FDA COMBATING COVID-19 WITH THERAPEUTICS

Since the beginning of the COVID-19 pandemic, the FDA has been working to facilitate development and availability of therapeutics for use by patients, physicians and health systems as expeditiously and safely as possible. In order to facilitate the development of potential COVID-19 treatments FDA created the Coronavirus Treatment Acceleration Program (CTAP), a new program designed to expedite the development of potential COVID-19 therapies by using every tool at the agency's disposal to determine if the therapies are safe and effective for their intended uses. Several therapies are currently being tested in clinical trials to evaluate whether they are safe and effective in combating COVID-19.

The FDA is taking the lead on a national effort to facilitate the development of, and access to, two investigational therapies derived from human blood. These are called convalescent plasma and hyperimmune globulin and are antibody-rich blood products made from blood donated by people who have recovered from the virus. The blood of those who have recovered contains antibodies, proteins the body makes to fight infections, to the COVID-19 virus. The products can be administered to individuals diagnosed with a serious or life-threatening case of COVID-19. There are some limited data to suggest that convalescent plasma and hyperimmune globulin may have benefit in the COVID-19 illness. This is why evaluation of these therapies in the context of a clinical trial and expanded access program is so important.

Developers of therapeutics for COVID-19 can submit information and questions via the CTAP email "COVID19-productdevelopment@fda.hhs.gov" or the Pre-IND Consultation program (see the web page). As of May 11, 2020, there are 144 active trials of therapeutics agents and another 457 development programs for therapeutic agents in the planning stages.

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 drug (IND) applications. Patients who are not eligible for a clinical trial, or when one is not available, can speak with their physician regarding whether an experimental treatment may be available through an expanded access program. For example, FDA recently announced expanded access pathways for obtaining convalescent plasma as a potential treatment for COVID-19.

For COVID-19 therapies, the FDA has accelerated the development and use of therapies to treat COVID and serious conditions caused by COVID-19 under these following options:

SPONSOR	PRODUCT (link to authorization letter)	DESCRIPTION
Assistant Secretary of Preparedness and Response (ASPR)	Chloroquine and hydroxychloroquine for treatment of COVID-19 *3/28/2020*	Allows hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. These drugs will be distributed from the SNS to states for doctors to prescribe to these patients. • Chloroquine Fact Sheet for Healthcare Providers Chinese | Korean | Spanish | Vietnamese • Chloroquine Fact Sheet for Patients Chinese | Korean | Spanish | Vietnamese • Hydroxychloroquine Fact Sheet for Healthcare Providers Chinese | Korean | Spanish | Vietnamese • Hydroxychloroquine Fact Sheet for Patients (148KB) Chinese | Korean | Spanish | Vietnamese • Hydroxychloroquine and Chloroquine drug safety communication about use for COVID-19 outside of a hospital setting or clinical trial
Collaboration between industry, academic and government partners, Mayo Clinic, Lead Institution	Convalescent Plasma	The FDA has led an effort, working collaboratively with our industry, academic, and government partners to develop and implement a protocol that will make available convalescent plasma to patients in need across the country who may not have access to institutions with clinical trials in place. This will provide a simplified process for health care providers that while helping to ensure patient safety, and also allowing for the collection of needed information about product efficacy.
Collaboration between industry, academic and government partners, National Institute of Allergy and Infectious	Hyperimmune Globulin	Hyperimmune globulin is a biological product manufactured from convalescent plasma. The FDA is helping to coordinate a study of hyperimmune globulin that will be conducted by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, as

Diseases of the National Institutes of Health Lead Institution		well as coordinating other efforts in this area. 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.
Gilead Sciences, Inc.	Remdesivir *5/1/2020*	The emergency use authorization allows for remdesivir to be distributed in the U.S. and administered intravenously by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. Severe disease is defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator. • Fact Sheet for Health Care Providers • Fact Sheet for Patients and Parent/Caregivers Spanish • Frequently Asked Questions on the Emergency Use Authorization for Remdisivir for Certain Hospitalized COVID-19 Patients
Fresenius Kabi USA, LLC.	Fresenius Propoven 2% Emulsion *5/8/2020*	Emergency Use Authorization allows for 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

Additional Resources for therapeutic developers:

- Sponsors wishing to develop therapeutics are encouraged to submit information and questions via the Pre-IND Consultation program (see the web page or call 301-796-1500 for additional information on this program).
- Please send requests for product development for proposed COVID-19 uses and drug development to: COVID19-productdevelopment@fda.hhs.gov.

Coronavirus Treatment Acceleration Program (CTAP) Website

- CTAP will use every available method to move new treatments to patients as quickly as possible, balancing patient needs for medicine while supporting trials to gather evidence and weighing the risks and benefits.

Guidances to support the accelerate development of novel prevention, 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. This guidance outlines a more efficient process for developers to receive agency feedback on their supporting data with the goal of starting clinical trials as soon as possible. The FDA is committed to helping sponsors get potentially effective products into study quickly, while protecting the safety of patients. To that end, the guidance provides sponsors clarity on the types of data and information they should provide to address clinical, nonclinical and quality considerations before submitting an application to initiate studies.

- COVID-19: Developing Drugs and Biologics for Treatment or Prevention. This guidance provides FDA current recommendations on later stage clinical trials intended to establish safety and effectivness for COVID-19 products. The guidance outlines critical sponsor considerations such as appropriate patient selection, including the evaluation of therapies in patients at high risk of complications from COVID-19 (e.g., the elderly). In addition, the guidance helps sponsors to understand how to design their trials, including considerations of study duration, assessment of efficacy and monitoring for safety. The FDA anticipates this guidance will help sponsors to efficiently design studies that may lead to the review and potential approval of safe and effective drugs and biological products to address the COVID-19 pandemic.

Clinical Trial Conduct

- Coordinating and managing responses to stakeholder inquiries on Clinical Trial Conduct during the COVID-19 pandemic. Please see the 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, please 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. 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
- 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 up to four patients. Those willing to donate are urged to visit the American Red Cross website at or contact their local blood donor or plasma collection center.
- Information for healthcare providers about convalescent plasma—plasma collected from the blood of fully recovered COVID-19 patients and administered to very ill COVID-19 patients: Revised Information for Investigational COVID-19 Convalescent Plasma.