



SuperGen Announces FDA Acceptance of Rolling NDA Request for Dacogen

DUBLIN, Calif., April 22 /PRNewswire-FirstCall/ -- SuperGen Inc. (Nasdaq: SUPG) announced today that the Food and Drug Administration has granted its request for a rolling NDA submission for Dacogen™ (decitabine) for injection. The planned NDA will focus on patients with Myelodysplastic Syndromes (MDS). SuperGen anticipates it will begin submitting data in this quarter, and will complete its submissions by the end of the third quarter of 2004.

The rolling submission is an FDA provision available to drug candidates that have received Fast Track designation, and allows for completed sections of an NDA to be submitted on an ongoing basis. Fast Track status for Dacogen™ was granted by the FDA on May 9, 2003.

"This is an important milestone for SuperGen," said Dr. James Manuso, President and Chief Executive Officer of SuperGen. "The rolling submission will help us to realize our commitment to bring Dacogen through the review process in a timely, thorough and efficient manner."

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.

Based in Dublin, Calif., 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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