VOL 1 | ISSUE 2

Lymphoma and Chronic Lymphocytic Leukemia™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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Lymphoma and Chronic Lymphocytic Leukemia™

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Lymphoma and Chronic Lymphocytic Leukemia Update
A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

The treatment of hematologic cancer remains a challenge for many healthcare professionals and patients despite recent gains in the management of this group of diseases. Determining which treatment approach is most appropriate requires careful consideration of patient characteristics, physician expertise and available health-system resources. To bridge the gap between research and patient care, this program features one-on-one discussions with leading hematology-oncology investigators. By providing information on the latest clinical developments in the context of expert perspectives, this activity assists medical oncologists, hematologists and hematology-oncology fellows with the formulation of evidence-based and current therapeutic strategies, which in turn facilitates optimal patient care.

LEARNING OBJECTIVES

- Review emerging clinical trial data on the efficacy and safety of brentuximab vedotin for patients with Hodgkin lymphoma and other CD30-positive lymphomas, and use this information to prioritize protocol and nonresearch options for these patients.
- Compare and contrast the mechanisms of action, efficacy and safety of approved immunotherapeutic approaches (eg, checkpoint inhibitors, chimeric antigen receptor-directed T-cell therapy) for the treatment of Hodgkin and non-Hodgkin lymphoma to determine the current and/or potential utility of each in clinical practice.
- Consider current and emerging clinical research data in the formulation of therapeutic recommendations for patients with newly diagnosed and relapsed/refractory follicular, mantle cell and diffuse large B-cell lymphomas.
- Formulate an evidence-based treatment approach that incorporates small-molecule inhibitors and third-generation monoclonal antibodies for the treatment of chronic lymphocytic leukemia, and develop a plan to monitor and manage their unique toxicities.
- Assess the benefits of ongoing clinical trials for patients with hematologic cancers, and inform appropriately selected patients about these options for treatment.

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Interview with Jeremy Abramson, MD

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Track 3	Immune checkpoint inhibitor-associated pneumonitis
Track 4	Recent FDA approval of ibrutinib for chronic graft-versus-host disease
Track 5	Management of cytokine release syndrome and neurotoxicity in patients undergoing CAR-T therapy
Track 6	Activity of axicabtagene ciloleucel in relapsed/refractory DLBCL
Track 7	Integration of anti-PD-1 checkpoint inhibitors into the therapeutic algorithm for HL
Track 8	Sustained responses to brentuximab vedotin versus checkpoint inhibitors in HL
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Track 21	Primary results of the Phase III GALLIUM study: Obinutuzumab-based induction and maintenance therapy prolongs PFS for patients with previously untreated FL

Interview with Ajay K Gopal, MD

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Track 7	Use of radioimmunotherapy for FL
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Interview with Dr Gopal (continued)

Track 9	Use of ibrutinib for patients receiving anticoagulants
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Track 16	Tolerability of PI3K inhibitors, including copanlisib
Track 17	**Case:** A 66-year-old man with advanced-stage activated B-cell–like (ABC) DLBCL experiences disease progression after R-CHOP and platinum salvage chemotherapy
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Track 23	Sequencing lenalidomide, bortezomib and venetoclax for relapsed MCL
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Track 25	Ongoing trial of enzalutamide for MCL
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Track 33	Initial treatment approach for peripheral T-cell lymphoma not otherwise specified

Video Program

View the corresponding video interviews with (from left) Drs Abramson and Gopal by Dr Love at www.ResearchToPractice.com/LymphomaCLLUpdate217/Video

SELECT PUBLICATIONS

A phase 3 open label randomized study to compare the efficacy and safety of rituximab plus lenalidomide (CC-5013) versus rituximab plus chemotherapy followed by rituximab in subjects with previously untreated follicular lymphoma (RELEVANCE). NCT01650701

Andorsky DJ et al. **Phase IIIb randomized study of lenalidomide plus rituximab (R2) followed by maintenance in relapsed/refractory NHL: Analysis of patients with double-refractory or early relapsed follicular lymphoma (FL).** *Proc ASCO* 2017;**Abstract 7502**.

Andorsky DJ et al. **MAGNIFY: Phase IIIb randomized study of lenalidomide plus rituximab (R2) followed by lenalidomide vs rituximab maintenance in subjects with relapsed/refractory follicular, marginal zone, or mantle cell lymphoma.** *Proc ASH* 2016;**Abstract 1798**.

