Where the patient's leukemic cells contain the Philadelphia chromosome, optimal treatment requires administering a tyrosine kinase inhibitor, such as imatinib (61,62). The decision to administer imatinib is based on the diagnostic test revealing the presence of the Philadelphia chromosome.

2. *Chronic lymphocytic leukemia*

In the United States, there are about 15,000 new cases of chronic lymphocytic leukemia (CLL) per year (63). CLL involves fever without evidence of infection, extreme fatigue, night sweats, weight loss (64,65). The disease also results in anemia or thrombocytopenia due to bone marrow failure. Infections are frequent. The disease also involves rapidly rising lymphocyte count in peripheral blood, with a doubling time of less than 6 months.

The criteria for response to treatment include blood counts (lymphocytes, platelets, neutrophils), blood hemoglobin, and the number of nodules in the bone marrow, as set forth by the Guidelines from the NCI-sponsored Working Group Response Criteria for CLL (66) as well as progression-free survival (PFS) (67) and time to progression (TPP) (68). The endpoints of PFS and TTP require and depend upon acquiring data as set forth in these Guidelines.

Hallek et al. (69) provide methods for diagnosing CLL, for assessing the course of CLL, for assessing the response of CLL to treatment, and the relevant endpoints. The diagnosis of CLL requires at least 5,000 B lymphocytes per microliter of peripheral blood. The levels of membrane-bound proteins on the surface of the B cells, CD20, and CD79b, are low compared with levels found on normal B cells. Abnormal cytogenetics occur in more than 80% of all CLL cases. The most common deletions are in the long arm of chromosome 13. This cytogenic abnormality is abbreviated to del(13q14.1). This deletion of part of chromosome 13 is determined by the technique of fluorescence in situ hybridization (FISH).

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