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EMERGINGTHERAPEUTICS

Coronavirus Disease 2019 (COVID-19) - The Search for a Treatment
Issues Document

Updated: February 12, 2020

Summary

SARS-CoV-2, the virus that can cause coronavirus disease 2019 (COVID-19), has officially been labeled a pandemic by the World Health Organization (WHO). While treatment of the disease currently centers on managing symptoms and supportive care for patients, there is a need for effective vaccines and medications to prevent and treat COVID-19. While pharmaceutical companies, universities and government agencies around the world are working to develop these therapies, there are currently no vaccines approved by the U.S. Food and Drug Administration (FDA) specifically for the prevention of COVID-19. However, Pfizer/BioNTech did receive Emergency Use Authorization (EUA) for its vaccine candidate, BNT162b2, on December 11, 2020. A second vaccine from Moderna (mRNA-1273) received EUA on December 18, 2020. Gilead Sciences received full FDA approval for Veklury® (remdesivir) injection on Oct. 22, 2020, which marks the first approved treatment for COVID-19. This document is intended to provide information regarding therapies in development for COVID-19; it will be updated as new data become available.

Highlights

- Coronavirus disease 2019 (COVID-19) is an infection from a new strain of coronavirus that has been associated with respiratory symptoms, including progression to severe respiratory illness and death in some patients.
- Currently, Gilead Sciences' Veklury® (remdesivir) is the only approved treatment for patients who are hospitalized with COVID-19 infections.
- Pharmaceutical companies, universities and government agencies around the world are working to develop vaccines and treatments for COVID-19.
- Vaccines are in both early and late clinical development with options reaching clinical trials within months. However, widespread commercial availability of a vaccine is still likely at least several months away.
- There are a vast array of compounds in early trials being evaluated for the treatment of COVID-19. The promising options will move rapidly through the FDA approval process.
- Another approach is to evaluate currently available therapeutic options to assess their effectiveness in treating and preventing the disease. Some data surrounding SARS and MERS coronaviruses have led investigators to a handful of products, hoping the similarity between these viruses and SARS-CoV-2 will lead to treatment options.
- As development of therapies is rapidly evolving, we intend to update this document frequently to provide the latest information on potential therapies for treating and preventing COVID-19.

Current Treatment Recommendations

To date, there are two vaccines under Emergency Use Authorization (EUA) and just one treatment approved by the U.S. Food and Drug Administration (FDA) to treat or prevent SARS-CoV-2, the virus known as COVID-19. Although there are investigational COVID-19 vaccines and treatments under development, these investigational products are in the early stages of product development and have not yet been fully tested for safety or effectiveness. According to the CDC, clinical management includes prompt implementation of recommended infection prevention and control measures and supportive management of complications, including advanced organ support if indicated.

FDA and Government Actions

To help expedite the availability of therapies for COVID-19, the FDA can loosen the process for medications and vaccines to enter the market. An Emergency Use Authorization (EUA) can be issued to permit the use, based on scientific data, of medical products that may be effective for the diagnosis, treatment, or prevention of a disease or condition when the U.S. Department of Health and Human Services makes the determination that there is a

public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens. Recently, the agency issued an EUA to expedite the availability of additional diagnostic tests for the SARS-CoV-2 virus.

The Search for Coronavirus Treatments

While Veklury® (remdesivir) is the first and only FDA approved treatment for COVID-19, pharmaceutical manufacturers, universities and government agencies are casting a wide net looking for effective therapies to treat and/or prevent the disease. SARS-CoV-2 is a coronavirus similar to viruses that cause Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV), previously have been associated with the development of severe illness. Therefore, many investigated compounds for treating MERS and SARS are now being evaluated for COVID-19.

Vaccines in Development

Several vaccines are in early-phase development, with a few in the final phase III stages, to protect against COVID-19. Once they reach clinical trials, data will be collected over at least six months, if not more, to determine if the vaccines are both safe and effective for preventing infection with SARS-CoV-2. FDA will expedite the more promising vaccines through the FDA approval process; however, the first vaccine is not expected to be fully approved for several months. On December 11, 2020, Pfizer/BioNTech was the first company to have its vaccine authorized under the EUA. On December 18, 2020, a second vaccine from Moderna was granted EUA. Table 1 includes examples of vaccines in development for COVID-19.

