Kadmon Initiates Phase 2 Clinical Trial Evaluating KD025 in Idiopathic Pulmonary Fibrosis

-- Trial Represents Kadmon’s Entry into Clinical Fibrosis Research --

NEW YORK, June 3, 2016 – Kadmon Corporation, LLC today announced that the first patient has been dosed in a Phase 2 clinical trial of KD025, the Company’s rho-associated coiled-coil kinase 2 (ROCK2) inhibitor, for the treatment of idiopathic pulmonary fibrosis (IPF), a chronic and ultimately fatal disease characterized by the scarring of lung tissue.

The randomized, open-label, 24-week study examines the safety, tolerability and activity of KD025 in IPF patients in the United States who have received or been offered pirfenidone and/or nintedanib. Thirty-six patients will be randomized into two cohorts: one cohort of 24 patients treated with KD025 at 400 mg QD, versus another cohort of 12 patients treated with standard of care.

In fibrotic diseases like IPF, ROCK2 signaling is up-regulated in fibrotic tissues, effecting macrophage infiltration, endothelial cell activation and myofibroblast differentiation. These processes result in excess collagen deposition, scar tissue formation, organ malfunction and death. Preclinical research conducted by Kadmon has demonstrated that ROCK2 inhibition has the potential to halt and reverse these fibrotic processes. ROCK2 inhibition with KD025 significantly reduced established lung fibrosis and inflammation and improved pulmonary function in a dose-dependent manner in a bleomycin-induced mouse IPF model.

“This study marks Kadmon’s entry into the field of fibrosis, a disease area where we believe ROCK2 inhibition represents a promising new therapeutic approach,” said Harlan W. Waksal, M.D., President and Chief Executive Officer at Kadmon. “Based on our preclinical studies demonstrating the potential anti-fibrotic effects of KD025, we believe our drug may have clinical utility in IPF, a significant unmet medical need.”

About Kadmon Corporation
Kadmon Corporation, LLC is a fully integrated biopharmaceutical company focused on developing innovative products for significant unmet medical needs. We have a diversified product pipeline in autoimmune and fibrotic diseases, oncology and genetic diseases.

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