EMPHYCORP INFLUENZA AND COVID-19 ANIMAL AND HUMAN STUDIES

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Reducing the number of cases, symptoms, and severity of seasonal flu respiratory tract infections and for COVID-19

Flu and COVID-19 are known to cause mortality and morbidity in the elderly who are immunocompromised.

However, it is often forgotten that both diseases afflict children, usually with mild symptoms.
In rare cases, there is mortality caused by complications during Flu infection.

Since 2010, Flu has caused between 7,000-26,000 hospitalizations annually in children under five years old. Compared to that of COVID-19 which has accumulated a total of 3,240 hospitalizations in school-aged children.

To date, 51 children, aged less than 18, have died in the United States from complications with COVID-19.

Comparatively, the CDC has reported a range of 37-188 deaths annually in children under five years of age from complications caused by Flu.

Potential proactive treatments, such as N115 (sodium pyruvate), would be of benefit to all Populations, especially children that are afflicted by both viruses. In both animal and human trials, N115 reduced viral titers (number of viruses), and reduced the number, symptoms, and severity of seasonal Flu respiratory tract infections in pregnant women, children, diabetic, and patients with COPD by over 52% annually. This would prevent the strain on Hospitals.

Inhibition of Viral Replication and Reduction of the "Cytokine Storm" with EmphyCorp's Proprietary Compounds - Potential Treatment and Preventative for COVID-19 and Flu

1. In tissue culture studies, in human studies and in animal studies when inhaled or applied topically, sodium pyruvate inhibited the ability of many viral strains from replicating due to the ability of Sodium Pyruvate to increase the synthesis of Nitric Oxide that is needed to kill infections.
   Mice studies conducted by Independent University Virologists, substantiated our finding by testing nebulized N115 in Flu (influenza A H1N1 virus) infected mice that decreased morbidity, weight loss, proinflammatory cytokines, and decreased viral titers (virus numbers) compared to the Placebo Control.1.

   Furthermore, they stated "we have preliminary data that suggest it may work similarly during other respiratory virus infections including COVID19/SARS-CoV-2. Proactive treatments with sodium pyruvate is not toxic and could be of benefit to children that are afflicted by many respiratory viruses".

   Sodium Pyruvate Ameliorates Influenza A Virus Infection

   In Vivo - on BioRxiv: https://www.biorxiv.org/content/10.1101/2020.11.25.396978v1

2. Independent University Research Virologists just completed a Clinical Study, where Nebulizing Mice with sodium pyruvate that were infected with the Influenza A Virus decreased morbidity and weight loss compared to the Placebo Control.

   Additionally, treated mice consumed more chow during infection indicating improved symptoms (same results reported in a pilot mice COVID-19 study).

   There were notable improvements in pro-inflammatory cytokine production (IL-1β) and lower virus titers (viral numbers) on days 7 post infection in mice treated with Sodium pyruvate compared to the Placebo Control animals. As pyruvate acts on the host immune response, metabolic pathways and not directly on the virus, our data demonstrates that sodium pyruvate is a promising treatment option that is safe, effective, and unlikely to elicit antiviral resistance.

3. A clinical survey of 367 patients over a two-year period demonstrated a statically significant decrease in the number, symptoms, and severity of seasonal flu respiratory tract infections after using the 20mM sodium pyruvate nasal spray (EmphyCorp, N115). The number of Flu or Colds was reduced by 70% in Children and approximately 52% in Pregnant Women, Patients with Allergic Rhinitis, Diabetes, and Pulmonary Fibrosis.

4. In numerous human clinical trials (17, phase I, II, III clinical trials) submitted to the FDA, with Pulmonary Fibrosis, COPD and Cystic Fibrosis patients, N115 reduced nasal and lung inflammation and congestion by reducing inflammatory cytokines including the IL-6 cytokine that causes the so-called cytokine storm with no known adverse reactions.

5. In a Phase III Placebo Controlled Clinical Trial with Idiopathic Pulmonary Fibrosis Patients, N115 Non-Steroidal Nasal Spray demonstrated a statistically and clinically significant increase in Nasal Nitric Oxide, FEV-1, SaO2, FVC, FEV-1/FVC ratios (52% to 86%), and a significant reduction in coughing, nasal and lung inflammation.

   N115 alleviated the symptoms associated with the COVID-19 infections in Patients with COPD and Pulmonary Fibrosis

   N115 increases Oxygen by reducing hypoxemia, and it also reduces lung inflammation, inflammatory cytokines, and coughing. These are critical benefits for treating the symptoms of Covid-19, as lung inflammation leads to pneumonia and death.

6. Reducing the Rate and Spread of COVID-19 Among Patients with Pulmonary Fibrosis, Cystic Fibrosis and Diabetics is important. As cited in hundreds of peer reviewed publications, naturally occurring nitric oxide in the nasal cavities is a primary defense in humans. Nitric Oxide is needed to kill invading bacteria, fungi, and viruses, and prevents/reduces the rate and severity of viral infections, viral replication from the Common Cold, Rhinoviruses, Flu, and Coronavirus.

7. Most Diabetic, Hypertensives, Pulmonary Fibrosis and Cystic Fibrosis Patients have extremely low nasal nitric oxide which makes them more susceptible to viruses and lung infections. The rate of infection increases with decreasing levels of Nitric Oxide making them more susceptible to all infections including COVID-19 and Flu. Elevated levels of glucose in patients with diabetes mellitus cause a deficiency in the production of nitric oxide by blunting nitric oxide synthesis, which may explain why diabetics have a high susceptibility to COVID-19 and Flu.

8. EmphyCorp Global Patented N115 Technology, including China, has been used to treat over 3 million Patients worldwide in 200+ hospitals with no adverse events. 17 human clinical trials that have been submitted to the FDA to support our NDA Phase III marketing application.