Latest News on FDA NDA Submission

New Non-Steroidal Treatment for Pulmonary Fibrosis (IPF) to improve Patient Quality of Life

EmphyCorp is proud to announce the completion of a clinical trial to define medical endpoints as requested by the FDA for the NDA marketing application in patients with Pulmonary Fibrosis, under its Orphan Drug Designations for the treatment of Interstitial Lung Diseases (ILD), which includes Pulmonary Fibrosis and Cystic Fibrosis.

The Clinical trials with our nasal spray demonstrated a statistically and clinically significant increase FEV-1, SaO2, FVC, FEV-1/FVC ratios (52% to 86%), and nitric oxide, (needed to increase bronchial dilation and fight infections), and a significant reduction of coughing, nasal erythema and inflammation and congestion, in all patients tested with Idiopathic pulmonary fibrosis.

Interstitial lung diseases encompass a large group of chronic lung disorders associated with excessive tissue remodeling, scarring, fibrosis, decreased FEV-1, FVC, PEF, FEV_1/FVC, SaO2, and nitric oxide. Currently 128,000 patients have Pulmonary Fibrosis with 48,000 new cases each year. Over 40,000 of these patients die each year. 96.88% of patients by age 60 with Pulmonary Fibrosis have nasal inflammation and congestion, which decreases the ability of nitric oxide to maintain normal lung functions[1] leading to increased lung and nasal infections, a reduced SaO2 level, post nasal drip that causes coughing, mouth breathing, and reduced FVC levels.

There were 32,381 complaints to the FDA that nasal steroidal products and all the over-the-counter products have failed to provide efficacy in the relief of nasal inflammation and have failed to increase lung function in patients with Pulmonary Fibrosis. Nasal steroids and other nasal treatments shut down the synthesis of nasal nitric oxide, which leads to decreased lung function and a 34% increase in infections

EmphyCorp globally patented nasal delivery system, with sodium pyruvate which is a naturally occurring antioxidant of the human body, has been shown to significantly reduce inflammatory agents throughout the human body, including the lungs as demonstrated in nineteen Phase I/II and Phase III human studies including eight human nasal studies submitted to the FDA in patients with, COPD, Pulmonary Fibrosis, and CF patients. .

Over three and a half million nasal spray units have been used to treat patients in over 200 hospitals, including an estimated 450,000 patients with COPD, and patients with “Unmet Needs”,

which includes Pregnant Women, small children, diabetics, pulmonary fibrosis and hypertensive who suffer from nasal congestion, nasal drip, Inflammation, but cannot take any nasal sprays with steroids.

Two recently approved drugs for the treatment of Pulmonary Fibrosis have a Patient cost of approximately $100,000 per year. The market size for the treatment of Pulmonary Fibrosis is estimated to reach 4 Billion Dollars per year by 2023.

[1] **Data from FDA reports and the FDA Voice of the Patient publication**

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