PRESS RELEASE

EmphyCorp Rx N115 Nonsteroidal Nasal Spray Expanded Phase III Clinical Trial results showed a 73% reduction in Coughing and clinically significant Improved Lung Function in Patients with Idiopathic Pulmonary Fibrosis (IPF)

Results are listed on the FDA ClinicalTrials.gov website.

Flemington, NJ – July 11, 2024 - EmphyCorp Inc. www.EmphyCorp.com, a Private Corporation, specializes in Rx Non-Steroidal Nasal Spray and Oral Spray Technology with no known side effects for all lung diseases. In numerous USA human clinical trials, N115 decreased lung and sinus inflammation, increased all lung functions and increased the synthesis of nasal Nitric Oxide that kills invading Bacteria, Fungi, and Viruses to prevent infection.

EmphyCorp announced the completion of an Expanded Phase III Clinical Trial with its Patented Rx N115 Non-Steroidal Nasal Spray demonstrating an extraordinary 73% reduction of Coughing in Patients with Idiopathic Pulmonary Fibrosis (IPF). *(This was a double-blinded randomized placebo-controlled Phase 3 Clinical Trial for Coughing and Improved Lung Function).*

The Phase III Clinical Trial Results for Rx N115 Nonsteroidal Nasal Spray for IPF Coughing and Improved Lung Function is listed on www.ClinicalTrials.Gov under Cellular Sciences (Listed as Sponsor): Study Details | The Effect of N115 on Coughing in IPF Patients | ClinicalTrials.gov.

Overview

Idiopathic Pulmonary Fibrosis (IPF) is a chronic progressive lung disorder associated with excessive tissue remodeling, scarring, and fibrosis, which makes the lungs unable to effectively transport oxygen into the bloodstream resulting in decreased forced expiratory volume in the first second (FEV_1) and forced vital capacity (FVC) values, decreased SaO_2, and a decrease in nitric oxide associated with nasal inflammation that causes congestion and coughing.

Nasal inflammation induces oxidative stress, decreases lung functions including FEV_1 and FVC values, and increases mucus and coughing. A decrease in total lung functions and capacity results in hypoxemia, dyspnea, and poor quality of life, especially sleep disorders.

Blockage of nasal nitric oxide by inflammation reduces the amount of nitric oxide reaching the lungs as nitric oxide is a bronchodilator, low levels reduce critical lung functions, leading to increased lung and nasal infections, a reduced SaO_2 level, reduced FEV_1 and FVC levels also leading to mouth breathing and coughing.

Methods

This was a 21-day double-blinded randomized placebo-controlled Phase III Clinical Trial.

24 saline placebo control patients and 26 N115 treated patients reported baseline coughs per day for one week and then were treated for 21 days while continuing to report daily coughing. Secondary endpoints included examining patients for FEV_1, FVC, and FEV_1/FVC ratios at baseline and over the course of 21 days.

Results

The data from this study demonstrated that coughing episodes per 24 hours were significantly reduced with no exceptions in all N115 treated patients by 38.4% on day 14 and by 73.2% on 22 day of the trial, whereas the placebo treated group reduced coughing by 16.1% on day 22 ($p < 0.0001$).

This correlated well with increased FEV1/FVC ratio, which were 27.9% on day 22 with N115 treated patients compared to 2.37% for placebo ($p < 0.0001$). In N115 treated patients at week 2 showed a significant 26.6% improvement in FEV-1 values compared to 6.83% in the placebo group ($p=0.0004$).

Week 3 showed a similar 26.6% mean improvement in the N115 treated group. No patients withdrew from the trial. No mild, moderate, or serious adverse events occurred. No safety or abnormal changes occurred with any vital signs, blood chemistry or hematology.

Conclusions

This randomized placebo controlled double blinded Phase 3 Clinical Trial demonstrated the efficacy of N115 Nasal Spray to clinically and statistically produce a significant decrease in coughing and increase lung functions compared to the saline control.

Overall, patients receiving N115 reported that their breathing was better, their coughing was reduced, and they were able to sleep better, thus improving their quality of life.

After day 21, patients discontinued use of the study medication. Patients were contacted by phone for follow up after 3 months.

Impressively, patients reported reduced coughing for a mean 38.8 days for N115 compared to only 5.54 days for the placebo ($p<0.0001$).

Patients on N115 also reported a sustained lower number of coughs per day relative to their baseline coughing (-23.7%) compared to the placebo (-11.9%) ($p=0.012$)).

