Utility of positron emission tomography-computed tomography in patients with chronic lymphocytic leukemia following B-cell receptor pathway inhibitor therapy

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SUPPLEMENTAL MATERIAL

METHODS

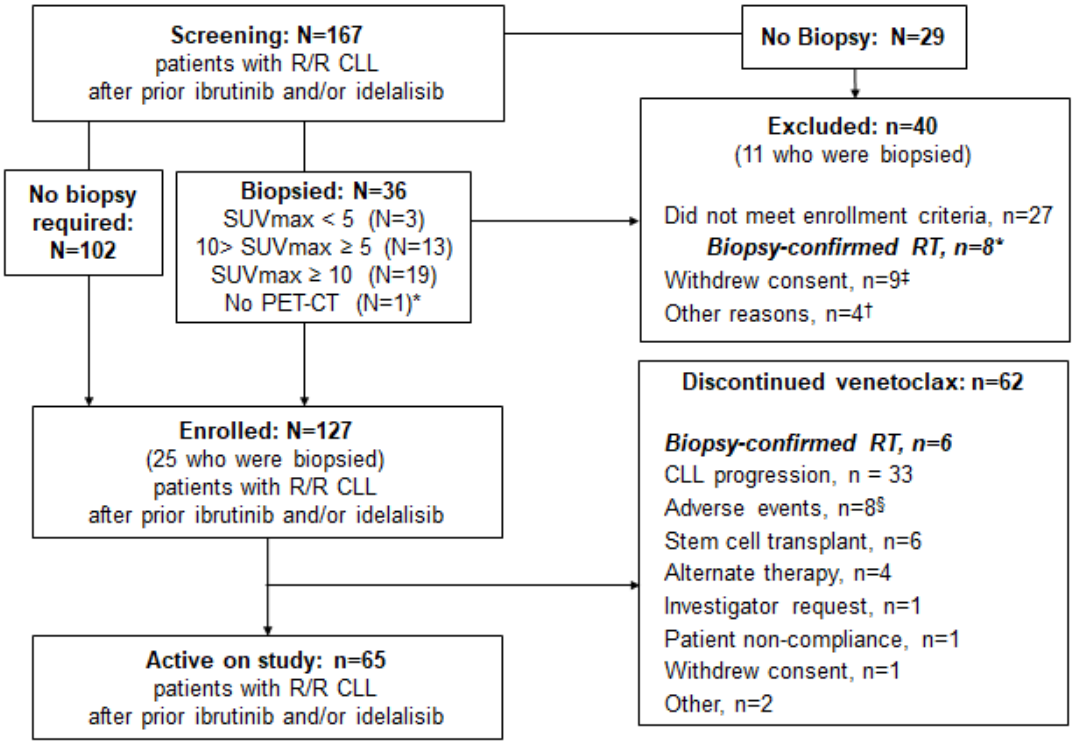
Screening Procedures continued

Study sites reported data on cytogenetics, histology, time since CLL diagnosis, disease stage, prior CLL therapies, and prior and concomitant medication usage. A complete physical examination, vital sign assessment, and clinical laboratory tests (including LDH and beta-2 microglobulin) were all performed. Data for complex karyotype were not available for analysis due to non-routine assessment. Mutation status for *IGHV* and *TP53* was reported by investigators and evaluated by local testing at each study site.

Assessments on Study

Disease assessments were performed at screening and at each study visit once in 8 weeks.(1) Responses were assessed by imaging and bone marrow evaluation according to 2008 iwCLL criteria.(2) CT (preferred) or magnetic resonance imaging was performed at screening and at weeks 8, 24, and every 12 weeks thereafter, up to 1 year for patients enrolled into the main cohort, and at screening and weeks 12, and 36 for patients enrolled into the expansion cohort. Responses were confirmed by a second assessment at least 2 months after first assessed. Bone marrow aspirate and biopsy were performed at screening and within 2 months after other criteria for complete response were observed. Minimal residual disease (MRD) in peripheral blood and bone marrow was assessed at a central laboratory using the standardized 6-color flow cytometry protocol published by the ERIC Consortium.(3, 4)

Figure A1. Trial Profile. *One patient with RT had an abnormal CT prior to screening for study, which led to a biopsy to confirm RT. PET-CT was not performed, but the patient was excluded based on biopsy findings. ‡Patients withdrew consent due to diagnosis of neuroendocrine tumor (n=1), anal cancer (n=1), patient started alternate therapy (n=3), patient decided not to participate in a clinical trial at that time (n=2), patient had 17p deletion and could get medication on market (n=1), and patient did not want to do through with screening procedures (n=1). †Other reasons for screen failure were investigator's decision, second primary malignancy discovered on screening (not RT), spleen biopsy required to assess for RT but not recommended by investigator, congestive heart failure (n=1 each). §Adverse events leading to venetoclax discontinuation were dysphagia, Corynebacterium sepsis, pneumonia, diarrhea, multi-organ failure, respiratory failure, salivary gland cancer, and unexplained death (n=1 each). R/R, relapsed/refractory; CLL, chronic lymphocytic leukemia, RT, Richter's transformation.



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