ALCL and other CD30-positive mature T-cell and NK-cell lymphomas

11 Ongoing Phase III study of brentuximab vedotin and CHP versus CHOP as front-line treatment for CD30-positive mature T-cell lymphomas

SELECT PUBLICATIONS

Ansell SM et al. **Frontline therapy with brentuximab vedotin combined with ABVD or AVD in patients with newly diagnosed advanced stage Hodgkin lymphoma.** *Proc ASH* 2012;**Abstract 798**.

Burger JA et al. **The Btk inhibitor ibrutinib (PCI-32765) in combination with rituximab is well tolerated and displays profound activity in high-risk chronic lymphocytic leukemia (CLL) patients.** *Proc ASH* 2012;**Abstract 187**.

Cervantes F et al. **Long-term safety, efficacy, and survival findings from Comfort-II, a Phase 3 study comparing ruxolitinib with best available therapy (BAT) for the treatment of myelofibrosis (MF).** *Proc ASH* 2012;**Abstract 801**.

Cortes JE et al. **A pivotal phase II trial of ponatinib in patients with chronic myeloid leukemia (CML) and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) resistant or intolerant to dasatinib or nilotinib, or with the T315I BCR-ABL mutation: 12-month follow-up of the PACE trial.** *Proc ASH* 2012;**Abstract 163**.

Cortes JE et al. **Final results of a phase 2 open-label, monotherapy efficacy and safety study of quizartinib (AC220) in patients ≥ 60 years of age with FLT3 ITD positive or negative relapsed/refractory acute myeloid leukemia.** *Proc ASH* 2012;**Abstract 48**.

Dimopoulos MA et al. **Pomalidomide in combination with low-dose dexamethasone: Demonstrates a significant progression free survival and overall survival advantage, in relapsed/refractory MM: A phase III, multicenter, randomized, open-label study.** *Proc ASH* 2012;**Abstract LBA-6**.

Fanale MA et al. **Brentuximab vedotin administered concurrently with multi-agent chemotherapy as frontline treatment of ALCL and other CD30-positive mature T-cell and NK-cell lymphomas.** *Proc ASH* 2012;**Abstract 60**.

Flinn IW et al. **An open-label, randomized study of bendamustine and rituximab (BR) compared with rituximab, cyclophosphamide, vincristine, and prednisone (R-CVP) or rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) in first-line treatment of patients with advanced indolent non-Hodgkin's lymphoma (NHL) or mantle cell lymphoma (MCL): The Bright study.** *Proc ASH* 2012;**Abstract 902**.

Jin J et al. **Homoharringtonine-based induction regimens for patients with de novo acute myeloid leukemia: A multicenter randomized controlled phase 3 trial.** *Proc ASH* 2012;**Abstract 45**.

Verstovsek S et al. **Long-term outcome of ruxolitinib treatment in patients with myelofibrosis: Durable reductions in spleen volume, improvements in quality of life, and overall survival advantage in COMFORT-I.** *Proc ASH* 2012;**Abstract 800**.

Wang M et al. **Interim results of an international, multicenter, phase 2 study of Bruton's tyrosine kinase (BTK) inhibitor, ibrutinib (PCI-32765), in relapsed or refractory mantle cell lymphoma (MCL): Durable efficacy and tolerability with longer follow-up.** *Proc ASH* 2012;**Abstract 904**.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Final results from a Phase II study of R^2 (lenalidomide/rituximab) demonstrated that this combination produces high complete response rates and durable remissions in patients with FL.**
   a. True
   b. False

2. **Patients with MF must have a JAK2 mutation to respond to treatment with ruxolitinib.**
   a. True
   b. False

3. **Which of the following is an approved treatment for CML?**
   a. Omacetaxine
   b. Bosutinib
   c. Ponatinib
   d. All of the above

4. **Carfilzomib is approved for use as single-agent therapy for patients with MM refractory to bortezomib and an IMiD.**
   a. True
   b. False