Overall, patients receiving N115 reported that their breathing was better, their coughing was reduced, and they were able to sleep better, thus improving their quality of life.

In this 21-day, A double-blinded randomized placebo-controlled Phase 3 Clinical Trial, no patients withdrew from the trial. No mild, moderate, or serious adverse events occurred. No safety or abnormal changes occurred with any vital signs, blood chemistry or hematology.

Previous Clinical Studies in IPF, Pulmonary Fibrosis Patients and in Long COVID Patients

In a Phase 2 Human Clinical Trial with 22 Pulmonary Fibrosis patients including 6 patients with IPF that remained on their current therapies, N115 demonstrated clinically and statistically significant improvements in lung function as determined by changes in FVC, FEV1, PEF, and FEV1/FVC ratios. N115 treatment also reduced coughing in all these patients.

Previous Clinical Studies over a 22-year period included data from over 2,100 patients in the U.S. treated with varying concentrations of N115 delivered orally or as a nasal spray in varying formulas for diseases ranging from allergic rhinitis, nonallergic rhinitis, COPD, asthma, cystic fibrosis, sinusitis, Long COVID, COVID-19, and Pulmonary Fibrosis (including IPF). These 23 Phase 1/2/3 clinical trials have shown that N115 (sodium pyruvate) is both safe and effective in reducing nasal and lung inflammation and in increasing all lung functions.

Many Long COVID patients are developing Pulmonary Fibrosis and IPF. In Long COVID patients, the inhalation of the N115 nasal spray demonstrated clinically and statistically significant improvements in headaches ($p = 0.0373$), improvements in coughing/sneezing ($p = 0.0091$) by 60%, and improvements in trouble breathing ($p < 0.0001$) 61%. Fatigue, anxiety, loss of taste/smell, congestion and body aches also showed some improvement.

EmphyCorp Nasal Spray and Oral Spray Formulations for Respiratory, Long COVID, and Flu

To date, EmphyCorp/Cellular Sciences Inc has completed and submitted over 24 human clinicals (Phase I, II, III including animal safety data) to the FDA for the reduction of respiratory inflammation and inflammatory cytokines including IL-6 the cause of the cytokine storm in COVID patients, along with clinical data in patients with COPD, Pulmonary Fibrosis, CF, Allergic Rhinitis, Chronic Rhinitis, Sinusitis, and Flu.

It has also submitted to the FDA Pharmacodynamic Pharmacokinetics and carcinogenetic studies performed by NIH in 38 human clinical trials, confirmed that hyperpolarized [^{13}C]pyruvate is taken up by all organs including the respiratory system and metabolized to acetate and CO_2 and H_2O and is also converted to lactate or alanine in a well-defined biochemical pathways.

Pyruvate is also secreted by cells, readily enters cells, and can directly react with toxic compounds such as H_2O_2 and peroxynitrites to “detoxify them”. In genetic toxicology test systems, N115 (sodium pyruvate) has never been found to mutate DNA, is not genotoxic, mutagenic, or carcinogenic.

EmphyCorp has Orphan Drug Designation for Interstitial Lung Disease that includes Pulmonary Fibrosis, Idiopathic Fibrosis (IPF), Cystic Fibrosis, and over 200 rare breathing diseases.

EmphyCorp has (8) US Drug Patents including three new Composition Patents for Hypoxemia/ Dyspnea/ Coughing, Apoptosis of Myofibroblasts (to slow/stop fibrosis of the lungs), Coronavirus/Influenza, and 70+ Global Drug Patents.

EmphyCorp N115 Nasal Sprays have been used to treat over 3.5 million patients globally in 200 hospitals, with no adverse events.

Dr. Alain Martin (CEO) created the EmphyCorp Patented Nasal and Oral Sprays, as well as Advanced Neosporin, Advanced Lubriderm, Early Pregnancy Test (EPT), Cool Mint Listerine, plus discovering the use of Rx Rezulin Drug for Type II Diabetes earlier in his career at Warner Lambert (Pfizer acquisition). He also created patented OTC and Rx products including next generation triple antibiotic, skincare, drug free post laser aftercare lotion with a cooling gel for pain, patented pet anxiety product (OTC or Rx) with no side effects for our sister company North Cell Pharmaceutical www.NorthCellPharma.com.

An Up-to-date Rx N115 Nasal Spray and Oral Spray Drug Pipeline, Peer Reviews, and Press Releases can be found on the EmphyCorp website www.EmphyCorp.com.

Please contact Robert Millar for more information and Partnership interest at 973-586-4421 or EmphyCorp@optonline.net.