FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Authorizes Drug for Treatment of COVID-19

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Español (/news-events/press-announcements/actualizacion-sobre-el-coronavirus-covid-19-la-fda-autoriza-un-medicamento-para-el-tratamiento-del)

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) (/media/150319/download) for the drug Actemra (tocilizumab) for the treatment of hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Actemra is not authorized for use in outpatients with COVID-19.

In clinical trials of hospitalized patients with COVID-19, Actemra in addition to the routine care patients receive for treatment of COVID-19, which included corticosteroid therapy, was shown to reduce the risk of death through 28 days of follow-up and decrease the amount of time patients remained hospitalized. The risk of patients being placed on ventilators or death through 28 days of follow-up was also decreased.

"Today's action demonstrates the FDA's commitment to making new therapies available through every stage of the global COVID-19 pandemic," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "Although vaccines have been successful in decreasing the number of patients with COVID-19 who require hospitalization, providing additional therapies for those who do become hospitalized is an important step in combating this pandemic."

Actemra is a monoclonal antibody that reduces inflammation by blocking the interleukin-6 receptor. In the case of COVID-19 infection, the immune system can become hyperactive, which may result in worsening of disease. Actemra does not directly target SARS-COV-2. Actemra is a prescription medication given by intravenous infusion that is FDA-approved for multiple inflammatory diseases, including rheumatoid arthritis. Under today's EUA, the FDA is authorizing the emergency use of Actemra for the treatment of certain hospitalized patients with COVID-19. Actemra is not approved as a treatment for COVID-19.

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available scientific evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA's review of the totality of the scientific evidence available, the agency has determined that it is reasonable to believe that Actemra may be effective in treating COVID-19 for the authorized population. And, when used to treat COVID-19 for the authorized population, the known and potential benefits of Actemra outweigh the known and potential risks for the drug. There are no adequate, approved and available alternative treatments to Actemra for the treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age or older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

The data supporting this EUA for Actemra are based on four clinical trials. These included one randomized, controlled, open-label, platform trial [Randomised Evaluation of COVID-19 Therapy (RECOVERY)] and three randomized, double-blind, placebo-controlled trials (EMPACTA, COVACTA and REMDACTA). While all four clinical trials contribute to the FDA's understanding of Actemra for the treatment of COVID-19, the most important scientific evidence on the potential benefit of Actemra for its authorized use came from the RECOVERY and EMPACTA trials.

In the RECOVERY trial, 4,116 hospitalized patients with severe COVID-19 pneumonia were randomized to receive either Actemra in addition to usual care (2,022 patients) or usual care alone (2,094 patients). The primary endpoint evaluated death through 28 days of follow-up, and the results of the primary analysis were statistically significant. The probabilities of death by day 28 were estimated to be 30.7% for patients receiving Actemra and 34.9% for patients receiving usual care alone. The median time to hospital discharge was 19 days for patients receiving Actemra and more than 28 days for patients receiving usual care alone.

In the EMPACTA trial, 389 hospitalized patients with COVID-19 pneumonia were randomized to receive Actemra (249 patients) or placebo (128 patients). The primary endpoint evaluated the need for mechanical ventilation or death through 28 days of follow-up. For patients receiving Actemra, there was an observed reduction in progression to mechanical ventilation or death compared to patients who received placebo, with the primary analysis results being statistically significant. The proportion of patients who required mechanical ventilation or died by day 28 was estimated to be 12.0% for patients receiving Actemra and 19.3% for patients receiving placebo.

In the COVACTA trial, 452 hospitalized patients with severe COVID-19 pneumonia were randomized to receive Actemra (294 patients) or placebo (144 patients). The primary endpoint was clinical status through 28 days of follow-up assessed on a 7-category ordinal scale. While

there was no statistically significant difference observed in clinical status on the 7-category ordinal scale at day 28 between treatment groups, the COVACTA trial contributed to the assessment of the safety for Actemra when used for the treatment of COVID-19.

In the REMDACTA trial, 649 hospitalized patients with severe COVID-19 pneumonia were randomized to receive Actemra in combination with remdesivir (430 patients) or placebo in combination with remdesivir (210 patients). The primary endpoint was time to hospital discharge or "ready for discharge" through 28 days of follow-up. Additionally, while there were no statistically significant differences observed between treatment groups with respect to time to hospital discharge or "ready for discharge" through 28 days of follow-up, the REMDACTA trial contributed to the assessment of the safety for Actemra when used for the treatment of COVID-19.

Under the EUA, fact sheets that provide important information about using Actemra in treating COVID-19 as authorized must be made available to health care providers (/media/150321/download) and to patients, parents, and caregivers (/media/150320/download). These fact sheets include dosing instructions, potential side effects and drug interactions. Common side effects of Actemra observed in the COVID-19 trials include constipation, anxiety, diarrhea, insomnia, hypertension and nausea.

The EUA was issued to Genentech Inc.

Related Information

- Actemra EUA Letter of Authorization (/media/150319/download)
- Frequently Asked Questions on the Emergency Use Authorization for Actemra (/media/150345/download)
- Emergency Use Authorization: Therapeutics (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)
- Coronavirus Disease (COVID-19) (/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19)

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