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Abstract

Phase IIb/III Studies in the cure of (AZEE Vaccine) in the COVID-19 with Co-morbid illness Patients

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Abstract:

Primary Objective:

To determine the efficiency rate of combination therapy (AZEE) as COVID -19/ Cure in Human

Design Overview:

Randomized, placebo-controlled trial master protocol to evaluate the safety and efficacy of AZEE Vaccine against COVID-19 for the treatment of adult patients with COVID-19 with comorbid illness who are hospitalized;

This Phase IIb platform design, safety will be evaluated and two intermediate outcomes will be assessed to determine whether an agent advances to phase III;

Estimated sample size of 1000 (100 in each group) for each study agent;

Participants can be randomized: to a single (it can be more, depending on the study drug) infusion of AZEE or placebo;

No restriction on Lasix and aspirin will be provided to all patients

Primary endpoints:

Stage 1: 7-ordinal outcome scale of pulmonary and extra-pulmonary disease progression, and or 13 basic Complications or death at Day 5;

Stage 2: sustained recovery defined as 7 consecutive days at pre-COVID home;

All participants in Stage 2 (which includes people who were enrolled in Stage 1) will be followed for 90 days in total.

Secondary Endpoints

To see therapeutic outcomes among demographic group, and geographic location of COVID-19 Positive with (ICU, Ward, with any co-morbid illness);

Describe the clinical trial design, based on available safety

data for the therapeutic agent;

Define the patient selection strategy;

Justify the number of patients chosen for the Phase III trial (based on the proposed outcome measures and the appropriateness of the statistical methods);

Justify the sample size and duration of the Phase III clinical trial for the specific disease population;

Provide assurance that the proposed study can be completed within its budget and within the time limits.

Result and conclusion

AZEE will be administered to patients at sufficiently high dose of Injection levels to maintain tolerance in the entire immune cells and restore immune dysfunction, enhance immune cells ability, and inhibitory in severe and acute viral disease states;

At low dose Inhalation kills SARS-CoV-2 and activate the phagocytic activity of lung macrophages in the Alveolar and activate the humeral immune responses;

Therefore, the combined therapy Injectable and Inhalation as immunotherapy have an effects and when combined they have synergetic effect in both innate and adaptive tissues

Webinar on Vaccine Research and Development, November 27, 2020.

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