Sigma-Tau Pharmaceuticals Announces Approval for New Manufacturing Process for ONCASPARÃ,® (Pegaspargase) Primary Ingredient

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GAITHERSBURG, Md., April 18, 2011 /PRNewswire/ -- Sigma-Tau Pharmaceuticals, Inc. is pleased to announce that it has received approval from the U.S. Food and Drug Administration (FDA) to manufacture L-asparaginase, the primary ingredient in the oncology medicine ONCASPAR® (pegaspargase). ONCASPAR is the only FDA-approved PEGylated formulation of L-asparaginase which is a key component in the treatment of acute lymphoblastic leukemia (ALL). The attempt to secure approval to manufacture L-asparaginase came after the previous supplier decided to cease production, leading to a three-year development effort to create a comparable active ingredient. The approval averts a potentially dangerous drug shortage situation in the U.S. which could have affected thousands of patients with ALL.

"To get a complex biologic medicine such as this exactly right takes a great deal of work for both the manufacturer and the FDA," said Gregg Lapointe, Chief Executive Officer, Sigma-Tau Pharmaceuticals, Inc. "We are pleased to announce that with this approval, there will be no interruption in either the production of the medicine or in the treatment of patients with ALL."

L-asparaginase is an enzyme that depletes the amino acid asparagine, which certain leukemic cells are dependent upon for survival. L-asparaginase was first approved in 1978 as a treatment for ALL. In 1994, the FDA approved the PEGylated formulation of the medicine (ONCASAPR) which has the unique therapeutic advantages of sustained duration and prolonged effect over the native L-asparaginase, resulting in enhanced convenience for patients and providers. ONCASPAR is given to patients with ALL as part of a multi-agent chemotherapeutic treatment regimen. Administering L-asparaginase results in the depletion of asparagine circulating in the blood, which starves the leukemic cells and results in their death. ONCASPAR was updated to first-line indication in 2006.

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