sigma-tau
PHARMACEUTICALS, INC.
Rare dedication

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Sigma-Tau Pharmaceuticals Cysteamine Eye Drop NDA Accepted for Filing

Cystinosis Treatment Granted Priority Review Status

GAITHERSBURG, MD – May 17, 2010 - Sigma-Tau Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has accepted the filing of the company's new drug application (NDA) for its cysteamine hydrochloride ophthalmic solution, an investigational therapy for the treatment of corneal cystine crystals in patients with cystinosis. The FDA also granted the NDA Priority Review status, a designation given to drugs that may provide major advances or a treatment where no adequate therapy exists.

Cystinosis is a rare disease affecting as few as 300 people in the U.S. The company has been granted orphan drug designation for this product and previously received a grant from the FDA's Orphan Drug Products Division to help fund the treatment research. If approved, this medicine will be the first FDA approved treatment for corneal cystine crystal accumulation, which can lead to changes in visual acuity and photophobia (i.e., sensitivity to light).

"Acceptance of the NDA marks an important milestone for both Sigma-Tau and the cystinosis community," said Gregg Lapointe, Chief Executive Officer of Sigma-Tau Pharmaceuticals. "If approved, this treatment has the potential to offer important benefits for patients—many of whom are children—whose care has been limited due to a lack of therapeutic options and access."

The NDA includes data from clinical trials conducted at the National Institutes of Health (NIH) National Eye Institute. Results of the studies indicate that administration of cysteamine hydrochloride eye drops may be effective in the prevention and treatment of corneal cystine crystals.

"Cystinosis is a devastating disease that too often robs children of normal vision," said Christy Greeley, President and Executive Director of the Cystinosis Research Network, Inc. "We are excited about the prospect of a new, accessible treatment option for our kids."

About Cystinosis
Cystinosis is a rare, genetic lysosomal storage disease characterized by the abnormal accumulation of the amino acid cystine. It is estimated that 2,000 individuals worldwide have cystinosis. Primarily affecting children, cystine crystals accumulate in the kidneys, liver, muscles, pancreas, brain, white blood cells and eyes. While treatment for reducing cystine accumulation in the body exists, there is currently no FDA approved treatment for corneal cystine crystal accumulation, which can lead to changes in visual acuity and photophobia (i.e., sensitivity to light).

About Sigma-Tau Pharmaceuticals, Inc.
Sigma-Tau Pharmaceuticals, Inc. is a U.S. based, wholly owned subsidiary of the sigma-tau Group, and is dedicated solely to the global development and commercialization of medicines for patients with rare diseases. Sigma-Tau Pharmaceuticals, Inc. is based in Gaithersburg, Maryland.

Since 1989, the company's products have been focused on rare diseases, kidney disease, and cancer. With more than 6,000 identified rare diseases that affect approximately 25 million patients in the United States, Sigma-Tau places its considerable scientific resources behind the development and commercialization of compounds that benefit the few. The company has substantial development programs focused on transplant, cancer, inherited genetic disorders, malaria, and other areas of unmet medical need.

For more information about the company, visit www.sigmatau.com.

About sigma-tau Group
sigma-tau Group is a leading, international, pharmaceutical group with a wholly Italian-owned capital that invests in the research, development and marketing of innovative and effective treatments to improve patient well-being and quality of life. sigma-tau has its headquarters in Pomezia (Rome, Italy), and subsidiaries in France, Switzerland, Belgium, the Netherlands, Portugal, Germany, the UK, USA and India, as well as in Spain and Sudan where the Group operates two production facilities. It has over 2300 employees and an extensive network of licensees worldwide. sigma-tau was founded in Italy in 1957 and achieved a global turnover of € 613 million ($909 million) in 2008. sigma-tau SpA consistently invests approximately 16% of its annual turnover in R&D. sigma-tau's R&D staff of approximately 400 people is currently running 46 R&D projects. A total of 13 NCEs and 12 known molecular entities in 33 different indications are at various stages of development. Among them, several are aimed at rare diseases. Therapeutic areas in which the company's research and development are focused include metabolism, neurology, cardiovascular, oncology and immunology. sigma-tau website: www.sigma-tau.it.

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