Table 1

Vaccine	Manufacturer	Route	Status
mRNA-1273	Moderna	Intramuscular (two doses)	Phase 3*
BNT-162b2	Pfizer/BioNTech	Intramuscular (two doses)	Phase 3*
Ad26.COV2.S	Janssen	Intramuscular (one dose)	Phase 3
NVX-CoV2373	Novavax	Intramuscular	Phase 3
ChAdOx1 nCoV-19	Oxford/AstraZeneca	Intramuscular	Phase 3
Coronavirus Vaccine	Sanofi/GlaxoSmithKline	Unspecified	Phase 1/2
INO-4800	Inovio	Intradermal	Phase 1
AdCOVID™	Altimmune	Intranasal (one dose)	Phase 1
Coronavirus Vaccine	CureVac	Intramuscular (one to three doses)	Preclinical
COVID-19 S-Trimer	GlaxoSmithKline/Clover	Unspecified	Preclinical

*EUA = Emergency Use Authorization

Novel Drugs in Development

There are multiple therapies in early-phase development for the treatment of COVID-19. Gilead's Veklury® (remdesivir), was granted EUA for hospitalized patients with severe COVID-19 on May 1, 2020, and received full FDA approval on Oct. 22, 2020. Table 2 highlights some of the novel drugs in development for COVID-19. Due to the large number of products being screened for possible use, the table is not intended to be an exhaustive list of potential therapies. Rather, we have highlighted some of the more promising agents progressing through the development process.

Table 2

Drug	Manufacturer	Mechanism	Route	Status
bamlanivimab	Eli Lilly	IgG1 monoclonal antibody	Intravenous (IV)	Phase 3*
etesevimab	Eli Lilly	Monoclonal antibody	Intravenous (IV)	Phase 3*
REGN-COV2	Regeneron	Combination of two monoclonal neutralizing antibodies	Intravenous (IV)	Phase 3*
favipiravir	FujiFilm Toyama Chemical	RNA polymerase antiviral	Oral (twice daily x 7 days)	Phase 3
leronlimab	CytoDyne	CCR5 viral entry inhibitor	Subcutaneous	Phase 3

*EUA = Emergency Use Authorization

Existing Drugs in Development

Several existing medications that are currently approved for other uses are being evaluated for efficacy in the treatment of COVID-19. These drugs may be used alone or in combination with other drugs to treat COVID-19.

Table 3 shows some of the existing drugs that are in development for COVID-19. However, the use of these products for COVID-19 is still considered investigational as ongoing clinical trials have yet to demonstrate whether or not the products are proven to be both safe and effective for treating COVID-19.

Table 3

Drug	Manufacturer	Mechanism	Route	Status
baricitinib (Olumiant®)	Eli Lilly	Janus kinase (JAK) inhibitor	Oral	Phase 3*
tocilizumab (Actemra®)	Genentech	Interleukin-6 inhibitor	IV infusion	Phase 3
dexamethasone	Generics	Glucocorticoid	Oral or IV	Phase 3
Immune Globulin (Human)	Octapharma	Intravenous Immunoglobulin (IVIG)	Intravenous	Phase 3

*EUA = Emergency Use Authorization

Express Scripts' Recommendations

There are currently no FDA approved therapies for the treatment or prevention of SARS-CoV-2 infections. While a lot of information is surfacing regarding the screening of potential drugs therapies, available data for the treatment and/or prevention of the virus are limited. The Office of Clinical Evaluation and Policy will continue to monitor the evolving literature, track utilization trends, and revise solutions, as needed. Express Scripts created a process for medical director review for medications when coverage is being requested for COVID-19 and developed anti-stockpiling policies. These policies are intended to protect the supply of specific, currently available medicines that may be used off-label to manage COVID-19. As always, the Office of Clinical Evaluation and Policy will continue to monitor this development and provide updates as more information becomes available.

Stay up to date with the latest information regarding COVID-19 infections in the United States at:
https://www.cdc.gov/coronavirus/2019-ncov/index.html
https://www.nih.gov/health-information/coronavirus

