SuperGen Reports Results from Dacogen(TM) Phase III Study in Myelodysplastic Syndromes (MDS)

Company anticipates completing 'rolling' NDA submission by end of third quarter

DUBLIN, Calif., March 31 /PRNewswire-FirstCall/ -- SuperGen Inc. (Nasdaq: SUPG -) today reported results from the Company's randomized Phase III study of Dacogen™ (decitabine) for injection as a treatment for myelodysplastic syndromes (MDS). The study enrolled 170 patients at 22 North American sites, with 89 randomized to Dacogen plus supportive care and 81 randomized to supportive care only. Supportive care included antibiotics, growth factors and/or transfusions. The data analysis was performed after 92 patients reached the primary endpoint of either progression to acute myelogenous leukemia (AML) or death.

Patients randomized to the Dacogen arm had an increased time to progression to AML or death (p=0.042 Wilcoxon test, p=0.198 log-rank test), compared to patients randomized to supportive care only. Median time to progression to AML or death in Dacogen patients was 338 days versus 263 days in supportive care patients. The overall response rate for patients randomized to Dacogen was 22 percent (9 complete responses and 11 partial responses) compared to 0 percent in patients on supportive care only (p<0.001 Fisher exact test). All analyses were specified by the protocol. The Company and its clinical advisors believe that these data are clinically significant and will form the basis of a New Drug Application.

More adverse events were reported for patients randomized to the Dacogen arm. Leucopenia and febrile neutropenia were observed more frequently in patients given Dacogen, as were nausea, constipation, diarrhea, vomiting, pneumonia, arthralgia, headache and insomnia. Severe adverse events observed more frequently in patients randomized to Dacogen, categorized as Grade 3 or 4, were leucopenia and febrile neutropenia. The rates of Grade 3-4 sepsis were similar (8 percent in the Dacogen arm versus 6 percent in the supportive care only arm). The mortality rate for patients on study is 12 percent for Dacogen and 9 percent for supportive care. This difference in mortality rates was not statistically significant.

"We are very pleased with the outcome of this study," said Dr. James Manuso, President and Chief Executive Officer of SuperGen. "We anticipate completing the submission of a 'rolling' New Drug Application to the FDA in the third quarter of this year."

MDS is a cancer of the bone marrow that is often fatal. Some cases of MDS progress to leukemia. According to the Aplastic Anemia and MDS International Foundation (http://aamds.org/), 20,000 to 30,000 new cases of MDS are diagnosed annually in the United States. The number of new cases diagnosed each year is increasing. The average life expectancy for patients diagnosed with MDS is 6 months to 5 years, depending on the severity of the disease.

Additional data from the clinical study is included at the end of this news release.

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. The company's website can be reached at www.supergen.com.

This press release contains "forward-looking" statements within the meaning of section 21A of the Securities Act of 1933, as amended, and section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created thereby. Such forward-looking statements include statements related to our expectations regarding Dacogen. The success of such product could differ materially from those discussed in the forward-looking statements as a result of known and unknown risk factors and uncertainties. Such factors include, but are not limited to: risks and uncertainties related to whether the Company will submit an NDA application to the FDA before the end of the third quarter, or at all, whether the FDA will accept the NDA filing for substantive review, whether additional clinical data will be needed before the FDA will approve the drug for commercialization or whether Dacogen will receive regulatory approval for any indication. References made to the discussion of the risk factors are detailed in the Company's filing with the Securities and Exchange Commission including the report on Form 10-K as amended for the year ended December 31, 2003. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.

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Selected data from the clinical study to follow ...

Investigator's Assessments of Patients' Reponses on Intent to Treat

	Dacogen (N=89)	Supportive Care (N=81)	P-Values
Best response on study			
Complete response	9 (10%)	0	<0.001(1)
Partial response	11 (12%)	0**	
Hematological improvement	10 (11%)	0	
Stable disease	33 (37%)	34 (42%)	
Progressive disease	15 (17%)	20 (25%)	
Not assessed for response*	11 (12%)	25 (31%)	

*Patients that withdrew from study prior to any response evaluation
**Two patients had a partial response to Dacogen after progressing on supportive care
(1)from 2-sided Fisher exact test for equal overall response rate (CR+PR)

Investigator's Assessments of Patients' Reponses Evaluable for Response

	Dacogen (N=78)	Supportive Care (N=56)	P-Values
Best response*			
Complete response	9 (12%)	0	<0.001(1)
Partial response	11 (14%)	0**	
Hematological improvement	10 (13%)	0	
Stable disease	33 (42%)	34 (61%)	
Progressive disease	15 (19%)	20 (36%)	

*Patients that withdrew from study prior to any response evaluation
**Two patients had a partial response to Dacogen after progressing on supportive care
(1)from 2-sided Fisher exact test for equal overall response rate (CR+PR)

Times to AML or Death

- (Patients withdrawing consent, not receiving randomized treatment or crossing over are censored)

Population	Dacogen (N=89)		Supportive Care (N=81)		P-Value
All Patients	89		81		0.042(1)
Number of Events (%)	46	(52%)	46	(57%)	0.198(2)
Median (days)	338		263		
High Risk IPSS Patients	23		21		0.001(1)
Number of Events (%)	14	(61%)	17	(81%)	0.004(2)

Median (days)	275		79		
Intermediate-2 IPSS	38		36		0.227(1)
Patients	20	(53%)	20	(56%)	0.417(2)
Number of Events (%)	340		275		
Median (days)					
Int-2 & High Risk IPSS					
Patients	61		57		0.005(1)
Number of Events (%)	34	(56%)	37	(65%)	0.040(2)
Median (days)	334		189		
Intermediate-1 IPSS					
Patients	28		24		0.624(1)
Number of Events (%)	12	(43%)	9	(38%)	0.508(2)
Median (days)	370		417		
Previously Treated MDS					
Patients	27		19		0.340(1)
Number of Events (%)	17	(63%)	9	(47%)	0.193(2)
Median (days)	300		417		
Treatment Naive MDS					
Patients	62		62		0.004(1)
Number of Events (%)	29	(47%)	37	(60%)	0.030(2)
Median (days)	354		189		

(1)2-sided Wilcoxon Test for homogeneity of survival distributions
(2)2-sided log-rank Test for homogeneity of survival distributions

Baseline Characteristics

	Dacogen (N=89)		Supportive Care (N=81)		P-Values(1)
Age (years)					
Median	70		70		0.113
IPSS Stage					
Intermediate-1	28	(31%)	24	(30%)	0.980
Intermediate-2	38	(43%)	36	(44%)	
High Risk	23	(26%)	21	(26%)	
Weeks Since MDS Diagnosis					
Median	29		35		0.990
Gender					
Male	59	(66%)	57	(70%)	0.622
Female	30	(34%)	24	(30%)	
Type of MDS					
De Novo	77	(87%)	70	(86%)	1.00
Secondary	12	(13%)	11	(14%)	
Previous MDS Therapy					
Yes	27	(30%)	19	(23%)	0.388
No	62	(70%)	62	(77%)	

(1)from 2-sided Fisher exact test