Frequently Asked Questions on the Emergency Use Authorization for Gohibic (Vilobelimab) Injection for Treatment of COVID-19

Q. What is an emergency use authorization (EUA)?

A. Under section 564 of the Federal Food, Drug & Cosmetic Act, after a declaration by the HHS Secretary based on one of four types of determinations, FDA may authorize an unapproved product or unapproved uses of an approved product for emergency use. In issuing an EUA, FDA must determine, among other things, that based on the totality of scientific evidence available to the agency, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition caused by a chemical, biological, radiological, or nuclear agent; that the known and potential benefits of the product, when used to treat, diagnose or prevent such disease or condition, outweigh the known and potential risks of the product; and that there are no adequate, approved, and available alternatives. Emergency use authorization is NOT the same as FDA approval or licensure.

Q. What does this EUA authorize?

A. This EUA authorizes the emergency use of Gohibic (vilobelimab) injection for the treatment of COVID-19 in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO).

Q: Is Gohibic FDA approved to prevent or treat COVID-19?

A. No, Gohibic is not FDA approved to prevent or treat COVID-19.

Q. Are there potential side effects of Gohibic?

A: Yes, there is a risk of serious infection. The most common adverse reactions with use of Gohibic are pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, hepatic enzyme increased, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash. Serious infections due to bacterial, fungal, or viral pathogens have been reported in patients with COVID-19 receiving Gohibic.

For more information about potential side effects, see the Fact Sheet for Healthcare Providers.

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Q. Are there data showing Gohibic may provide benefit for treatment of COVID-19 in the authorized patient population?

A: The clinical trial supporting the EUA for Gohibic showed that patients treated with Gohibic had a lower risk of death by day 28 and by day 60 of treatment compared to placebo. Details on the clinical trial results can be found in Section 14 of the authorized Fact Sheet for Healthcare Providers.

Q. Are there reporting requirements for health care facilities and providers as part of the EUA?

A. Yes. As part of the EUA, FDA requires health care providers who prescribe Gohibic to report all medication errors and serious adverse events considered to be potentially related to Gohibic through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA's Fact Sheet for Health Care Providers. FDA MedWatch forms should also be provided to the EUA holder, InflaRx.

Q. Can health care providers share the patient/caregiver Fact Sheet electronically?

A. Under the authorization, the EUA holder, InflaRx, must make available the authorized Fact Sheets on its website at: www.gohibic.com. Health care facilities and health care providers must ensure that fact sheets are made available to patients, parents, and caregivers through "appropriate means" and electronic delivery of the Fact Sheet is an appropriate means.