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DCGI approves Sepsivac trial for COVID-19 treatment

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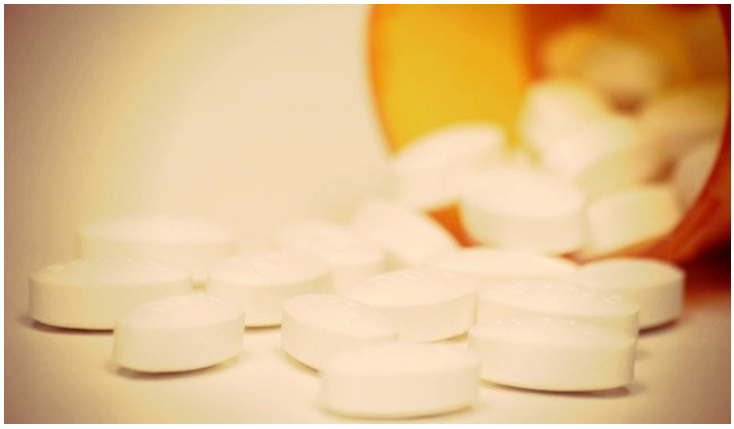
Looking at similarities between clinical characteristics of patients suffering from COVID-19 and Gram-negative sepsis



The Council of Scientific and Industrial Research (CSIR), through its flagship New Millennium Indian Technology Leadership Initiative (NMITLI) program, has been supporting Cadila Pharmaceuticals Ltd., Ahmedabad since 2007 for developing a drug to save lives of critically ill patients suffering from Gram-negative sepsis.

This entire development effort ***(pre-clinical and clinical studies)*** has been supervised by CSIR appointed Monitoring Committee. The drug has been shown to reduce the mortality of critically ill patients by more than half. It also leads to faster recovery of organ dysfunction seen in this condition. It is now approved for marketing in India. It will be available commercially as *Sepsivac*® from Cadila Pharmaceuticals Ltd.

This is a moment of pride for all of us as, despite best efforts, no other drug was approved in Gram-negative sepsis for reducing mortality (death) globally.

In Gram-negative sepsis as well as in critically ill COVID-19 patients, there is an altered immune response leading to a massive change in their cytokine profile. The drug modulates the immune system of the body and thereby inhibits the cytokine storm leading to reduced mortality and faster recovery.

Looking at similarities between clinical characteristics of patients suffering from COVID-19 and Gram-negative sepsis, CSIR, is now initiating a randomized, blinded, two arms, active comparator-controlled clinical trial to evaluate the efficacy of the drug for reducing mortality (deaths) in critically ill COVID-19 patients. The Drugs Controller General of India (DCGI) has approved the trial and it will start soon at multiple hospitals.

The drug contains heat-killed Mycobacterium W (Mw). It is found to be extremely safe in patients and no systemic side effects are associated with its use.It can be used concurrently with any other therapies required in the management of such critically ill patients without any restriction. Its unique properties include boosting protective immunity (Th1, TLR2 agonist) and suppressing non-protective response (Th2).

CSIR has also planned to evaluate Mw for faster recovery of hospitalized COVID-19 infected patients and minimize the spread of disease through them as well for providing prophylaxis to persons coming in contact with COVID-19 infected

patients like family members and health care workers.