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Sigma-Tau PharmaSource, Inc. and Aradigm Corporation Sign Manufacturing Agreement for the Clinical and Commercial Supply of Pulmaquin

INDIANAPOLIS & HAYWARD, Calif.--(BUSINESS WIRE)-- Sigma-Tau PharmaSource, Inc. (a wholly owned subsidiary of Sigma-Tau Pharmaceuticals Inc.), a biopharmaceutical contract manufacturer specializing in complex injectable formulations, including liposomal drug delivery technology and PEGylation, and Aradigm Corporation (OTC BB: ARDM.OB), an emerging specialty pharmaceutical company focused on the development and commercialization of drugs delivered by inhalation for the prevention and treatment of severe respiratory diseases, today announced that they have entered into a broad manufacturing services agreement whereby Sigma-Tau PharmaSource will provide Aradigm with clinical and commercial supplies of Pulmaquin®. Pulmaquin is Aradigm's proprietary formulation of inhaled ciprofloxacin for the treatment of severe respiratory diseases, including non-cystic fibrosis bronchiectasis (BE).

Under terms of the agreement, Sigma-Tau PharmaSource will manufacture all product for Aradigm's Phase 3 clinical studies, and will support Aradigm in the preparation of its submissions to regulatory authorities in pursuit of marketing approval for the product. Subsequent to market approval, Sigma-Tau PharmaSource will produce the product commercially for patients using Pulmaquin. Financial terms of the agreement were not disclosed.

BE is a chronic orphan condition characterized by abnormal dilatation of the bronchi and bronchioles often associated with chronic lung infection. The disease is frequently observed in patients with cystic fibrosis (CF). However, it also affects over 110,000 people without CF in the U.S. and elsewhere, and results from a cycle of inflammation, recurrent infection, and bronchial wall damage.

Commenting on today's news, Dave Lemus, Chief Executive Officer of Sigma-Tau Pharmaceuticals, noted, "We are delighted to be able to expand our partnership with Aradigm, as Pulmaquin enters Phase 3 trials and Aradigm pursues potential future commercialization of this promising therapeutic for its underserved patient population. Moreover, this latest manufacturing services agreement underscores the strong fit that this project has, with not only our very significant expertise in complex liposomal formulations, but also with the capabilities of our manufacturing facility in the wake of extensive upgrades recently made to the plant."

"Sigma-Tau PharmaSource and Aradigm have a long history of working together on multiple programs, including manufacture of our AERx® inhaler dosage forms and, importantly, all of our Phase 1 and Phase 2 clinical supplies of our inhaled ciprofloxacin formulations. We are therefore delighted to be entering this exciting new phase of our Pulmaquin development with them," said Igor Gonda, President and Chief Executive Officer of Aradigm.

About Sigma-Tau PharmaSource, Inc.

Sigma-Tau PharmaSource, Inc., a wholly owned subsidiary of Sigma Tau Pharmaceuticals, Inc., is located in Indianapolis, IN, on a 26 acre site, with a manufacturing facility of 56,000 sq. ft. in addition to a leased facility of 13,500 sq. ft. for warehousing and offices. The site manufactures the key products for Sigma-Tau Pharmaceuticals, Inc. (Oncaspar, Adagen, and Abelcet) and provides third party manufacturing services for customers, together serving global markets (US, Canada, Mexico, Brazil, Europe, Middle East, Africa). All products manufactured are sterile, aseptically filled vial products. The plant's focus for third party manufacturing is on small to medium scale liquid injectables, with particular emphasis on complex liposomal or pegylated formulations.

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 to the global development and commercialization of medicines for patients with rare diseases. Sigma-Tau Pharmaceuticals, Inc. is based in Gaithersburg, Maryland, and the company's marketed products are focused on cancer, kidney disease, gastrointestinal and genetic related disorders. The company also has clinical development programs focused on transplant, inflammation related disorders, hematological cancer, certain inherited genetic disorders, malaria, and other areas of unmet medical need. For more information about the Sigma-Tau Pharmaceuticals, Inc., visit www.sigmatau.com.

About Aradigm Corporation

Aradigm is an emerging specialty pharmaceutical company focused on the development and commercialization of drugs

delivered by inhalation for the prevention and treatment of severe respiratory diseases. Aradigm has product candidates addressing the treatment of bronchiectasis, cystic fibrosis, inhalation tularemia and anthrax infections, and prevention of respiratory and other diseases in tobacco smokers through smoking cessation. More information about Aradigm can be found at www.aradigm.com.

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Photos/Multimedia Gallery Available: <http://www.businesswire.com/multimedia/home/20130916005063/en/>

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