FDA COMBATING COVID-19 WITH THERAPEUTICS

Since the beginning of the COVID-19 pandemic, the FDA has worked to facilitate the development and availability of therapeutics as expeditiously and safely as possible for use by patients, physicians, and health systems.

As of November 23, 2020, the FDA has approved one treatment for COVID-19. The antiviral drug Veklury (remdesivir) is approved for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a health care setting capable of providing acute care comparable to inpatient hospital care.

In order to facilitate the development of potential COVID-19 treatments, the FDA created the Coronavirus Treatment Acceleration Program (CTAP) to expedite the development of therapeutics by using every tool at the agency's disposal to determine if they are safe and effective for their intended uses.

Numerous other therapeutics are currently being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19. The CTAP webpage includes a dashboard with a snapshot of the development of potential COVID-19 therapeutics. As of October 31, 2020, there were more than 370 active trials of therapeutic agents and more than 560 development programs for therapeutic agents in the planning stages.

The FDA continues to provide advice, guidance, and technical assistance to help expedite the development of these products and intends to use regulatory flexibility in making these products and other critical medical countermeasures available to prevent and treat COVID-19. Sponsors wishing to develop therapeutics for proposed COVID-19 use are encouraged to submit information and requests for drug development to: COVID19-productdevelopment@fda.hhs.gov.

The FDA and other government partners are working with industry to make treatment options available to patients and providers who are not able to participate in clinical trials, including through expanded access under investigational new drug (IND) applications.

Additionally, if certain statutory criteria are met, the FDA may issue an emergency use authorization (EUA) to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear threat agents when, among other factors, there are no adequate, approved, and available alternatives.

As of November 30, 2020, the following EUAs permit the use of drugs or biological products to treat COVID-19 and serious conditions caused by COVID-19:

EMERGENCY USE AUTHORIZATION	SPONSOR	DESCRIPTION
Casirivimab and Imdevimab	Regeneron Pharmaceuticals, Inc.	This EUA authorizes the use of casirivimab and imdevimab, administered together, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. • Fact Sheet for Heath care Providers • Fact Sheet for Patients, Parents, and Caregivers • Dear Heath care Provider Letter • Information Sheet ("Fact Sheet Directions") • Frequently Asked Questions on the Emergency Use Authorization of Casirivimab + Imdevimab
Baricitinib (Olumiant) in Combination with remdesivir (Veklury)	Eli Lilly and Company	This EUA authorizes the use of baricitinib (Olumiant) in combination with remdesivir (Veklury) by health care providers for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). • Fact Sheet for Health care Providers • Fact Sheet for Patients, Parents, and Caregivers • Frequently Asked Questions on the Emergency Use Authorization for Olumiant (baricitinib) in Combination with Veklury (remdesivir) for Treatment of Mild to Moderate COVID-19
Bamlanivimab	Eli Lilly and Company	This EUA authorizes the use of bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. • Fact Sheet for Health care Providers • Fact Sheet for Patients, Parents, and Caregivers (Spanish version) • Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab

EMERGENCY USE AUTHORIZATION	SPONSOR	DESCRIPTION
Veklury (Remdesivir) Emergency Use Authorization	Gilead Sciences, Inc.	This EUA, originally issued on May 1, 2020 and revised on October 22, 2020, authorizes the use of Veklury (remdesivir) by licensed health care providers for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg **or** hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. • Fact Sheet for Health Care Providers • Fact Sheet for Patients and Parent/Caregivers • Frequently Asked Questions for Veklury (remdesivir)
Convalescent Plasma Emergency Use Authorization	Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services	This EUA authorizes the distribution of COVID-19 Convalescent Plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with the disease. • Updated Evidence to Support Emergency Use of COVID-19 Convalescent Plasma • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Parents/ Caregivers Fact sheets for patients/caregivers and health care providers are also available in multiple languages.
REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit Emergency Use Authorization	Baxter Healthcare Corporation	This EUA authorizes REGIOCIT to be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting. • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Caregivers • REGIOCIT package insert for EUA
Fresenius Propoven 2% Emulsion Emergency Use Authorization	Fresenius Kabi USA, LLC.	This EUA authorizes the use of Fresenius Propoven 2% Emulsion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an ICU setting. • Fact Sheet for Healthcare Providers • Fact Sheet for Patients and Parent/Caregivers • Propoven 2% Wall Chart

EMERGENCY USE AUTHORIZATION	SPONSOR	DESCRIPTION
multiFiltrate PRO System and multiBic/multiPlus Solutions Emergency Use Authorization[1]	Fresenius Medical Care	This EUA authorizes this continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic. • Fact Sheet for Health Care Providers • Fact Sheet for Patients

Additional Resources for Therapeutic Developers:

- Guidances to support the accelerated development of prevention and treatment options for COVID-19
  - COVID-19 Public Health Emergency: General Considerations for Pre-IND (Investigational New Drug application) Meeting Requests for COVID-19 Related Drugs and Biological Products
  - COVID-19: Developing Drugs and Biologics for Treatment or Prevention
  - Guidance on Conduct of Clinical Trials for Medical Products during COVID-19 Pandemic. For further questions on clinical trial conduct during the COVID-19 pandemic, email Clinicaltrialconduct-COVID19@fda.hhs.gov.

- FDA Emergency Use Authorization Information and list of all current EUAs

  - Those interested in pre-EUA discussions, or have general questions about EUAs for CDER-regulated products, can email COVID19-ProductDevelopment@fda.hhs.gov. Those interested in pre-EUA discussions, or have general questions about EUAs for CBER-regulated products, can email CBEREUA@fda.hhs.gov. Formal EUA requests can be sent via email to EUA.OCET@fda.hhs.gov.

Additional Resources for Patients and Providers:

- Coronavirus Disease 2019 (COVID-19) Resources for Patients
- FDA Statement: FDA's Ongoing Commitment to Transparency for COVID-19 EUAs
- People who have fully recovered from COVID-19 for at least two weeks are encouraged to consider donating plasma, which could potentially help save the lives of COVID-19 patients. Those willing to donate are urged to visit the FDA website for information about donating or contact their local blood donor or plasma collection center.
- Information for health care providers about the administration and study of investigational convalescent plasma: Recommendations for Investigational COVID-19 Convalescent Plasma

[1] The multiBic/multiPlus Solutions include multiBic dialysate and replacement fluid and multiPlus dialysate. The multiFiltrate PRO System, multiBic dialysate and the multiPlus dialysate solutions are regulated as devices by CDRH. The multiBic replacement fluid is regulated as a drug by CDER.