Gohibic™ (vilobelimab) – New emergency use authorization

- On April 4, 2023, the FDA announced the emergency use authorization (EUA) of InflaRx's Gohibic (vilobelimab), for the treatment of coronavirus disease 19 (COVID-19) in hospitalized adults when initiated within 48 hours of receiving invasive mechanical ventilation (IMV), or extracorporeal membrane oxygenation (ECMO).
    - InflaRx plans on submitting a Biologics License Application to the FDA to get full approval.
    - Gohibic will be administered only to hospitalized patients.
- Gohibic is the first authorized drug to control complement factor C5a, a protein that plays an important and often harmful role in the body´s immune response.
- The efficacy of Gohibic was established in PANAMO, a double-blind, randomized, placebo-controlled study. Efficacy analyses were based on 368 adult (≥ 18 years) patients for the treatment of COVID-19 requiring IMV or ECMO. Patients received Gohibic + standard of care (SoC) or SoC alone. The primary endpoint in the study was time to death through day 28.
    - At day 28, 31.7% of the Gohibic + SoC vs. 41.6% of SoC group died (Hazard ratio 0.67; 95% CI: 0.48, 0.96; $p < 0.05$).
- Warnings and precautions for Gohibic include serious infections and hypersensitivity reactions.
- The most common adverse reactions (≥ 3%) with Gohibic use were pneumonia, sepsis, delirium, pulmonary embolism, hypertension, pneumothorax, deep vein thrombosis, herpes simplex, enterococcal infection, bronchopulmonary aspergillosis, increased hepatic enzyme, urinary tract infection, hypoxia, thrombocytopenia, pneumomediastinum, respiratory tract infection, supraventricular tachycardia, constipation, and rash.
- The recommended dose of Gohibic is 800 mg administered by intravenous infusion after dilution for a maximum of 6 (six) doses over the treatment period as described below.
    - Treatment should be started within 48 hours of intubation (day 1) followed by administration on days 2, 4, 8, 15 and 22 as long as the patient is hospitalized (even if discharged from intensive care unit).
- InflaRx launch plans for Gohibic are pending. Gohibic will be available as a 200 mg/20 mL (10 mg/mL) injectable solution in a single-dose vial.
- InflaRx is working to ramp up production at its third-party manufacturer to roll out supply in the U.S. as soon as possible. More detailed information will be supplied once it is available.