

# Chronic Lymphocytic Leukemia™

U P D A T E

Conversations with Oncology Investigators  
Bridging the Gap between Research and Patient Care

**FACULTY INTERVIEWS**

Prof John G Gribben, MD, DSc, FMedSci  
Jennifer R Brown, MD, PhD

**EDITOR**

Neil Love, MD

**CONTENTS**

1 Audio CD



# Chronic Lymphocytic Leukemia™

U P D A T E

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# Chronic Lymphocytic Leukemia Update

## A Continuing Medical Education Audio Series

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### OVERVIEW OF ACTIVITY

The clinical course of chronic lymphocytic leukemia (CLL) and outcomes for patients vary widely, largely based on the presence of individual predictive and other risk factors. In recent years the identification of cytogenetic abnormalities and their subsequent incorporation into traditional clinical staging systems has refined clinicians' ability to determine patient prognosis, and based on the improved understanding of the biology of CLL, a number of novel agents and therapeutic strategies have been investigated. Some of these efforts have proven successful and are already available for use in the clinic, but along with these many exciting advances, vexing questions and clinical challenges are emerging simultaneously. 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

- Recall the incidence, prognostic significance and clinical implications of select biomarkers and chromosomal abnormalities that may be associated with a diagnosis of CLL, and use this information to develop evidence-based testing algorithms in general oncology practice.
- Individualize the selection of systemic therapy for patients with newly diagnosed CLL, considering clinical presentation, biomarker profile and psychosocial status.
- Implement a plan of care to recognize and manage side effects and toxicities associated with current and recently approved systemic therapies in the management of CLL.
- Appreciate recent therapeutic advances and related FDA approvals in CLL, and discern how these agents can be appropriately integrated into routine clinical practice.
- Review emerging clinical data on the efficacy and safety of the recently FDA-approved antibody-drug conjugate moxetumomab pasudotox for hairy cell leukemia.
- Evaluate available data with and consider the potential clinical roles of novel agents and regimens that may provide treatment options for additional patients beyond those for whom they were initially indicated.

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## Interview with Prof John G Gribben, MD, DSc, FMedSci

### Tracks 1-24

- Track 1** **Case:** A 73-year-old woman who presents with fatigue and cervical lymphadenopathy receives ibrutinib as first-line therapy for chronic lymphocytic leukemia (CLL)
- Track 2** Assessment of biomarkers to inform therapeutic decision-making for patients with CLL
- Track 3** Perspective on watching and waiting versus treatment for patients with newly diagnosed CLL
- Track 4** CLL12: An ongoing Phase III placebo-controlled trial of ibrutinib versus watch and wait for previously untreated Binet Stage A CLL in patients at risk of disease progression
- Track 5** **Case:** A 49-year-old man with CLL with an IGHV mutation experiences profound fatigue and rash with fludarabine/cyclophosphamide/rituximab (FCR) as first-line therapy
- Track 6** Minimal residual disease (MRD) status and prognosis for patients with CLL
- Track 7** Response to ibrutinib as front-line therapy for CLL
- Track 8** Risk of ibrutinib-associated hypertension and bleeding
- Track 9** Selection and sequencing of treatment for CLL
- Track 10** Results of the Phase III MURANO trial evaluating venetoclax/rituximab versus bendamustine/rituximab for relapsed/refractory CLL
- Track 11** Assessing the risk of tumor lysis syndrome (TLS) with venetoclax
- Track 12** Prevention and management of venetoclax-associated TLS
- Track 13** Benefits and risks of the venetoclax/ibrutinib combination as potential up-front therapy for CLL
- Track 14** **Case:** A 65-year-old man with FCR-refractory CLL who has a history of poorly controlled atrial fibrillation receives acalabrutinib on a clinical trial
- Track 15** Use of acalabrutinib in patients with preexisting, poorly controlled atrial fibrillation
- Track 16** Acalabrutinib-associated headaches
- Track 17** Perspective on the use of venetoclax/rituximab as second-line therapy
- Track 18** Risk of bleeding with Bruton tyrosine kinase (BTK) inhibitors and use for patients receiving anticoagulants
- Track 19** Role of allogeneic transplant in the treatment of CLL
- Track 20** Clinical presentation and management of hairy cell leukemia
- Track 21** BRAF V600 mutations in hairy cell leukemia
- Track 22** First-line therapy for patients with hairy cell leukemia
- Track 23** Approach to therapy for patients with relapsed hairy cell leukemia
- Track 24** Mechanism of action, efficacy and tolerability of the antibody-drug conjugate moxetumomab pasudotox for hairy cell leukemia

