Itolizumab: Emergency Covid-19 Drug

Why in News

Recently, the **Drugs Controller General of India** (DCGI) has cleared **Itolizumab** for **restricted emergency use in Covid-19 cases.**

Itolizumab is a drug used to treat **severe chronic plaque psoriasis.**

Plaque psoriasis is a **chronic autoimmune condition** in which skin cells build up and form scales and itchy, dry patches.

Key Points

- Itolizumab is for emergency use only in the treatment of **Cytokine Storm Syndrome** (CSS) in moderate to Severe **Acute Respiratory Distress Syndrome** (ARDS) patients due to Covid-19.
    - **CSS** is an uncontrolled attempt by the immune system to neutralise the virus that often ends up damaging the lungs and other organs and even death.
    - **ARDS** is a disease in which the lung loses its capacity to expand further.
- It will be **manufactured and formulated as an intravenous (IV) injection** at the bio-manufacturing facility in Bengaluru.
- Itolizumab is the **first novel biologic therapy** to be approved anywhere in the world for treating patients with moderate to severe Covid-19 complications.
    - Itolizumab is a **biologic/biologic drug** given by injection (shot) or IV infusion.
    - A biologic is a **protein-based drug derived from living cells cultured in a laboratory.**
    - Biologics are **different from traditional systemic drugs** that impact the entire immune system.
    - Biologics **only target specific parts of the immune system** and biologics used to treat psoriatic disease block the action of a specific type of immune cell called a **T-cell.**

Reasons for its Approval

- DCGI's approval for the repurposed drug comes after the **successful conclusion of a randomised, controlled clinical trial** at multiple hospitals.
    - The trial was designed employing a method called **Simon's Two-Stage Design,** an approach in executing **phase-2 clinical trials where the efficacy of a drug is tested.**
- Other criteria such as **improvement in oxygen levels** and **reduced inflammation** were also convincing to several doctors who used the drug on their patients.
- The evaluation also **rests on Itolizumab being added to the 'best standard of care'** which slightly varied across hospitals.
    - In general, this consisted of **hydroxychloroquine** (HCQ), **ritonavir** (antivirals), oxygen therapy, antibiotics, heparin (to avoid clotting) and some got methylprednisolone (a corticosteroid).
- Its usage was justified because of its l**arge trials and safety assessments are already done for psoriasis.** Plus, it is **hard to recruit a larger number of patients in critical care conditions** so numbers had to be kept low.
    - There are **no hard rules on a minimum number** of recruits.
    - For an **orphan drug** (used to treat **orphan or rare diseases**), small numbers of recruits are approved.
- The available evidence for **remdesivir** suggests that it may decrease the time for clinical improvement when used in moderate to severe cases and has no benefits in terms of reduced mortality.
    - Remdesivir has to be used with **extreme caution** due to its potential for **serious adverse effects including liver and kidney injury.**
- Another drug **Tocilizumab** has not shown any benefits in mortality reduction.
- **Criticism:**
    - Itolizumab appears to have been **tested on too few patients to reliably conclude on its benefits** and with such a small sample size it would be unwise to claim it as the final and fully successful drug.
    - 30 patients were recruited across four hospitals and 20 of them were given Itolizumab along with the 'standard of care treatment' and 10 were given only standard of care.
    - Nobody died from the set of 20 patients and 3 patients died from the set of 10 patients.

Drug Controller General of India

- It is responsible for **approval of licences of specified categories of drugs** such as blood and blood products, **IV fluids, vaccines and sera** in India.
- It comes under the **Ministry of Health and Family Welfare.**

Source: TH