Burger JA et al; RESONATE-2 Investigators. **Ibrutinib as initial therapy for patients with chronic lymphocytic leukemia.** *N Engl J Med* 2015;373(25):2425-37.

Byrd JC et al. **Acalabrutinib (ACP-196) in relapsed chronic lymphocytic leukemia.** *N Engl J Med* 2016;374(4):323-32.

Chen R et al. **Five-year survival and durability results of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma.** *Blood* 2016;128(12):1562-6.

Furman RR et al. **Idelalisib and rituximab in relapsed chronic lymphocytic leukemia.** *N Engl J Med* 2014;370(11):997-1007.

Goede V et al. **Obinutuzumab plus chlorambucil in patients with CLL and coexisting conditions.** *N Engl J Med* 2014;370(12):1101-10.

Gopal AK et al. **Continued excellent outcomes in previously untreated follicular lymphoma patients after treatment with CHOP plus rituximab or CHOP plus (131) iodine-tositumomab — Long term follow-up of phase III randomized study SWOG S0016.** *Proc ASH* 2016;**Abstract 616**.

Gopal AK et al. **Sequential RCHOP, radioimmunotherapy and rituximab maintenance improves early outcomes in advanced stage follicular lymphoma: 5 year outcomes from SWOG 0801.** *Proc ASH* 2016;**Abstract 614**.

Lampson BL et al. **Idelalisib given front-line for treatment of chronic lymphocytic leukemia causes frequent immune-mediated hepatotoxicity.** *Blood* 2016;128(2):195-203.

Le Gouill S et al. **Rituximab maintenance after autologous stem cell transplantation prolongs survival in younger patients with mantle cell lymphoma: Final results of the randomized phase 3 LyMa trial of the Lysa/Goelams Group.** *Proc ASH* 2016;**Abstract 145**.

Marcus R et al. **Obinutuzumab-based induction and maintenance prolongs progression-free survival (PFS) in patients with previously untreated follicular lymphoma: Primary results of the randomized phase 3 GALLIUM study.** *Proc ASH* 2016;**Abstract 6**.

Moskowitz CH et al. **Brentuximab vedotin as consolidation therapy after autologous stem-cell transplantation in patients with Hodgkin's lymphoma at risk of relapse or progression (AETHERA): A randomised, double-blind, placebo-controlled, phase 3 trial.** *Lancet* 2015;385(9980):1853-62.

O'Brien S et al. **Ibrutinib for patients with relapsed or refractory chronic lymphocytic leukaemia with 17p deletion (RESONATE-17): A phase 2, open-label, multicentre study.** *Lancet Oncol* 2016;17(10):1409-18.

Salles G et al. **Efficacy and safety of idelalisib in patients with relapsed, rituximab- and alkylating agent-refractory follicular lymphoma: A subgroup analysis of a phase 2 study.** *Haematologica* 2017;102(4):e156-9.

Sehn LH et al. **Obinutuzumab plus bendamustine versus bendamustine monotherapy in patients with rituximab-refractory indolent non-Hodgkin lymphoma (GADOLIN): A randomised, controlled, open-label, multicentre, phase 3 trial.** *Lancet Oncol* 2016;17(8):1081-93.

Updated efficacy and safety data from the AETHERA trial of consolidation with brentuximab vedotin after autologous stem cell transplant (ASCT) in Hodgkin lymphoma patients at high risk of relapse. *Clin Adv Hematol Oncol* 2016;14(2 Suppl 1):17-8.

Weirda WG et al. **Management of transaminase elevations in patients receiving idelalisib.** *Proc ASCO* 2016;**Abstract 7532**.

Younes A et al. **The landscape of new drugs in lymphoma.** *Nat Rev Clin Oncol* 2017;14(6):335-46.

