Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of ACTEMRA® (tocilizumab) for Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you or your child with ACTEMRA for the treatment of coronavirus disease 2019 (COVID-19). Taking ACTEMRA may benefit certain people in the hospital with COVID-19 who are receiving corticosteroids and require supplemental oxygen, or a machine that helps with their breathing (ventilator) or a machine that adds oxygen to the blood outside the body (extracorporeal membrane oxygenation or ECMO). This Fact Sheet contains information to help you understand the risks and benefits of taking ACTEMRA you or your child have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make ACTEMRA available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). ACTEMRA is not FDA-approved for use in patients with COVID-19 under 18 years of age. Read this Fact Sheet for information about ACTEMRA. Talk to your or your child's healthcare provider about your options or if you have any questions. It is your choice for you or your child to take ACTEMRA or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. You or your child can get COVID-19 through close contact with another person who has the virus.

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 happen and may cause some of your or your child's other medical conditions to become worse. Older people and people of all ages with severe, long lasting (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 are the symptoms of COVID-19?
The symptoms of COVID-19 are fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness, including breathing problems, can occur and may cause your or your child's other medical conditions to become worse.

What is ACTEMRA?
ACTEMRA is a FDA-approved prescription medicine that is used to treat adults with moderately to severely active rheumatoid arthritis (RA), after at least one other medicine called a Disease-Modifying Anti-Rheumatic Drug (DMARD) has been used and did not work well, to treat adults with giant cell arteritis (GCA), for slowing the rate of decline in lung function in adults with systemic sclerosis-associated interstitial lung disease (SSc-ILD), and to treat people aged 2 years and older with polyarticular juvenile idiopathic arthritis, systemic

juvenile idiopathic arthritis, and chimeric antigen receptor (CAR) T-cell induced severe or life-threatening Cytokine Release Syndrome (CRS). ACTEMRA is FDA-approved to treat COVID-19 in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrance oxygenation (ECMO). ACTEMRA is not authorized for subcutaneous use in people with COVID-19.

There is limited information known about the safety or effectiveness of using ACTEMRA to treat children in the hospital with COVID-19. Available results from clinical trials in adults indicate that treatment with ACTEMRA may decrease the risk of dying in hospitalized patients with COVID-19 who are receiving corticosteroids and who require supplemental oxygen, or a ventilator or ECMO. The safety and effectiveness of ACTEMRA have not been studied in children hospitalized with COVID-19.

The FDA has authorized the emergency use of ACTEMRA for the treatment of COVID-19 in hospitalized children (2 years of age and older) who are receiving corticosteroids and who require supplemental oxygen, or a ventilator or ECMO under an EUA. For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

What should I tell my or my child's healthcare provider before I or my child take ACTEMRA?

Tell your or your child's healthcare provider if you or your child:

- Have an infection other than COVID-19
- Have liver problems
- Have any stomach-area pain or have had diverticulitis or ulcers in your stomach or intestines
- Have any allergies, including to any of the ingredients in ACTEMRA
- Have or had a condition that affects your nervous system, such as multiple sclerosis
- Have recently received or are scheduled to receive a vaccine
- Plan to have surgery or a medical procedure
- Are pregnant or plan to become pregnant
- Are breast-feeding a child or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, or herbal products)

How will I receive ACTEMRA?

ACTEMRA is given to you or your child through a vein (intravenous or IV) 1 time as a single dose. If you or your child do not improve after receiving one dose of ACTEMRA, a second dose may be given at least 8 hours after the first dose.

Who should generally not take ACTEMRA?

Do not take ACTEMRA if:

You or your child are allergic to tocilizumab, the active ingredient in ACTEMRA, or any of the ingredients in ACTEMRA. For a complete list of ingredients in ACTEMRA, refer to the Medication Guide for ACTEMRA® (tocilizumab) at https://www.gene.com/download/pdf/actemra_medguide.pdf.

What are the important possible side effects of ACTEMRA?
The most important side effects of ACTEMRA are:

Serious infections: ACTEMRA is a medicine that affects your or your child's immune system. ACTEMRA can lower the ability of your or your child's immune system to fight infections other than COVID-19.

ACTEMRA can make you or your child more likely to get infections or worsen any infection that you or your child have, other than COVID-19.

Tears (perforation) of the stomach or intestines: Some people taking ACTEMRA get tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.

Liver problems (hepatotoxicity): Some people taking ACTEMRA have experienced serious life-threatening liver problems, which required a liver transplant or led to death.

Changes in certain laboratory test results: Your or your child's healthcare provider should do blood tests before you or your child start receiving ACTEMRA. You or your child should not receive ACTEMRA if your or your child's neutrophil (white blood cells that help the body fight off bacterial infections) or platelet (blood cells that help with blood clotting and stop bleeding) counts are too low or your or your child's liver function tests are too high.

Allergic reactions: Tell your or your child's healthcare provider right away if you or your child have symptoms such as rash, swelling of your lips, tongue, or throat, or hives (raised red patches of skin that are often very itchy). This may mean you or your child are having an allergic reaction.

Nervous system problems: While rare, Multiple Sclerosis has been diagnosed in people who take ACTEMRA. It is not known what effect ACTEMRA may have on some nervous system disorders.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

For more information see the Medication Guide for ACTEMRA® (tocilizumab), at https://www.gene.com/download/pdf/actemra_medguide.pdf.

What other treatment choices are there?

Like ACTEMRA, FDA may allow for the emergency use of other medicines to treat people in the hospital with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19. Please consult your or your child's healthcare provider on which medicine or combination of medicines might be right for you or your child. Your or your child's healthcare provider may talk with you about clinical trials you or your child may be eligible for.

It is your choice for you or your child to be treated or not to be treated with ACTEMRA. Should you decide not to receive it or for your child to not receive it, it will not change your or your child's standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience giving ACTEMRA to pregnant women or breastfeeding mothers. ACTEMRA may harm your unborn baby. It is unknown if ACTEMRA passes into your breast milk. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

Pregnancy exposure registry
Genentech has a registry for pregnant women who take ACTEMRA. The purpose of this registry is to check the health of the pregnant mother and her baby. If you are pregnant or become pregnant while taking ACTEMRA, talk to your healthcare provider about how you can join this pregnancy registry or you may contact the registry at 1-877-311-8972 to enroll.

How do I report side effects or adverse events with ACTEMRA?
Contact your or your child's healthcare provider if you or your child have any side effects that bother you or do not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Genentech, Inc. by calling 1-888-835-2555.

How can I learn more about COVID-19?
- Ask your or your child's healthcare provider
- Visit https://www.cdc.gov/COVID19
- Contact your local or state public health department

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

ACTEMRA as a treatment for COVID-19 in children has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of

scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of patients during the COVID-19 pandemic.

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

This Fact Sheet may be updated as new data become available. The most recent version of this Fact Sheet is available at https://www.gene.com/download/pdf/actemra_eua_patient_fact_sheet.pdf for download.

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