Amira Pharmaceuticals Receives Orphan Drug Status for a Novel LPA1 Antagonist, AM152, for the Treatment of Idiopathic Pulmonary Fibrosis

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SAN DIEGO, April 19, 2011 /PRNewswire/ -- Amira Pharmaceuticals, Inc. announced today that AM152, the company's lead LPA1 antagonist, has been granted an orphan drug designation by the U.S. Food and Drug Administration for the treatment of idiopathic pulmonary fibrosis. Commonly referred to as IPF, this fibrotic disease affects the lungs of patients and their ability to breathe.

"This is an important development for Amira, and potentially patients suffering from IPF, as we continue to move this promising therapeutic candidate forward in development," said Bob Baltera, Chief Executive Officer. "We are currently completing our Phase 1 studies with AM152 and expect to begin a Phase 2 study by the end of 2011 or in early 2012. Currently there are no FDA-approved therapies for IPF, and we look forward to better understanding the potential therapeutic benefit of an LPA1 antagonist in this disease area."

AM152 is a lysophosphatidic acid (LPA) receptor 1 antagonist. Activation of the LPA1 receptor by LPA has been implicated in a number of disease processes, including tissue fibrosis. LPA1 receptor antagonists have displayed efficacy in a wide range of preclinical fibrosis models, including lung, skin, eye, liver and kidney.

About Orphan Drug Designation

The United States Orphan Drug Act of 1983 was created to promote and support the development of new drug therapies for diseases that affect fewer than 200,000 people in the United States. Orphan Drug Designation provides a sponsor seven years of market exclusivity for the designated therapeutic indication in the United States, from the point at which the therapy is granted marketing approval. Orphan Drug Designation also provides access to regulatory support from the FDA, potential FDA fee reductions and tax credits related to development expenses.

About Amira

Founded in 2005 and headquartered in San Diego, Amira Pharmaceuticals i
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Links:
[1] http://www.bio-medicine.org/medicine-technology-1/Amira-Pharmaceuticals-Receives-Orphan-Drug-Status-for-a-Novel-LPA1-Antagonist--AM152--for-the-Treatment-of-Idiopathic-Pulmonary-Fibrosis-16492-1/