Call for Expression of Interest for Covid 19 Medicine Phase 1 Trial

Background:

LiveViroTreat, an anti Covid-19 aerosol-based medicine, ***invented in India***, is a simple yet effective solution to Covid-19. This medicine, nebulized into the respiratory system, directly attacks **ALL strains of Covid-19** and kills the Covid-19 virus in the respiratory system. So, LifeViroTreat works against ***all strains*** of Corona Virus.

Complementary to vaccination program: LifeViroTreat complements the vaccine program. Together, they are better. Not everyone will be able to get vaccine in time. Also, since effectiveness of vaccination is going to be 75+%, there are still some people who will get Covid-19 post vaccination. LifeViroTreat can cure those people.

Invention: LifeVirotreat is invented by India's top drug researchers, **Dr. Keshav Deo** (350+ drug innovation patents, 35+ years of drug research at Lupin, Alembic, SunPharma,Wockhardt and Cempra) and **Dr. Dinesh Panchasara** (20+ years in drug innovation).

Non-Toxic and production ready: LiveViroTreat medicine is ready for production. LifeViroTreat's acute toxicity and 28 days sub-acute toxicity tests were successfully completed at prestigious NIPER, Hyderabad. To stress test the safety of the product, the dose on rats/ rabbits was increased to ***10 times*** of that recommended for humans. ***NOT even a single rat/rabbit*** died even with such high dosage, clearly showing negligible to zero toxicity in LifeViroTreat. ***The report will be shared with parties who are interested in responding to EOI***

Current Status: Given acute toxicity and 28 days sub-acute toxicity is already completed, we need to get to next step:

1. **Trial LifeViroTreat in Phase I immediately with just 16-20 healthy volunteers:** We are so confident of zero toxicity and side effects of this drug that ***me and my family member are ready to volunteers for Phase I trial*** because we KNOW, this drug works.

2. Trial LifeViroTreat in Phase II in parallel with only 24 COVID-19 infected volunteers: LifeViroTreat can cure these people right in their homes since the usage mechanism just requires a common nebulizer, making it reachable to the poorest of the poor.

The advantages of this approach are:

1. LifeViroTreat will cure a patient regardless of the strain of the Covid-19, as it attaches to the RNA of the virus itself and stops it replication. Thus, it brings **new hope against the mutated virus strains that are coming out every day.**
2. **Those who either did not get vaccine or get Covid-19 even after the vaccination** can be treated and cured. This will speed up recovery from pandemic and start the economy much faster.
3. Treatment can be administered at home. Just as **paracetamol** is taken for fever at home, similarly, LifeViroTreat can be used at home without stressing para medical support.
4. LifeViroTreat can be used as prophylactic thus reducing spread of Covid-19

Objective / Scope of Work:

The objective of this EOI is to identify organisations with capability and interest in acting as sponsors or CROs for clinical trials for COVID-19 medicine phase 1 trial.

- To evaluate the safety (toxicity) of Lifevirotreat nebulizer based medicine and its maximum tolerated dose (MTD) on humans to be used in subsequent stages and to observe preliminary signs of drug efficacy against covid 19.
- To test the medicine in healthy volunteers or patients with Covid Phase on smaller number of patients typically 12-20 subjects for Phase 1 and subsequent Phase 2 trials
- To collect raw data and potentially prepare a report from the time of enrolling the participants to the completion of Phase 1 and Phase 2 trials for the period of study.

Potential trial subjects may be recruited:

- from a paper or electronic database of people who have indicated their willingness to take part in a trial
- by advertisements in a newspaper or magazine, or on a noticeboard in places such as a
- university or hospital, or on the radio or television, or on a website
- by word of mouth, or
- by referral from another doctor

Whatever the method of recruitment, subjects must be recruited of their own free will.

They should not be made to feel obliged to take part in a trial, nor should they suffer in any way if they do not take part. Additionally, they should be recruited only if they are capable of giving valid written consent, and have been fully and properly informed so that they understand the nature and purpose of the trial. They should be made aware of any risks, either known or suspected. They should also be informed that should they suffer any inconvenience or discomfort or pain, they can withdraw from either from Phase 1 or Phase 2 trial at any time without giving a reason. Further, the CRO should also inform the volunteers that they that the investigator may withdraw volunteers at any time from Phase 1 and Phase 2 trial if they do not follow the protocol or if their health is at risk.

Expression of Interest (EOI) is being solicited from:

Clinical Research Organisations: Past experience in clinical trials is not mandatory for submitting the EOI. Commitment of time of Principal Investigator and co-investigator will be considered as one of the key factors while shortlisting the trial sites.

Expectations from the professional organization/ agency: -

Apart from the scope of work described in earlier section, the agency is expected to understand the specific needs of Lifevirotreat in this endeavour and come up with a complete plan. The representatives from the organization / agency should interact with the concerned officials/Investigators from Lifeviro during the pre EOI meeting to understand the requirement.

S. No.	Item/area/activity	Yes	No	NA	Remarks/Comments/Details
1.	**ORGANIZATION AND PERSONNEL**				
1.1	Do you have experience of doing regulated clinical trials? *If yes, provide details of the last clinical trial mentioning type, duration, phase, and current status particularly any trial related to Corona Virus vaccine or drugs*				
1.2	Do you have adequate time to devote for trial related activities, besides current work load? Please mention number of hours possible to devote everyday				
1.3	How many clinical trials/studies are currently ongoing in your department? *Please provide status of the studies.*				
1.4	Do you have any research staff presently at your site? (*Can they manage an additional study?)*				

Financials: Suitable financials with the CRO can be discussed based on interest of CRO, their capability in efficaciously performing these trials and the capacity they can bring to successfully completing the the assignment in time.

The application may be addressed to LifeViroTreat and sent via e-mail at lifeviro@procuretech.in by 20th Feb, 2021 by 1800 hrs IST. Contact Details: Name: Pradeep, Phone: 9768465650