SuperGen Granted Orphan Drug Designation for MP-470 in Glioblastoma Multiforme

DUBLIN, Calif., Aug. 7 /PRNewswire-FirstCall/ -- SuperGen, Inc. (Nasdaq: SUPG), a pharmaceutical company dedicated to the discovery, rapid development and commercialization of therapies for solid tumors and hematological malignancies, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for the company's lead drug candidate, MP-470, for the treatment of glioblastoma multiforme (GBM), an often fatal form of brain cancer.

The FDA accepted SuperGen's application upon review of data from in vitro studies in glioblastoma cell lines that demonstrate that either MP-470 or ionizing radiation (IR) alone induce cell death, but when used in combination they synergistically increase cell death by more than two-fold over either agent alone.

MP-470 is currently being evaluated in phase 1 trials as a single agent and in combination with chemotherapy in patients with solid tumors, and a phase 1b study in patients with GBM is planned.

"Glioblastoma is the most common malignant primary brain tumor, representing approximately 10% of all brain tumors," said Gregory Berk, MD, SuperGen's Chief Medical Officer. "This designation not only underscores the need for improved therapies in GBM, it also underscores the company's development strategy in pursuing areas of unmet need."

About MP-470

MP-470 is an oral, selective multi-targeted tyrosine kinase inhibitor that suppresses c-MET, c-RET and the mutant forms of c-KIT, PDGFR and FLT3. MP470 also suppresses Rad51 protein, a critical component of double-stranded DNA repair in cancer cells. Preclinical testing of MP-470 has identified anti- tumor activity against a wide spectrum of cancers.

About Glioblastoma Multiforme

GBM, also known as grade IV astrocytoma, is the most common and aggressive malignant brain tumor in adults. Brain tumors are the second leading cause of cancer-related deaths in males ages 20-39 and the fifth leading cause of cancer-related deaths in women ages 20-39. Approximately 50,000 cases of primary central nervous system (CNS) cancers are diagnosed each year in the United States, of which 22,000 are malignant tumors. More than 35,000 Americans have GBM, which accounts for approximately 52% of all primary malignant brain tumors, and approximately 13,000 will die each year from the disease. The tumor forms in the glial (supportive) tissue of the brain and invades adjacent tissue. The tumor cells do not spread throughout the body and symptoms are caused by the tumor invading the brain.

Surgery is generally the first line of treatment, followed by radiation therapy and chemotherapy, either individually or in combination. Although primary treatment is often successful in temporarily stopping the progression of the tumor, glioblastoma multiforme tumors almost always recur and survival rates remain low. Thus the disease remains a significant unmet clinical need in oncology.

About Orphan Drug Designation

"Orphan drug" is a designation by the FDA indicating a therapy developed to treat rare diseases affecting fewer than 200,000 persons in the United States. Orphan drug designation entitles SuperGen to seven years of market exclusivity for MP-470 in the treatment of patients with GBM. Additional incentives include potential tax credits related to certain clinical trial expenses, a possible exemption from the FDA user fee, and assistance in clinical trial protocol design.

About SuperGen

Based in Dublin, Calif., SuperGen, Inc. is a pharmaceutical company dedicated to the discovery, rapid development and commercialization of therapies for solid tumors and hematological malignancies. SuperGen is developing a number of therapeutic anti-cancer products focused on kinase and cell signaling inhibitors and DNA methyltransferase inhibitors. For more information about SuperGen, please visit http://www.supergen.com.

Forward-Looking Statements

This news release contains certain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that may cause actual results to differ materially from the results discussed in these statements. Factors that might cause the company's results to differ materially from those expressed or implied by such forward-looking statements include, but are not limited to, the ability to discover, develop and move target compounds into clinical development and other risks and uncertainties detailed from time to time in the company's filings with the Securities and Exchange Commission including its most recently filed Form 10-Q and 10-K. SuperGen, Inc. undertakes no duty to update any of these forward-looking statements to conform them to actual results.

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