

## Indian Initiative to Fight COVID-19, Enhancing Natural Defense

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New clinical trials are now approved by the Drugs Controller General of India (DCGI)

They will be randomized, double-blind, two-arm, controlled clinical trials

These two clinical trials are in addition to the recently announced trial on evaluating the efficacy of the drug for reducing mortality (deaths) in critically ill COVID-19 patient

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Natural defense mechanism of the body (innate immunity) plays a key role in the fight against COVID-19 and other viral infections. It is a fast, first and efficient immune response for identifying and eliminating COVID-19 and other viruses. The majority of persons coming in contact with COVID-19 or other viruses either do not get the disease or get a milder form of the self-limiting disease as Innate immunity is adequate. Cells of human immune system like Macrophages, NK cells offer such protection. While the world is working towards developing

vaccines and antiviral agents for the management of COVID-19, the Council of Scientific and Industrial Research (CSIR) has decided to develop/repurpose an approved immunomodulator, Sepsivac<sup>®</sup>, to enhance innate immunity of the body to limit the spread of COVID-19 and fasten the recovery of the patients of COVID-19, through its flagship New Millennium Indian Technology Leadership Initiative (NMITLI) program.

*Sepsivac*<sup>®</sup> is expected--

1. to protect the close contacts of COVID-19 patients and health care staff by boosting their innate response and thereby preventing them from acquiring the disease.
2. to provide quicker recovery to the hospitalized COVID-19 patients, who are not critically ill. It will also prevent the progression of disease wherein patients will need ICU management.

**Both these new clinical trials are now approved by the Drugs Controller General of India (DCGI). They will be randomized, double-blind, two-arm, controlled clinical trials. These two clinical trials are in addition to the recently announced trial on evaluating the efficacy of the drug for reducing mortality (deaths) in critically ill COVID-19 patient.**

*Sepsivac*<sup>®</sup> 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. *Sepsivac*<sup>®</sup> was also developed under the NMITLI program of CSIR and is manufactured by Cadila Pharmaceuticals Ltd., Ahmedabad.

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KGS/(CSIR release)

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