

UPDATES ON LYMPHOMA & CLL CLINICAL TRIALS

HIGHLIGHTS • EDUCATION • RESOURCES



NOVEMBER 2018

Dear LC Members:

Welcome to the inaugural edition of LC's clinical trial update.

As we all know, there are not yet effective treatment options for all lymphoma subtypes. There are many reasons why it may be difficult to treat a patient, including age, comorbidities, drug resistance, being diagnosed with a particularly difficult to treat subtype, to name a few.

This is why clinical trials are so important. Trials may lead to new or better therapies for lymphoma patients.

To ensure all LC members are well informed, the new clinical trials update will be distributed quarterly and will focus on:

- Education, including how the system works and where changes are needed
- Highlighting trials addressing unmet needs for lymphoma patients
- Providing updates on select trial outcomes, with a focus on those that may change treatment decisions

In comparison to many other cancers, there is a lot of clinical trial activity in the lymphoma area, led by industry and educational institutions, researching new and improved treatments. This is good news – we want and need better therapies – yet it brings with it its own set of challenges.

- As science has improved and we know more about the characteristics of each subtype, trials are being focused on an increasingly small subset of patients who may be hard to reach and recruit; and if target recruitment numbers are not met, the trial extends over a long timeframe or cannot continue.
- There are more instances where media highlights trials using words like ‘breakthrough’ or “treatment changing” or “miraculous” without reporting a full analysis on actual trial results to date, leading patients to make treatment decisions based on inaccurate or incomplete data.
- The large number of trials can make it difficult for everyone (including doctors) to stay up-to-date and figure out which trial is best for the patient.
- The abundance of trials means doctors and patients may have multiple options to choose from, creating competition amongst trials to recruit patients.
- There is still a tendency for a number of trials to focus on the same subtypes, leaving a void for other subtypes where better treatments are desperately needed.
- More new treatments are being brought forward for regulatory approval based on phase 2 data, leading to long-term data being collected during ‘real world’ use of the therapy rather than through phase 3 trials. In countries who require more data for approval, this can make it challenging to get the data required.

Patient organisations have an important role to play informing patients about trials, including aspects like how trials work, what's available to patients locally and who is eligible to participate.

Lymphoma Coalition currently provides support through the [Global Database](#), which includes a searchable list of phase II and phase III clinical trials running globally.

As well, the [Resource Library](#) includes information on clinical trial reported outcomes, so you can track what science is happening in a particular subtype or care category.

Hopefully, this newsletter will be a useful tool. Feedback is welcome and can be sent to lorna@lymphomacoalition.org.

Trials Addressing Unmet Needs

[Study of Ibrutinib Combined with Venetoclax in Subjects with Mantle Cell Lymphoma \(SYMPATICO\)](#)

- Phase 3 multinational, randomized, double-blind study is designed to compare the efficacy and safety of the combination of ibrutinib and venetoclax vs. ibrutinib and placebo in subjects with MCL.

[Study of Brentuximab Vedotin in Patients with Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma](#)

- Single-arm, open-label, multicentre, phase 4 clinical trial to evaluate the efficacy and safety of brentuximab vedotin as a single agent in patients with relapsed or refractory Systemic Anaplastic Large Cell Lymphoma (SALCL).

[Efficacy and Safety of Oral Azacitidine \(CC-486\) Compared to Investigator's Choice Therapy in Patients with Relapsed or Refractory Angioimmunoblastic T Cell Lymphoma](#)

- This study is a multicentric, open-label, randomized phase 3 trial.

Updates on Select Trial Outcomes

[Definitive radiotherapy for localized follicular lymphoma staged by 18F-FDG PET-CT: a collaborative study by ILROG](#)

- Outcome following radiotherapy for stage I and localized stage II follicular lymphoma after PET-CT staging is better than previously shown.
- More than two-thirds of patients remain in remission at 5 years and most relapses occur in distant sites.

[R-CHOP14 and 21 equally safe and effective for DLBCL](#)

- Fourteen- and 21-day cycles of R-CHOP (rituximab, cyclophosphamide, doxorubicin, prednisone, vincristine) are similarly safe and effective in the treatment of diffuse large B-cell lymphoma (DLBCL).
- R-CHOP14 remains a viable option in patients who prefer a shorter therapy course.

[Five-year follow-up of lenalidomide plus rituximab as initial treatment of mantle cell lymphoma](#)

- Lenalidomide plus rituximab as induction and maintenance therapy for MCL can achieve durable MRD-negative complete remissions.
- Chronic therapy-associated adverse events are generally non-accumulative and remain manageable.