Updates

Date	Drug/Vaccine	Comment
3.17.2020	hydroxychloroquine/ azithromycin	An open-label non-randomized clinical trial in France showed that 20 patients treated with hydroxychloroquine had significant COVID-19 viral load reduction and the effects were improved with the addition of azithromycin. https://www.mediterranee-infection.com/wp-content/uploads/2020/03/Hydroxychloroquine_final_DOI_IJAA.pdf However, the regimen has not been proven and additional clinical information is required before routinely used.
3.22.2020	remdesivir	Due to overwhelming demand, Gilead temporarily stopped patient access to its investigational antiviral drug, remdesivir. Exceptions will be made for pregnant women and children younger than 18 years who have severe disease confirmed as COVID-19. Gilead's compassionate use program is becoming expanded access to speed availability for severely ill patients and allow Gilead to collect data on all patients. https://www.statnews.com/2020/03/22/gilead-suspends-access-to-experimental-covid-19-drug-remdesivir/
3.28.2020	chloroquine hydroxychloroquine (EUA)	The FDA issued an Emergency Use Authorization (EUA) to allow chloroquine and hydroxychloroquine products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. Chloroquine Phosphate Fact Sheet for Healthcare Providers Hydroxychloroquine Phosphate Fact Sheet for Healthcare Providers
4.24.2020	chloroquine hydroxychloroquine	The FDA issued a warning against the use of hydroxychloroquine and chloroquine for treating COVID-19 outside a hospital or clinical trial setting due to the increased risk for heart rhythm issues. These medications have not been shown to be safe and effective for treating or preventing COVID-19. Upon review of case reports and published literature of hydroxychloroquine and chloroquine, either alone or with azithromycin or other medications that can cause QT prolongation, the FDA was

		concerned about serious heart related side effects and deaths. Prescribers are encouraged to monitor heart function, electrolytes, renal function, and liver tests along with any medications that could potentially cause QT-prolongation while using these products. https://www.fda.gov/media/137250/download
4.29.2020	remdesivir (ACTT)	Preliminary results from the randomized, placebo-controlled Phase 3 Adaptive COVID-19 Treatment Trial, or ACTT, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), were released. The study of 1,063 hospitalized patients with advanced COVID-19 and lung involvement found that patients treated with remdesivir recovered faster than those receiving placebo (11 days vs. 15 days), a 31% improvement. https://www.niaid.nih.gov/news-events/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19 While this information looks promising, we caution that the data are unpublished and still requires peer review.
4.29.2020	remdesivir (SIMPLE trial)	Top-line results from the open-label, Phase 3 SIMPLE trial found that 5-day dosing in hospitalized patients with severe manifestations of COVID-19 disease was as effective as 10-day dosing. Remdesivir was generally well-tolerated in both regimens. Grade 3 or higher liver enzyme elevations occurred in 7.3% of patients leading to discontinuation in 3% of patients. https://www.gilead.com/news-and-press/press-room/press-releases/2020/4/gilead-announces-results-from-phase-3-trial-of-investigational-antiviral-remdesivir-in-patients-with-severe-covid-19 This trial could help determine a dosing regimen for remdesivir. Recently, Gilead indicated that 140.000 treatments (assuming a 10 day course) of the drug could be available by the end of May 2020. This study could help maximize the use of available remdesivir supplies. https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19
5.1.2020	remdesivir (EUA)	The FDA issued Emergency Use Authorization (EUA) for Gilead's remdesivir for hospitalized patients with severe COVID-19 disease. At this time, the medication is on limited supply and will be allocated to maximize access for appropriate patients who have a severe COVID-19 disease. Hospitals with intensive care units and deemed most in need will receive priority. Since the best dosing regimen is still being investigated, both the 5-day and 10-day treatment durations are suggested. The EUA is temporary and does not take place of the new drug application (NDA) or formal approval process. Therefore, it remains an investigational drug that has not been approved by the FDA. Remdesivir is only authorized for use in suspected or laboratory confirmed COVID-19 and severe disease defined as SpO2 ≤ 94% on room air, requiring oxygen supplementation, ventilation, or extracorporeal membrane oxygenation (ECMO) and must be administered intravenously (IV) by a healthcare provider at an in-patient setting. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment
6.22.2020	Dexamethasone (RECOVERY trial)	Preliminary results from a randomized, controlled, open-label, adaptive study compared a ten day course of dexamethasone 6mg once per day vs. standard hospital care for COVID-19 patients. A total of 6,461 patients were randomly assigned 2:1 to receive either dexamethasone 6mg once per day for ten days or standard hospital supportive care. A total of 21.6% of patients treated with dexamethasone died at 28 days vs. 24.6% of patients who died following standard care. However, dexamethasone did reduce mortality in patients receiving machine-driven ventilated breathing by one third (29% vs. 40.7%). In addition, patients treated with oxygen and no ventilation had a reduction in 28 day death rate by 20%. Patients who did not receive any breathing support, via oxygen or machine driven ventilation, saw no reduction in mortality benefit from dexamethasone. The authors concluded that patients who are suffering from severe respiratory complications due to COVID-19 would see a 28 day mortality reduction by up to 33% when treated with dexamethasone.

