FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF COVID-19 CONVALESCENT PLASMA FOR TREATMENT OF COVID-19 IN HOSPITALIZED PATIENTS

You are being given COVID-19 convalescent plasma to treat COVID-19. This fact sheet contains information to help you understand the risks and benefits of taking the COVID-19 convalescent plasma you have received or may receive.

There is no U.S. Food and Drug Administration (FDA) approved product available to treat COVID-19. Transfusion of COVID-19 convalescent plasma may benefit patients hospitalized with COVID-19.

Read this Fact Sheet for information about COVID-19 convalescent plasma. Talk to your health care provider if you have questions. It is your choice to accept treatment with COVID-19 convalescent plasma or stop it at any time.

WHAT IS COVID-19?

You have been diagnosed with disease caused by the SARS-CoV-2 virus also known as coronavirus disease 2019 (COVID-19). This type of coronavirus has not been seen before. This new virus has caused a worldwide pandemic with many patients developing severe respiratory illness and other serious complications. You can get COVID-19 through contact with another person who has the virus.

WHAT ARE THE SYMPTOMS OF COVID-19?

Common symptoms are fever, cough, and shortness of breath, which may appear 2-14 days after exposure. COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID- 19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe chronic medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

WHAT IS COVID-19 CONVALESCENT PLASMA?

The blood from people who recover from COVID-19 contains substances called antibodies, which are capable of fighting the virus that causes the illness. For some other diseases caused by respiratory viruses, giving people the liquid portion of blood that contains these antibodies, called plasma, obtained from those who have recovered from the virus, may lead to more rapid improvement of the disease. Patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.

HOW IS COVID-19 CONVALESCENT PLASMA GIVEN?

You will be given plasma, the liquid portion of the blood, from a person who has recovered from COVID-19. It will be given into one of your veins, using a sterile single use needle, and will be given over the course of up to about one to two hours. Approximately 200 mL (a little less than 8 ounces) of plasma will be given in an initial infusion. Additional infusions of plasma may occur throughout your hospital stay if the treating physician determines that additional treatments are clinically justified.

WHAT ARE THE POSSIBLE BENEFITS OF GETTING COVID-19 CONVALESCENT PLASMA?

This treatment might be effective in improving the likelihood of you recovering from the disease.

WHAT ARE THE COMMON AND/OR POSSIBLE SIDE EFFECTS (RISKS) OF COVID-19 CONVALESCENT PLASMA?

Transfusion carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload, or lung damage with profound breathing difficulty, cardiac (heart) rhythm irregularities, and blood clotting.

As with receipt of any blood product, there is a risk of transfusion-transmitted infection including HIV, hepatitis B, and hepatitis C. The risk of these infections is very low, because only screened blood is used for transfusion.

You may have other side effects that are not known at this time and may include serious injury or pain, disability, or death. There is also a chance that confidentiality of your private information could be lost; however, procedures are in place to minimize this risk.

WHO SHOULD NOT GET COVID-19 CONVALESCENT PLASMA?

Discuss with your health care provider if previously you had any reactions to plasma products or other blood products.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

The safety and effectiveness of COVID-19 convalescent plasma in pregnancy and nursing mothers has not been evaluated. If you are pregnant or breastfeeding, please talk with your health care provider to decide if you should receive COVID-19 convalescent plasma.

HOW DO I REPORT SIDE EFFECTS?

After receiving COVID-19 convalescent plasma, if you are experiencing any side effects that are bothersome, serious, or that do not go away, please contact your health care provider. When you are reporting a side effect, you should identify that you received COVID-19 convalescent plasma.

ARE THERE OTHER ALTERNATIVES TO COVID-19 CONVALESCENT PLASMA?

There are no drugs or other therapeutics approved by the FDA to prevent or treat COVID-19 infection. Like convalescent plasma, FDA may allow for the emergency use of other medicines to treat people in the hospital with COVID-19.

In addition, your health care provider may talk to you about clinical trials you may be eligible for. It is your choice to be treated or not to be treated with COVID-19 convalescent plasma. You can decide not to get it or stop it at any time. Whether you decide to take COVID-19 convalescent plasma or not, it will not change your standard medical care. You may be given other available treatments that may include oxygen, fluids, and medications depending on your condition and determined by your doctor.

HOW CAN I LEARN MORE?

1. Ask your health care provider
2. Contact your local or state public health department

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made COVID-19 convalescent plasma available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

COVID-19 convalescent plasma has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate,

approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product. All of these criteria must be met to allow for the authorized product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for COVID-19 convalescent plasma is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).