



CLL SOCIETY

## The CLL Bloodline September 2020

**MONTHLY QUIZ:** The cancerous B lymphocytes that cause our CLL can proliferate in all the following areas of the body except:

1. The lymph nodes
2. The bloodstream
3. The bone marrow
4. The spleen

**ANSWER: The correct answer is # 2.** CLL is a cancer of the B cells. It is both a leukemia and lymphoma. The cancer clonal cells accumulate in the blood hence the high lymphocyte count. However, they only proliferate or reproduce in the nodes, bone marrow and the spleen. They cannot reproduce in the bloodstream.

### NEWS:

August 20, 2020: Genmab and Novartis announced plan to transition Arzerra (ofatumumab), a monoclonal antibody similar to rituximab, to an Oncology Access Program for Chronic Lymphocytic Leukemia patients in the U.S where it will be offered for free. Ofatumumab is rarely used in CLL. It is also helpful for some Multiple Sclerosis (MS) patients at much lower doses. In giving up the CLL market, the companies can charge more for ofatumumab to treat MS.

Save the date: The CLL Society Virtual Global Education Forum will be held on 10/10/2020. Registration is open.

The CLL Society Limited Duration and MRD Survey examines critical patient issues. It's available now. Thanks!

### BASICS: Clinical Trials Phases – This applies to all trials, including those for CLL and COVID-19

**Phase 1:** Is the drug safe and what's the best dose? There is no placebo arm. These are small trials. While there are officially designed to check for safety, clearly efficacy is also looked for.

**Phase 2:** Does the drug work? Is it effective? Medium size trials where there is no placebo or control arm. There can be different arms with different combinations or sequencing of the drugs.

**Phase 3:** Is it better than the standard of care? These are large trials where there is randomization to either a control arm of standard care or the new therapy. Only when there is no "standard of care," there might be a placebo arm. This is never the case in CLL. Ask if the trial allows "crossover" so that if one progresses on one arm, one can transfer to the other. That's important because it allows patients to get the benefit of the best treatment, no matter how matter to which arm they were randomized.

**Phase 4:** What else do we need to know about this approved drug or vaccine or treatment?

### WORD OF THE MONTH: Heterogeneity

**Heterogeneity** is the quality of being diverse in character or content. CLL is a heterogenous disease in that we are all different in how our disease progresses and is managed. In clinical trials and in statistics, the concept of **heterogeneous** populations is critical. Trials need to compare "apples to apples." This particularly applies in CLL where there is such heterogeneity. One easy example is that you can't compare relapsed patients to frontline patient from different trials.

*The CLL Society is invested in your long life. Please invest in the long life of the CLL Society*