5. **A Phase I/II trial of carfilzomib and pomalidomide with dexamethasone in patients with relapsed/refractory MM demonstrated an overall response rate of _____.**
   a. 30%
   b. 50%
   c. 70%

6. **A Phase III study of homoharringtonine-based induction regimens for patients with de novo AML demonstrated that these regimens are associated with higher response rates and improved survival compared to an anthracycline and cytarabine regimen.**
   a. True
   b. False

7. **The side effects associated with quizartinib when used to treat FLT3-ITD-positive or negative relapsed/refractory AML include:**
   a. Gastrointestinal toxicities
   b. QT prolongation
   c. Myelosuppression
   d. All of the above

8. **A study on the long-term outcomes of ruxolitinib in patients with MF on the COMFORT-I study demonstrated _____.**
   a. A continued survival advantage
   b. Sustained reductions in spleen volume
   c. Continued improvement in symptoms and quality of life
   d. All of the above

9. **High cereblon protein expression correlates with response in patients with MM treated with lenalidomide.**
   a. True
   b. False

10. **A study evaluating single-agent ibrutinib in treatment-naïve and relapsed/refractory CLL or SLL reported high response rates for _____.**
    a. Treatment-naïve patients
    b. Patients with relapsed/refractory disease
    c. Patients with high-risk disease (those with deletion 17p)
    d. All of the above

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Cancer Conference Update — Issue 1, 2013

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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
Clinical trial results and ongoing studies of R^2 for indolent lymphomas and of R^2-CHOP for aggressive lymphomas	4 3 2 1	4 3 2 1
Lack of correlation between JAK2 mutation status and response and survival outcomes with the JAK2 inhibitor ruxolitinib in MF	4 3 2 1	4 3 2 1
Use of low-dose dexamethasone and hydration in conjunction with carfilzomib to maintain a favorable therapeutic index	4 3 2 1	4 3 2 1
Survival advantage with pomalidomide in combination with low-dose dexamethasone in relapsed/refractory MM	4 3 2 1	4 3 2 1
Ongoing Phase III study of brentuximab vedotin and CHP versus CHOP as front-line treatment for CD30-positive mature T-cell lymphomas	4 3 2 1	4 3 2 1
Results of the Phase III Intergroup APL0406 study of ATRA and arsenic trioxide versus ATRA and idarubicin for newly diagnosed, nonhigh-risk APL	4 3 2 1	4 3 2 1

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.

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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:

- Apply emerging clinical research data to the rational selection of treatment for patients with hematologic cancers. . . . . 4 3 2 1 N/M N/A
- Evaluate the safety profiles and response outcomes observed in studies of next-generation proteasome inhibitors, immunomodulatory agents, histone deacetylase inhibitors, elotuzumab and other novel agents alone or in combination with approved systemic treatments for relapsed/refractory multiple myeloma. . . . . 4 3 2 1 N/M N/A
- Appropriately incorporate ruxolitinib into the treatment of JAK2 mutation-positive or mutation-negative myelofibrosis, with consideration of dosing based on platelet counts. . . . . 4 3 2 1 N/M N/A
- Integrate new therapeutic strategies into the best-practice management of Hodgkin lymphoma. . . . . 4 3 2 1 N/M N/A
- Recall potentially practice-changing clinical research on the care of patients with newly diagnosed, nonhigh-risk acute promyelocytic leukemia. . . . . 4 3 2 1 N/M N/A
- Develop an understanding of emerging efficacy and side-effect data with novel agents and combination regimens under evaluation for indolent and aggressive B-cell non-Hodgkin lymphomas. . . . . 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?

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.....

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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
Bruce D Cheson, MD	4 3 2 1	4 3 2 1
Moshe Talpaz, MD	4 3 2 1	4 3 2 1
Kenneth C Anderson, MD	4 3 2 1	4 3 2 1
Brad S Kahl, MD	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

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and editor for this activity:

.....

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.....

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