

FOR IMMEDIATE RELEASE:

Rare dedication

Sigma-Tau Pharmaceuticals Seeking FDA Approval of Medicine for Rare Genetic Disease Affecting Less than 100 Americans

July 9, 2008, Gaithersburg, MD – Sigma-Tau Pharmaceuticals, Inc. is pleased to announce the acquisition of Chenofalk[®] (chenodeoxycholic acid) from the Germany-based, Dr. Falk Pharma GmbH. Chenofalk[®] is approved in Germany for the dissolution of gallstones, and Sigma-Tau's German affiliate, Sigma-Tau Arzneimittel GmbH, will immediately assume distribution of this important medicine, ensuring there is no interruption in availability to patients.

The acquisition of Chenofalk[®] is important not only to ensure continued supply in Germany, but Sigma-Tau Pharmaceuticals also intends to accumulate the appropriate clinical and regulatory documentation required to support the filing of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the use of chenodeoxycholic acid (CDCA) in the treatment of Cerebrotendinous Xanthomatosis (CTX) disease. CTX is an extremely rare genetic disease which is believed to affect fewer than one hundred people in the U.S.

“We are pleased to add CDCA to Sigma-Tau's rare disease portfolio. Sigma-Tau is committed to the development of medicines for patients with rare diseases, and the acquisition of Chenofalk[®] provides relief to patients concerned about a disruption in supply” said Gregg Lapointe, Chief Executive Officer of Sigma-Tau Pharmaceuticals. “Acquiring the underlying clinical, manufacturing and safety data contained in the Chenofalk[®] dossier is also an important milestone in Sigma-Tau's goal of ultimately securing FDA approval for the use of CDCA in patients with CTX.”

CTX is a metabolic disorder with no FDA approved treatment in the United States. People with this disorder cannot break down certain cholesterol effectively. Consequently, these cholesterol accumulate in various areas of the body. Some features of CTX include chronic diarrhea during infancy, clouding of the lens of the eye (cataracts) developing in late childhood, progressively brittle bones that are prone to fracture, and neurological problems in adulthood, such as dementia, seizures, hallucinations, depression, and difficulty with coordinating movements (ataxia) and speech (dysarthria).

In 2007, Sigma-Tau obtained an Orphan Drug Designation from the FDA for the use of CDCA in CTX. Since then, Sigma-Tau has worked closely with the United Leukodystrophy Foundation (ULF) to better understand the impact of CTX disease on patients and the importance of proper newborn screening for the disease.

About Cerebrotendinous Xanthomatosis (CTX)

Cerebrotendinous Xanthomatosis (CTX) is a rare, autosomal recessive metabolic disorder caused by mutations in a gene called CYP27A1, which produces an enzyme called sterol 27-hydroxylase. Sterol 27-hydroxylase is required to turn cholesterol into bile acids, which are important in the absorption of fat in the intestine. In addition, when sterol-27 hydroxylase is not working properly, cholesterol and precursors of bile acids will accumulate in tissues throughout the body causing a variety of physiologic and neurological problems.

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 U.S., Sigma-Tau places its considerable scientific resources behind the development and commercialization of compounds that benefit the few. The company has a substantial development program 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 research-based Italian pharmaceutical company with a 2007 consolidated turnover equal to approximately US\$ 980 million and over 2,500 employees worldwide. Therapeutic areas in which Sigma-Tau Group's research and development are focused include cardiovascular disease, metabolism, oncology, immunology, central and peripheral nervous system with 47 projects, 30 clinical indications studied with 17 proprietary molecules, most of which are new and original. For additional information about Sigma Tau Group, please visit www.sigma-tau.it.

About United Leukodystrophy Foundation (ULF)

The United Leukodystrophy Foundation (ULF) is dedicated to helping patients and family members afflicted with various types of leukodystrophies including CTX. The ULF is committed to the identification, treatment and cure of all leukodystrophies through programs of education, advocacy, research and service.

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