CLL SOCIETY

The CLL Bloodline

September 2019

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

1. The lymph nodes
2. The blood stream
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 stream causing the high white count. However, they only proliferate or reproduce in the nodes, bone marrow and the spleen.

NEWS:

On August 14, the FDA announced Breakthrough Therapy Designation for Acalabrutinib to treat CLL making it one step closer to approval. Acalabrutinib is a next generation BTK inhibitor similar to ibrutinib but it has different and perhaps easier to tolerate side effects.

The CLL Society launched its TEST BEFORE TREAT project to ensure every patient gets the right tests and their best treatment. See https://cllsociety.org/cll-101/test-before-treat/ for more.

BASICS: Clinical Trial Phases

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 not the case in CLL. Ask if the trial allows "crossover" so that if one progresses on one arm one can transfer to the other.

Phase 4: What else do we need to know about this already approved drug?

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 example is that you can't compare relapsed /refractory patients to frontline patient from different trials.

If the CLL Society has helped you or a loved one, please consider making a donation.