8.23.2020	Convalescent plasma (EUA)	The FDA issued an Emergency Use Authorization (EUA) for COVID-19 convalescent plasma (CCP) for the treatment of COVID-19 in hospitalized patients. CCP is a blood product collected from patients who have recovered from COVID-19 with natural antibodies and who meet all blood donor eligibility requirements. The blood is screened and isolated to contain high antibody titers. The EUA gives health care providers the authority to administer CCP to hospitalized patients with suspected or confirmed COVID-19. The EUA is temporary and does not take place of the biologics license application (BLA) or the formal approval process. Therefore, it remains an investigational drug that has not been approved by the FDA. The EUA was issued, following several months of data review, indicating the potential benefits of CCP outweigh the risks and it is potentially effective at reducing the severity and duration of COVID-19 in hospitalized patients. Under the terms of the EUA, each health care provider and patient must be given a fact sheet providing dosing, side effects and other important information. Known adverse drug reactions (ADRs) include allergic reactions, transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI) and potential for infection transmission. Dosing is based on standard hospital procedures and practices with a considered starting dose of one CCP unit, around 200mL. Each additional unit may be administered based on patient response and professional clinical judgment of the provider. The fact sheet for CCP can be viewed here.
8.28.2020	Hydroxychloroquine and chloroquine removed from the Existing Drugs in Development table.	Based on several studies, including one in the ***New England Journal of Medicine*** (***NEJM***) on June 3, 2020, and another from the National Institutes of Health (NIH) on June 20, 2020; hydroxychloroquine and chloroquine have been removed from Table 3. Neither study was able to show that hydroxychloroquine treats COVID-19. The ***NEJM*** study, conducted by researchers at the University of Minnesota, showed that hydroxychloroquine was not effective at preventing COVID-19 when used as post-exposure prophylaxis. The NIH study was halted due to lack of evidence that hydroxychloroquine provided benefit to hospitalized patients who have COVID-19. You can read about the NEJM study here and the NIH study here.
9.29.2020	REGN-COV2 (Regeneron) - Preliminary Results in Non-Hospitalized Patients	On Sept. 29, 2020, Regeneron announced preliminary results from its Phase I/II/III trial of REGN-COV2, its combination monoclonal antibody (Mab) cocktail, in non-hospitalized COVID-19 positive patients. Results showed that it reduced both viral load and time to alleviate symptoms. In addition, patients who were treated with REGN-COV2, needed fewer medical visits during their illness. Patients, who were confirmed to be COVID-19 positive by a laboratory test, were randomized 1:1:1 to receive a single dose of either REGN-COV2 high dose (8gm), REGN-COV2 low dose (2.4gm) or placebo by IV infusion. Participants' serological immune response to COVID-19 was tested and classified as seropositive (having an immune response) or seronegative (lacking an immune response). Patients considered seropositive started with lower viral loads before treatment, whereas seronegative patients had much higher levels. REGN-COV2 met a key virologic endpoint by reducing viral loads in seronegative patients through day seven. Patients who had higher baseline viral levels saw greater reductions, ranging from 50% to 99%, in viral load when treated with REGN-COV2 vs those who received a placebo infusion. Furthermore, seronegative patients saw greater benefits in terms of days until symptom alleviation; eight days for the high dose and six days for the low dose as compared with 13 days for placebo. This study is part of a larger one that is evaluating the use of REGN-COV2 both in hospitalized patients and for prevention of COVID-19 for patients who have been exposed to the virus. More information can be found here.
10.14.2020 10.26.2020	Bamlanivimab – Eli Lilly (ACTIV-3) Study Enrollment Paused	On Oct. 14, 2020, a trial pause was recommended by an independent data safety monitoring board (DSMB) for part of the ACTIV-3 study of bamlanivimab (Eli Lilly). Bamlanivimab is a neutralizing IgG1 mAb that targets attachment and entry of the SARS-CoV-2 spike protein. The DSMB determined that hospitalized patients were unlikely to realize a benefit when treated with bamlanivimab. The pause does not affect ongoing trials evaluating bamlanivimab for the treatment of less severe or early stages of COVID-19 infection or for its prevention. For more information on the trial pause, see here. On Oct. 26, 2020, Eli Lilly confirmed they have reviewed the data and will not continue enrollment in the (ACTIV-3) study in hospitalized patients with COVID-19, but will continue with other trials. Eli Lilly's statement is found here.

