Fact Sheet for Patients and Caregivers
Emergency Use Authorization (EUA) of
GOHIBIC for
Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with GOHIBIC (vilobelimab) for the treatment of coronavirus disease 2019 (COVID-19). Taking GOHIBIC may benefit adults in the hospital with COVID-19 who require a machine that helps with breathing (invasive mechanical ventilation) 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 potential risks and potential benefits of receiving GOHIBIC.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make GOHIBIC available for use as a treatment for certain adults with COVID-19 (for more details about EUA please see "**What is an Emergency Use Authorization**?" at the end of this document). GOHIBIC is not FDA-approved for this use. Read this Fact Sheet for information about GOHIBIC. Talk to your healthcare provider about your options or if you have any questions. It is your choice for you to take GOHIBIC or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through 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 other medical conditions to become worse. 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 may include fever, cough, and shortness of breath, which can appear 2 to 14 days after exposure. Serious illness, including breathing problems, can occur and may cause your other medical conditions to become worse.

What is GOHIBIC?
GOHIBIC is an investigational medicine used for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). GOHIBIC is investigational because it is still being studied. GOHIBIC is not FDA-approved to treat COVID-19.

There is limited information known about the safety or effectiveness of using GOHIBIC to treat people in the hospital with COVID-19. Available results from clinical trials in adults indicate that treatment with GOHIBIC may decrease the risk of dying in hospitalized adults with COVID-19 when initiated within 48 hours of receiving invasive mechanical ventilation or ECMO. The safety and effectiveness of GOHIBIC have not been studied in children hospitalized with COVID-19.

The FDA has authorized the emergency use of GOHIBIC for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation 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 healthcare provider before I receive GOHIBIC?
Tell your healthcare provider about all of your medical conditions including if you:

- Have allergies.
- Have an infection other than COVID-19.
- Are pregnant or plan to become pregnant.
- Are breast-feeding or plan to breastfeed.
- Have any serious illnesses.

Tell your healthcare provider about all the medicines you take, including prescription and, over-the-counter medicines, vitamins, and herbal supplements.

How will I receive GOHIBIC?
GOHIBIC is given to you through a vein (intravenous or IV) as an infusion. GOHIBIC will be given up to six doses. The first dose will be given within 48 hours of a tube being inserted (intubation) and a machine to help you breathe (ventilator), this is Day 1. The following administration of GOHIBIC will be given on Days 2, 4, 8, 15, and 22 as long as you are hospitalized [even discharged from the Intensive Care Unit (ICU)].

What are the important possible side effects of GOHIBIC?
GOHIBIC may cause serious side effects, including:

- **Serious infections: GOHIBIC** is a medicine that affects your immune system. **GOHIBIC** can lower the ability of your immune system to fight infections other than COVID-19.
- **Allergic Reactions:** Serious allergic reactions can happen during or after treatment with **GOHIBIC**. These reactions may be severe or life-threatening.

  Signs and symptoms of a serious allergic reaction with GOHIBIC may include:

  - trouble breathing
  - rash
  - swelling of your face, eyes, lips mouth, tongue and throat.

The most common side effects of GOHIBIC may include: Lung infection, sepsis, sudden confusion, sudden lung artery blockage, high blood pressure, collapsed lung, venous blood clotting (usually in the leg), herpes infection, certain infections caused by enterococci, urinary tract infection, low blood oxygenation, low platelets, the presence of air in the space in the chest between the two lungs, infection of the respiratory tract, heart arrythmia, constipation, and rash.

What other treatment choices are there?
Olumiant (baricitinib), Actemra (tocilizumab), and Veklury (remdesivir) are FDA-approved medicines for the treatment of COVID-19 in hospitalized patients who require invasive mechanical ventilation or ECMO. Talk with your healthcare provider to see if those therapies are appropriate for you. Like GOHIBIC, FDA may allow for the emergency use of other medicines to treat people in the hospital with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on emergency use of other medicines that are not approved by FDA to treat people in the hospital with

COVID-19. Please consult with your healthcare provider on which medicine or combination of medicines might be right for you. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with GOHIBIC. Should you decide not to receive it, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is no experience giving GOHIBIC to pregnant women or breastfeeding mothers. GOHIBIC may harm your unborn baby. It is unknown if GOHIBIC passes into your breast milk. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects or adverse events with GOHIBIC?
Contact your healthcare provider if you 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 InflaRx GmbH by calling 1-888-254-0602.

How can I learn more about COVID-19?

- Ask your healthcare provider
- Visit https://www.cdc.gov/COVID19
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made GOHIBIC available under an emergency access mechanism called an 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.

GOHIBIC, as a treatment for COVID-19 has not undergone the same type of review as an FDA-approved product for this indication. The 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 the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for GOHIBIC as a treatment for certain people with COVID-19 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 www.gohibic.com.

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