Zelenetz AD et al. **Idelalisib or placebo in combination with bendamustine and rituximab in patients with relapsed or refractory chronic lymphocytic leukaemia: Interim results from a phase 3, randomised, double-blind, placebo-controlled trial.** *Lancet Oncol* 2017;18(3):297-311.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Which of the following categories reflects the mechanism of action of obinutuzumab?**
   a. Anti-CD20 monoclonal antibody
   b. Immunomodulatory drug
   c. Anti-PD-1/PD-L1 antibody
   d. Proteasome inhibitor

2. **Which of the following observations was made in the Phase III GALLIUM study evaluating obinutuzumab- versus rituximab-based induction and maintenance therapy for previously untreated FL?**
   a. No difference in PFS
   b. PFS favored rituximab
   c. PFS favored obinutuzumab

3. **Hospitalization for the purpose of monitoring for TLS is required for all patients starting therapy with venetoclax.**
   a. True
   b. False

4. **Which of the following categories reflects the mechanism of action of copanlisib?**
   a. Anti-PD-1/PD-L1 antibody
   b. Bruton tyrosine kinase inhibitor
   c. CAR-T therapy
   d. PI3K inhibitor

5. **Results of the Phase III AETHERA trial evaluating brentuximab vedotin versus placebo as consolidation therapy after ASCT for patients with HL at risk of relapse or disease progression demonstrated a statistically significant improvement in _____ with brentuximab vedotin.**
   a. Overall survival
   b. PFS
   c. Both a and b
   d. Neither a nor b

6. **The Phase III LyMa trial _____ a statistically significant overall survival advantage with rituximab maintenance therapy after ASCT for younger patients with MCL.**
   a. Demonstrated
   b. Did not demonstrate

7. **Which side effect is of the greatest concern for patients with acute lymphomas receiving CAR-T therapy?**
   a. Cytokine release syndrome
   b. Renal failure
   c. TLS

8. **The majority of patients with del(17p) CLL _____.**
   a. Present up front with the 17p deletion
   b. Acquire the 17p deletion over the course of their disease

9. **Venetoclax is dosed and administered in which of the following manners?**
   a. 20 mg once daily
   b. 400 mg once daily
   c. Initiated at 20 mg and gradually escalated to the target dose of 400 mg once daily

10. **_____ is an orally bioavailable inhibitor of the delta isoform of PI3 kinase that is approved by the FDA for the treatment of relapsed CLL.**
    a. Copanlisib
    b. Ibrutinib
    c. Idelalisib
    d. TGR-1202

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Lymphoma and Chronic Lymphocytic Leukemia Update — Volume 1, Issue 2

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
Results of the Phase III GALLIUM study comparing obinutuzumab- to rituximab-based induction and maintenance therapy for previously untreated FL	4 3 2 1	4 3 2 1
Strategies to effectively mitigate TLS in patients starting venetoclax treatment (dose ramping, prophylaxis, monitoring, et cetera)	4 3 2 1	4 3 2 1
Cytokine release syndrome and neurotoxicity associated with CAR-T therapy	4 3 2 1	4 3 2 1
Tolerability and side-effect differences among Bruton tyrosine kinase inhibitors, particularly lower risk of atrial fibrillation and bleeding with acalabrutinib compared to ibrutinib	4 3 2 1	4 3 2 1
Activity and immune-related toxicities of recently FDA-approved PI3K inhibitors (idelalisib and copanlisib) for indolent non-Hodgkin lymphoma	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?

CLL..... HL..... FL.....
MCL..... DLBCL..... T-cell lymphoma.....

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:

- Review emerging clinical trial data on the efficacy and safety of brentuximab vedotin for patients with Hodgkin lymphoma and other CD30-positive lymphomas, and use this information to prioritize protocol and nonresearch options for these patients..... 4 3 2 1 N/M N/A
- Compare and contrast the mechanisms of action, efficacy and safety of approved immunotherapeutic approaches (eg, checkpoint inhibitors, chimeric antigen receptor-directed T-cell therapy) for the treatment of Hodgkin and non-Hodgkin lymphoma to determine the current and/or potential utility of each in clinical practice..... 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:

- Consider current and emerging clinical research data in the formulation of therapeutic recommendations for patients with newly diagnosed and relapsed/refractory follicular, mantle cell and diffuse large B-cell lymphomas. . . . . 4 3 2 1 N/M N/A
- Formulate an evidence-based treatment approach that incorporates small-molecule inhibitors and third-generation monoclonal antibodies for the treatment of chronic lymphocytic leukemia, and develop a plan to monitor and manage their unique toxicities. . . . . 4 3 2 1 N/M N/A
- Assess the benefits of ongoing clinical trials for patients with hematologic cancers, and inform appropriately selected patients about these options for treatment. . . . . 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: . . . . . .

Additional comments about this activity:

. . . . . .

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

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Jeremy Abramson, MD	4 3 2 1	4 3 2 1
Ajay K Gopal, 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

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