10.22.2020	Veklury Approved as the First Drug to Treat COVID-19	Gilead Sciences received full FDA approval on Oct. 22, 2020, for Veklury® (remdesivir) injection. Previously available only under an EUA, it is approved to treat patients who are 12 years old or older, who weigh at least 40kg (88 pounds) and who are hospitalized with COVID-19 infections. After one 200mg dose on the first day of treatment, Veklury is administered over one-half hour to two hours at 100mg/day for adult patients. At the same time, the FDA revised an EUA for treating children under 12 years old who weigh at least 3.5kg (about eight pounds) and who are hospitalized with COVID-19. Pediatric patients must receive the lyophilized powder form of Veklury administered at a loading dose of 5mg/kg on day one followed by 2.5mg/kg per day. For all patients, treatment is continued for five days, but it may be extended up to a total of 10 days for patients who have not improved significantly after five days and for patients who need mechanical ventilation. Veklury is administered intravenously (IV) and it will be dispensed only to hospitals. For complete prescribing information, look here. A fact sheet on the pediatric EUA is here.
11.10.2020	Bamlanivimab Receives FDA Emergency Use Authorization (EUA)	On November 9, 2020, Eli Lilly's bamlanivimab injection received an emergency use authorization (EUA) for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients 12 years and older who weigh at least 40kg, who have a positive COVID-19 test and who are at high risk for progressing to severe COVID-19 and/or hospitalization. The BLAZE-1 trial, which led to the decision, showed that the drug reduced viral loads, symptoms and need for hospitalization when used as a monotherapy in an outpatient setting. The BLAZE-1 study is ongoing with additional treatment arms. Bamlanivimab is a neutralizing human IgG1 monoclonal antibody, designed to block viral attachment and entry of the SARS-CoV-2 virus into human cells. The one-time infusion should be administered at a dose of 700mg as soon as possible after a positive COVID-19 test and within 10 days of symptom onset. The EUA, which is temporary, does not replace the formal FDA review process. The EUA includes a warning about possible infusion-related reactions as well as a risk of anaphylaxis. The U.S. government will purchase 300,000 doses and will allocate distribution. The government will not charge for the cost of the medication, but healthcare facilities may charge an administration fee. The EUA comes with a fact sheet for healthcare providers found here and for patients and caregivers here. Bamlanivimab Receives FDA Emergency Use Authorization (EUA)
11.19.2020	Olumiant (baricitinib) Receives FDA Emergency Use Authorization (EUA)	On, November 19, 2020, Incyte/Eli Lilly's Olumiant® (baricitinib) received Emergency Use Authorization (EUA) through the FDA to use in combination with Veklury (remdesivir – Gilead Sciences) in hospitalized patients two years of age or older with suspected or laboratory-confirmed COVID-19 infection who require supplemental oxygen, invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). The authorization does not replace the formal FDA review process and is temporary. The first combination therapy authorized, Olumiant on its own is not authorized to treat COVID-19; however, trials are ongoing to determine safety and efficacy. Based on the trial (ACTT-2), patients who used the combination saw improvement in time to recovery from a median of 8 days to 7 days and by day 15, patients treated with the combination had a better clinical status, including a reduced need for ventilation. The combination also saw less mortality by day 29, a relative reduction of 35%. The EUA recommended dose for Olumiant is 4mg once daily for 14 days or until hospital discharge. Olumiant is also under The EUA fact sheet for healthcare providers is here. For the patient EUA fact sheet see here. Olumiant, is a Janus kinase (JAK) inhibitor previously approved on June 1, 2018, for the treatment of Rheumatoid arthritis (RA). Olumiant (baricitinib) Receives FDA Emergency Use Authorization (EUA)
11.21.2020	Regeneron's Casirivimab/ Imdevimab Antibody Receives Emergency Use Authorization (EUA)	On November 21, 2020, Regeneron Pharmaceuticals received Emergency Use Authorization (EUA) for their combination monoclonal antibody (Mab) cocktail, casirivimab and imdevimab (REGN-COV2). The EUA was granted based on data from an outpatient trial in September showing that the drugs reduced both viral load and time to alleviate symptoms. Following a positive COVID-19 viral test, the combination can be administered in patients with mild to moderate COVID-19, at high risk for progressing to severe COVID-19 and/or hospitalization and who are