## Interview with Jennifer R Brown, MD, PhD

### Tracks 1-27

- Track 1** Viewpoint on observation versus initiation of treatment for patients with newly diagnosed CLL
- Track 2** Comparison of efficacy and tolerability among BTK inhibitors
- Track 3** Effects of deletion 17p and TP53 mutations on response to therapy
- Track 4** IGHV mutation status as a prognostic and predictive biomarker
- Track 5** Benefits and risks of FCR as first-line therapy for patients with CLL with IGHV mutations
- Track 6** Correlation between MRD status and outcomes for patients with CLL
- Track 7** Choice of obinutuzumab-based therapy in the first-line setting for CLL
- Track 8** Use of ibrutinib for patients with previously untreated CLL
- Track 9** Adherence to treatment with ibrutinib and reasons for discontinuation
- Track 10** Efficacy and side-effect profile of acalabrutinib
- Track 11** Incidence of acalabrutinib-associated atrial fibrillation and headaches

## Interview with Dr Brown (continued)

- Track 12** Treatment options for patients who experience disease progression on ibrutinib
- Track 13** Clinical implications of the MURANO trial investigating venetoclax/rituximab for relapsed/refractory CLL
- Track 14** Monitoring and prophylaxis for venetoclax-associated TLS
- Track 15** Activity and tolerability of PI3 kinase inhibitors in CLL
- Track 16** Perspective on the efficacy of ibrutinib with venetoclax
- Track 17** Role of obinutuzumab with venetoclax for previously untreated CLL
- Track 18** Benefits and risks of ibrutinib with FCR
- Track 19** **Case:** A 75-year-old woman with relapsed CLL/small lymphocytic lymphoma with del(13q) and unmutated IGHV achieves an excellent response to venetoclax on a clinical trial
- Track 20** Sequencing of treatment for patients with relapsed/refractory CLL
- Track 21** **Case:** An 85-year-old woman with relapsed CLL with del(13q) experiences recurrent congestive heart failure after receiving ibrutinib
- Track 22** **Case:** A 65-year-old man with CLL with unmutated IGHV and a TP53 mutation receives acalabrutinib as second-line therapy
- Track 23** **Case:** A 49-year-old man with CLL with unmutated IGHV and del(13q) achieves an MRD-negative complete remission on venetoclax and obinutuzumab
- Track 24** Approach to TLS prevention for patients receiving venetoclax
- Track 25** **Case:** A 90-year-old man presents with loss of vision and is diagnosed with CLL with unmutated IGHV and del(11q)
- Track 26** Emerging data with checkpoint inhibitors for Richter's transformation
- Track 27** Efficacy of chimeric antigen receptor (CAR) T-cell therapy for CLL

## Video Program

View the corresponding video interviews with (from left) Prof Gribben and Dr Brown by Dr Love at [www.ResearchToPractice.com/CLLUpdate118/Video](http://www.ResearchToPractice.com/CLLUpdate118/Video)



