SuperGen Announces Results From Combination Study in CLL Published in the Journal of Clinical Oncology

DUBLIN, Calif., March 14 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG) announced today that an article entitled, "Pentostatin, Cyclophosphamide, and Rituximab Is an Active, Well-Tolerated Regimen for Patients With Previously Treated Chronic Lymphocytic Leukemia," appearing in the April issue of the Journal of Clinical Oncology, was published ahead of print on March 6, 2006. Mark A. Weiss and colleagues at the Cleveland Clinic and Memorial Sloan Kettering Cancer Center demonstrated higher response rates and similar or less toxicity using a three-drug combination therapy of pentostatin, cyclophosphamide and rituximab (PCR) for previously treated patients with Chronic Lymphocytic Leukemia (CLL) or other low-grade B-cell neoplasms.

The abstract, 10.1200/JCO.2005.04.3836, was published ahead of print on March 6, 2006, and is available online at http://www.jco.org/cgi/doi/10.1200/JCO.2005.04.3836 . The JCO's decision to publish ahead of print is made by the editors in conjunction with an article's authors, and is based on whether the research findings could have a substantial and immediate impact on clinical practice.

Study Purpose

The abstract updates a previously reported study on the use of pentostatin and cyclophosphamide (PC) in 23 patients with relapsed or refractory CLL. The two-drug combination therapy was active and well-tolerated. The study achieved an overall response rate of 74%, including 4 complete responses (17%). In these responders, 41% achieved their best response with PC versus any prior therapy. Encouraged by those results, the researchers undertook the recent study to investigate how the addition of rituximab to the combination therapy would affect the incidence of response, and to characterize the toxicity of the three-drug regimen with PCR in patients with previously treated B-cell CLL or other low-grade B-cell neoplasms.

Methodology

A total of 46 patients with either previously treated CLL (32 patients) or other low-grade B-cell neoplasms (14 patients) were treated. The median age was 62 years, with two prior regimens. Patients received pentostatin 4 mg/m2, cyclophosphamide 600 mg/m2, and rituximab 375 mg/m2 (PCR). All drugs were administered on the same day (rituximab omitted from cycle 1), and patients received six cycles at 3-week intervals. Filgrastim, sulfamethoxazole/ trimethoprim, and acyclovir were administered prophylactically.

Results

For CLL patients, there were 24 responses (75%), including eight complete responses (25%), one nodular response (NR) and 15 PRs (47%). In fludarabine- refractory patients, 75% responded. Toxicity levels were acceptable, with grade 3/4infections (including fever of unknown origin) in 28% of those treated. The regimen was well-tolerated, with 72% of patients receiving the planned treatment at full dose.

Response Duration and Survival

The addition of rituximab improved response duration, survival and overall toxicity. These studies were done sequentially and are not randomized comparisons. The median survival rate for the 32 CLL PCR patients was 44 months versus 17 months for patients on the two-drug combination therapy (PC). The use of pentostatin in a combination regimen (PCR) appears to be better- tolerated than fludarabine, cyclophosphamide and rituximab (FCR). Comparing this study to results from a similar study using FCR, results included 9% infusion-related toxicity in the PCR group versus 63% with FCR, and infectious complications (including fever of unknown origin) 28% in PCR patients versus 47% in the FCR group.

Conclusion

Combination therapy with pentostatin, cyclophosphamide, and rituximab is an active regimen. The addition of rituximab does not appear to significantly increase overall toxicity, but does appear to confer a survival advantage. As a result of these findings, the researchers are now investigating PCR as initial therapy for CLL patients.

About SuperGen

Based in Dublin, California, SuperGen is a pharmaceutical company dedicated to the acquisition, rapid development and commercialization of therapies for solid tumors, hematological malignancies and blood disorders. SuperGen's product portfolio includes: Nipent® (pentostatin for injection); Mitomycin (generic brand of Mutamycin®); and SurfaceSafe® cleaner.

About Nipent

Nipent® (pentostatin for injection) is currently approved as a single- agent treatment for patients with hairy cell leukemia and is not approved as either a single agent or as part of a combination regimen for treatment for any other indication.

For more information about SuperGen, please visit http://www.supergen.com .

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