		12 years of age and older weighing more than 40kg. For best results, it should be administered as soon as possible in an outpatient setting. The authorization excludes patients that are hospitalized or using oxygen treatment for any condition. Regeneron expects to have completed the distribution of 300,000 doses by the end of January 2021. As part of Operation Warp Speed, the drug will be provided at no cost to patients, however, healthcare providers may charge an administration fee. The recommended dose is 1200mg of each component, casirivimab and imdevimab, for a total of 2400mg in a single intravenous infusion. The EUA, which is temporary, does not replace the formal FDA review process. The factsheet for healthcare providers can be found here and for patients here. Regeneron's Casirivimab/Imdevimab Antibody Receives Emergency Use Authorization (EUA)
12.11.2020	Emergency Use Authorization for the First COVID Vaccine	As expected, the U.S. Food and Drug Administration (FDA) followed its independent Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommendation to approve an emergency use authorization (EUA) for the Pfizer/BioNTech COVID-19 vaccine, BNT162b2, on Dec. 11, 2020. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) gave its authorization on Dec. 12, 2020, allowing distribution to begin. Administered as two intramuscular (IM) injections at least three weeks apart, the vaccine is indicated to prevent COVID-19 for individuals age 16 years and older. The first vaccine that is based on mRNA, BNT162b2 must be stored at ultra-low temperatures. Under Operation Warp Speed, shipments to more than 600 designated distribution centers began immediately, with the Federal Aviation Administration (FAA) giving priority airspace to planes carrying the vaccine. Initially, each state will receive a supply of vaccine decided by the state's population and administered according to state rules. Most of the first immunizations are earmarked for front-line healthcare workers and the residents and staff of long-term care facilities. The EUA is provided with a factsheet for healthcare providers found here. The EUA factsheet that should be provided to recipients and caregivers can be found here. Pfizer-BioNTech COVID-19 Vaccine Receives Emergency Use Authorization (EUA)
12.18.2020	Second COVID-19 Vaccine Approved Under Emergency Use Authorization	The U.S. Food and Drug Administration (FDA) granted an emergency use authorization (EUA) on Dec. 18, 2020, for Moderna's vaccine to prevent COVID-19. Approval on the following day from the Centers for Disease Control and Prevention (CDC) allowed for immediate shipping. The first doses are expected to be given on Dec. 21, 2020. Administered by intramuscular (IM) injection, it needs two 100mcg doses that are 28 days apart to be fully effective. Because it can withstand higher temperatures, handling for Moderna's vaccine is less complicated than transporting and administering Pfizer's COVID-19 vaccine, which got an EUA earlier in December. No cost will be charged for the vaccine, although administration fees may apply in some cases. Moderna plans to provide the U.S. with enough doses for 10 million patients by the end of 2020. An additional 180 million doses have been contracted by the U.S government with the possibility of 300 million more in negotiation. Operation Warp Speed will manage allotment and delivery to regional distribution centers. Here is Moderna's Fact Sheet for providers of its COVID-19 vaccine and here is one for patients. Second COVID-19 Vaccine Approved Under Emergency Use Authorization
2.9.2021	Etesevimab and Bamlanivimab Receive Emergency Use Authorization	On Feb. 9, 2021, Eli Lilly received emergency use authorization (EUA) to use two investigational products, etesevimab and bamlanivimab, together to treat adult and pediatric patients 12 years of age and older weighing at least 40kg for mild to moderate COVID-19, as confirmed by a viral test, and who are high risk for progressing to severe COVID-19 and/or hospitalization. The combination is not authorized for patients who have COVID-19 if they are hospitalized or on oxygen therapy. The combination will be administered as a single intravenous (IV) infusion at a dose of 1,400mg etesevimab and 700mg bamlanivimab as soon as possible following a positive COVID-19 test and within 10 days of symptoms starting. In the trial that led to its approval, patients given the combination had a 70% reduction in death or hospitalization. Patients and caregivers should be given a fact sheet found here, and one for healthcare providers is here. The EUA, which is temporary,

		does not replace the formal FDA review process. The EUA includes a warning about possible infusion-related reactions as well as a risk of anaphylaxis. Etesevimab and Bamlanivimab Receive Emergency Use Authorization