

## **Dearth of working capital hindering development of safer COVID-19 drug?**

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### **iSERA Biological has developed an anti-sera drug for COVID-19 treatment**

Pune-based startup iSERA Biological has recently entered the COVID-19 battle field with a new anti-serum drug that is currently undergoing phase 1 clinical trials. But the fight is turning out to be an arduous one due to dearth of working capital for the company.

Although the government is providing financial support to public research institutes and industry for COVID-19 vaccine and drug development by the way of the Department of Biotechnology (DBT), Ministry of Science & Technology, through its Public Sector Undertaking, the Biotechnology Industry Research Assistance Council (BIRAC), the funding criteria is very limited. As a result, startups such as iSERA Biological are unable to avail any such financial benefits.

iSERA Biological's anti-sera drug, which is the blood serum containing antibodies against the viral antigens, is being raised from horses. The systematic immunization process involves the use of high quality antigen conjugate mixed with Freund's adjuvant administered via the subcutaneous route.

"After obtaining requisite regulatory clearance we have started our production in Jan 2020 and immediately after one month, entire world started witnessing a highly spread and most life threatening pandemic disease COVID-19. Right now, we have a shortage of working capital. We need funds for maintaining animal facilities, to bear production costs, to carry out processes such as immunization, plasma collection, fractionation, purification etc.", points out Pratap Deshmukh, Director, iSERA Biological, Pune.

He further says, "Antibodies against the specific infection or disease are manufactured by injecting the virus or bacteria (dead or inactive) of the disease into the horse's body and after completion of successful immunization cycle, antibodies are separated from the blood and post purification it is given to the patient. If it is given in the early stage of the infection, then the success rate of patient recovery will be very much assured. This is called passive immunization. On this basis, a large number of such medicines have already been manufactured in India in the last several decades and many patients have been cured successfully. In fact, it has been proven that other than antisera no medicine is that much effective against life

threatening conditions such as snake bites and scorpion bites. As a recent example, Argentina based firm Inmunova Laboratories has started the research on an anti-COVID-19 serum in March 2020 and in Jan 2021, the company successfully launched the drug.

Currently, a big support for the startup is being provided by Pune-based vaccine manufacturer Serum Institute of India, by choosing it as a partner in research and development of this new anti-serum drug for COVID-19.

“We are closely working together with SII as our technology partner since last five months and successfully passed various stages up to its clinical trials. We are working on the hyper immune plasma production, while Premium Serums and Vaccine will carry out the fill finish manufacturing”, says Deshmukh.

In addition, Prithviraj Chavan, former Chief Minister, Maharashtra had recently visited the startups’ facility in Sangli district, which was his former Lok Sabha constituency.

“We have been granted test license for COVID-19 Anti-Serum drug from CDSCO. We are on the right path to develop one of the safest and most effective antidotes in next few days which will be available to serve for the mankind. The animal study ensures neutralization efficacy against all variants of concern. Also, our drug is much safer than remdesivir. For instance, the protein concentration in remdesivir is around 700mg which can be dangerous. While our product has a protein concentration that is 15-20 times lesser”, adds Deshmukh.

This observation makes us recall the recommendation issued by the World Health Organization (WHO) few months back against the use of remdesivir in hospitalized COVID-19 patients. In addition, there have been reports suggesting the harmful effects of the drug on heart activity.

It is indeed surprising that a huge amount is being spent by the government on the production of a drug in our country that might not even be safe.

The need of the hour is for the government to recognize the efforts being made by such startups in offering a safer solution for COVID-19 that might not only help in reducing the cost of hospitalization and fear but substantially help our affected economy to normalize.

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