Why is a psoriasis drug being used to treat COVID-19 patients?

Context

- Biocon announced that it had received the approval of the Drugs Controller General of India (DCGI) to market Itolizumab for treatment of cytokine release syndrome (CRS) in moderate to severe acute respiratory distress syndrome patients due to COVID-19.
- Itolizumab is a monoclonal antibody which is used to treat acute psoriasis.

What are monoclonal antibodies?

- Monoclonal antibodies are proteins cloned in the lab to mimic antibodies produced by the immune system to counter an infection.
- They have their genesis in serum, the colourless constituent of blood that contains antibodies.
- These proteins bind to an antigen, the fragment of an infectious virus in the case of SARS-CoV-2, and either destroy it or block its action.
- In the case of COVID-19, there are yet no proven drugs to treat moderate or severe manifestations of the disease.
- Among the therapies being tested is convalescent plasma, which is a constituent of blood and recovered from those who have successfully fought the disease.
- This blood contains antibodies produced within a week or two of being infected.
- While plasma therapy involves injecting this entire antibody-soup into another sick patient, a monoclonal antibody can be made by isolating specific antibodies and multiplying them via various techniques.
- Isolating plasma and serum is laborious and time-consuming when it must be administered to every patient.
- However, since 1975, several techniques have been perfected that allow antibodies once isolated to be easily replicated. These are stored in vials and can be injected into patients.

How useful are they in treating COVID-19 patients?

- While eight in 10 of those infected by the disease recover with little more than a few days of cough and fever, about one in 10 can manifest severe systems of the disease irrespective of their age and medical history.
- Experts are not sure why, but have observed that many who died were victims of a cytokine storm — when the immune system goes into overdrive to flush out the virus.
Pro-inflammatory cytokines recruit a host of specialised immune system cells to neutralise antigens. However, these cytokines can aggravate inflammation and injury in lung cells as well as in several other organs. A challenge in treatment is how to prevent this over-reaction. One method is to use antibodies that can block a particular protein, called CD6. They are found on the surface of T-cells, a class of cells that are a central prong in the body’s defence system. Experts say if this CD-6 is suppressed, it will prevent the T-cells from releasing a cytokine cascade and thus better regulate the immune system.

Is there a downside?

- Itolizumab is an approved drug for acute psoriasis since 2013 and has passed safety and efficacy trials for that disease in over 500 patients.
- However, independent experts have pointed out that the efficacy of the drug in treating COVID-caused Acute Respiratory Disease Syndrome has not been conclusively demonstrated because it has, as part of a clinical trial, only been tested on 30 patients.
- However, the drug has been approved by the DCGI for emergency use in the treatment of moderate to severely-ill patients as per the discretion of physicians.
- The DCGI also directed Biocon to conduct a phase-4 study — it must monitor it for adverse reactions or side-effects after it has been administered in large groups of patients and report back to the authorities.
- Experts pointed out that the normal process for approving a drug includes a phase-3 trial, where the drug’s safety and efficacy are first evaluated in the wider population.