A Phase 1/2 Trial of Rituximab, Imprime PGG, and Alemtuzumab in the Early Treatment of Patients with High Risk Chronic Lymphocytic Leukemia (CLL)

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Background

Chronic Lymphocytic Leukemia (CLL) is the most common leukemia in adults. Certain markers of high-risk CLL, such as p53 mutations and IGHV mutation diversity, are associated with a higher chance of progression, and clinical trials have been developed to identify patients who may benefit from early treatment. However, clinical trials for high-risk CLL are limited, and the optimum treatment is still a subject of ongoing research.

Objectives

The objectives of this trial were to determine the maximum tolerated dose (MTD) of the combination of Imprime PGG and Rituximab, and the safety, efficacy, and immunogenicity of the combination in patients with high-risk CLL.

Methods

Eligible patients were randomized to receive either Imprime PGG and Rituximab or Rituximab alone. The regimen of Imprime PGG included Imprime PGG, rituximab, and alemtuzumab. The primary endpoint was the complete response rate, with secondary endpoints including duration of response, and time to subsequent treatment.

Hypothesis

Imprime PGG is a novel compound that enhances the ability of macrophages to activate neutrophils and monocytes, which may lead to improved clinical outcomes in patients with CLL.

Results

All 14 subjects had adverse events. Table 2 shows the number of subjects with identified adverse events considered by investigators to be unlikely or unrelated to study.

Adverse event data showed that the combination of Imprime PGG and Rituximab was well tolerated, with the majority of adverse events being grade 1 or 2. The most common adverse events were fever, nausea, and myalgia.

Conclusions

The combination of Imprime PGG and Rituximab was found to be safe and well tolerated in patients with high-risk CLL. Further studies are needed to determine the optimal dose and schedule of administration, and to evaluate the long-term efficacy and safety of this combination.

References