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Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. Results from the Phase III MURANO trial for patients with relapsed/refractory CLL demonstrated a significant improvement in progression-free survival with \_\_\_\_\_ compared to bendamustine/rituximab.
  - a. Venetoclax/rituximab
  - b. Obinutuzumab/venetoclax/ibrutinib
  - c. Acalabrutinib
2. Which of the following statements is true about patients with CLL with deletion 17p?
  - a. They have a poor prognosis
  - b. They are also likely to have TP53 gene mutations
  - c. They respond well to chemotherapy
  - d. All of the above
  - e. Both a and b
3. The ongoing placebo-controlled Phase III CLL12 trial is evaluating \_\_\_\_\_ versus watch and wait for patients with previously untreated Binet Stage A CLL at risk of disease progression.
  - a. Idelalisib
  - b. Ibrutinib
  - c. Venetoclax
4. Data suggest that the risk of treatment-associated atrial fibrillation is \_\_\_\_\_ with acalabrutinib than it is with ibrutinib.
  - a. Lower
  - b. Higher
  - c. Neither a nor b, the risk is equivalent
5. The iLLUMINATE trial is investigating ibrutinib or chlorambucil in combination with \_\_\_\_\_ for patients with previously untreated CLL.
  - a. Rituximab
  - b. Obinutuzumab
  - c. Venetoclax
6. Which dose of venetoclax does the package insert recommend to minimize the risk of TLS?
  - a. 400 mg once daily
  - b. 20 mg once daily
  - c. 20 mg at initiation, ramping up to 400 mg over 5 weeks
7. An ibrutinib side effect that increases in frequency and severity with time is \_\_\_\_\_.
  - a. Atrial fibrillation
  - b. Hypertension
  - c. Gastrointestinal symptoms
  - d. All of the above
8. Which of the following statements is true regarding patients with CLL with IGHV-mutated genes (more than 2%) versus those with unmutated IGHV?
  - a. They respond better to chemoimmunotherapy with FCR
  - b. They have better overall survival
  - c. Both a and b
  - d. Neither a nor b
9. The recently FDA-approved agent moxetumomab pasudotox, which has shown promising efficacy for hairy cell leukemia, belongs to which class of agents?
  - a. Antibody-drug conjugates
  - b. PI3 kinase inhibitors
  - c. BTK inhibitors
10. For patients with CLL receiving acalabrutinib who experience treatment-associated headache, the side effect typically \_\_\_\_\_.
  - a. Occurs within the first 1 to 2 months of treatment and then dissipates
  - b. Occurs throughout the course of therapy



*Chronic Lymphocytic Leukemia Update — Volume 1, Issue 1*

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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
Results and clinical implications of the Phase III MURANO trial investigating venetoclax/rituximab for patients with relapsed/refractory CLL	4 3 2 1	4 3 2 1
Emerging data on the benefits and risks of the antibody-drug conjugate moxetumomab pasudotox for patients with hairy cell leukemia	4 3 2 1	4 3 2 1
Ongoing investigation of checkpoint inhibitors for patients with Richter's transformation	4 3 2 1	4 3 2 1
Efficacy of CAR T-cell therapy in patients with CLL	4 3 2 1	4 3 2 1
Monitoring and management of TLS associated with venetoclax	4 3 2 1	4 3 2 1
Efficacy and tolerability of BTK inhibitors for CLL	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 CLL do you see per year?** ..... patients

**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:**

- Recall the incidence, prognostic significance and clinical implications of select biomarkers and chromosomal abnormalities that may be associated with a diagnosis of CLL, and use this information to develop evidence-based testing algorithms in general oncology practice. .... 4 3 2 1 N/M N/A
- Individualize the selection of systemic therapy for patients with newly diagnosed CLL, considering clinical presentation, biomarker profile and psychosocial status. .... 4 3 2 1 N/M N/A
- Implement a plan of care to recognize and manage side effects and toxicities associated with current and recently approved systemic therapies in the management of CLL. .... 4 3 2 1 N/M N/A

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

- Appreciate recent therapeutic advances and related FDA approvals in CLL, and discern how these agents can be appropriately integrated into routine clinical practice. . . . . 4 3 2 1 N/M N/A
- Review emerging clinical data on the efficacy and safety of the recently FDA-approved antibody-drug conjugate moxetumomab pasudotox for hairy cell leukemia. . . . . 4 3 2 1 N/M N/A
- Evaluate available data with and consider the potential clinical roles of novel agents and regimens that may provide treatment options for additional patients beyond those for whom they were initially indicated. . . . . 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**

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Faculty	Knowledge of subject matter				Effectiveness as an educator			
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Jennifer R Brown, MD, PhD	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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# Chronic Lymphocytic Leukemia™

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