REGEN-COV authorized for postexposure prophylaxis in high-risk individuals

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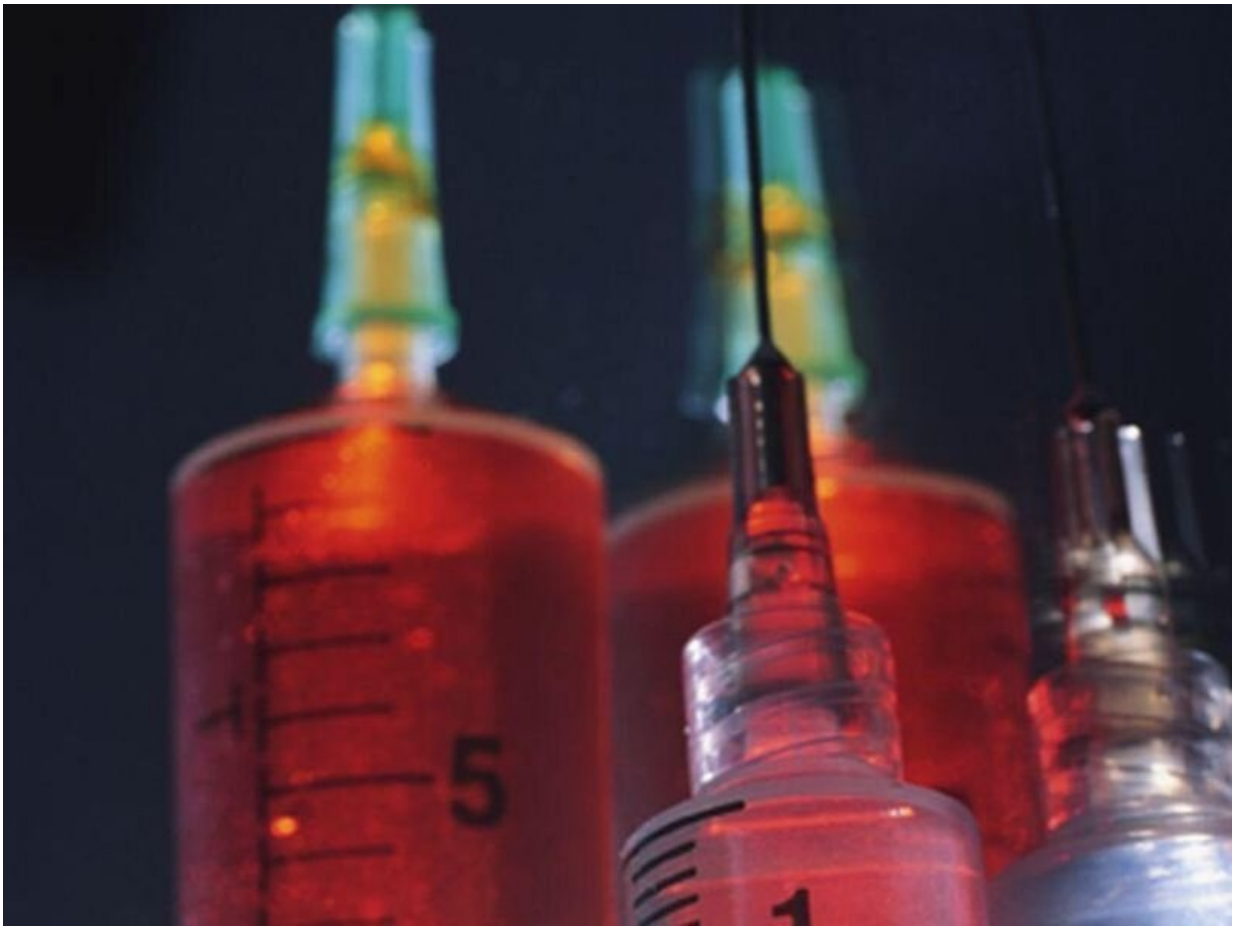

(HealthDay)—The monoclonal antibody therapy REGEN-COV was

authorized for emergency use as a postexposure prophylaxis for COVID-19 in those at high risk for severe disease, the U.S. Food and Drug Administration announced Friday.

REGEN-COV, a combination of 600 mg casirivimab and 600 mg imdevimab, is not authorized for those who have not been exposed to COVID-19. Under the new emergency use authorization, the FDA has approved REGEN-COV for use in those 12 years and older who are not fully vaccinated or have an immunocompromising condition and were either exposed to someone with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or are at risk for exposure because of an occurrence in the same institutional setting such as a nursing home or prison.

The postexposure prophylaxis emergency use authorization was based on data from COV-2067, a phase 3 randomized, double-blind, placebo-controlled clinical trial of household contacts of people infected with SARS-CoV-2. Researchers observed an 81 percent reduction at day 29 in confirmed symptomatic COVID-19 cases among those who received REGEN-COV subcutaneously within 96 hours of the index case's positive SARS-CoV-2 test compared with those who received placebo.

The most commonly reported side effects with REGEN-COV are injection site reactions, including erythema, pruritis, and ecchymosis. No severe hypersensitivity or potentially life-threatening allergic reactions were reported.

More information: More Information

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