To: 5.1.2e , 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e , 5.1.2e . (5.1.2e)[5.1.2e @minvws.nl]
From: 5.1.2e , 5.1.2e . 5.1.2e (5.1.2e)
Sent: Wed 2/10/2021 2:34:58 PM
Subject: FDA emergency use authorization (EUA) for bamlanivimab and etesevimab
Received: Wed 2/10/2021 2:34:58 PM

Ha collega's,

Zoals net beloofd, hierbij het nieuws over de noodtoelating door FDA voor product van Lilly:

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) who test positive for SARS-CoV-2 and who are at high risk for progressing to severe COVID-19. The authorized use includes treatment for those who are 65 years of age or older or who have certain chronic medical conditions.

In a clinical trial of patients with COVID-19 at high risk for disease progression, a single intravenous infusion of bamlanivimab and etesevimab administered together significantly reduced COVID-19-related hospitalization and death during 29 days of follow-up compared to placebo. The safety and effectiveness of this investigational therapy for use in the treatment of COVID-19 continue to be evaluated.

Bamlanivimab and etesevimab are not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. Treatment with bamlanivimab and etesevimab has not been studied in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab and etesevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

"Today's action, which provides another treatment for COVID-19, reflects the FDA's strong commitment to working with sponsors to expand potential treatment options health care providers can use to fight this pandemic," said Patrizia Cavazzoni, M.D., acting director of the FDA's Center for Drug Evaluation and Research. "The data supporting this emergency authorization add to emerging evidence that points to the clinical utility of neutralizing antibodies for the treatment of COVID-19 in certain patients. As part of our Coronavirus Treatment Acceleration Program, the FDA uses every resource at our disposal to make treatments such as these monoclonal antibodies available while continuing to study their safety and effectiveness."

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. Bamlanivimab and etesevimab are monoclonal antibodies that are specifically directed against the spike protein of SARS-CoV-2, designed to block the virus' attachment and entry into human cells. Bamlanivimab and etesevimab bind to different but overlapping sites on the spike protein of the virus.

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available scientific evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA's review of the totality of the scientific evidence available, the agency has determined that it is reasonable to believe that bamlanivimab and etesevimab administered together may be effective in treating certain patients with mild or moderate COVID-19. When used to treat COVID-19 for the authorized population, the known and potential benefits of these antibodies outweigh the known and potential risks. There are no adequate, approved and available alternative treatments to bamlanivimab and etesevimab administered together for the authorized population.

The data supporting this EUA for bamlanivimab and etesevimab are based on a randomized, double-blind, placebo-controlled clinical trial in 1,035 non-hospitalized adults with mild to moderate COVID-19 symptoms who were at high risk for progressing to severe COVID-19. Of these patients, 518 received a single infusion of bamlanivimab 2,800 milligrams and etesevimab 2,800 milligrams together, and 517 received placebo. The primary endpoint was COVID-19 related hospitalizations or death by any cause during 29 days of follow-up. Hospitalization or death occurred in 36 (7%) patients who received placebo compared to 11 (2%) patients treated with bamlanivimab 2,800 milligrams and etesevimab 2,800 milligrams administered together, a 70% reduction. All 10 deaths (2%) deaths occurred in the placebo group. Thus, all-cause death was significantly lower in the bamlanivimab 2,800-milligram and etesevimab 2,800-milligram group than the placebo group.

The authorized dosage of 700 milligrams bamlanivimab and 1400 milligrams etesevimab administered together is based on analyses of available preclinical, clinical, and virologic data, as well as pharmacokinetic

and pharmacodynamic modeling, which, in totality, support that the authorized dosage is expected to have a similar clinical and virologic effect to 2,800 milligrams bamlanivimab and 2,800 milligrams etesevimab administered together.
On Nov. 9, 2020, the FDA issued an EUA for a single infusion of 700 mg bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and certain pediatric patients. While bamlanivimab and etesevimab administered together resulted in a lower risk of resistant viruses developing during treatment compared with bamlanivimab administered alone, both treatments are expected to benefit patients at high risk of disease progression. At present, both 700 milligrams bamlanivimab alone as well as 700 milligrams bamlanivimab and 1,400 milligrams etesevimab administered together will be available under an EUA.

Under the EUA, fact sheets that provide important information about using bamlanivimab and etesevimab administered together in treating COVID-19 as authorized must be made available to health care providers and to patients and caregivers. These fact sheets include dosing instructions, potential side effects and drug interactions. Serious and unexpected adverse events including hypersensitivity, anaphylaxis, and infusion-related reactions have been observed with bamlanivimab with and without coadministration of etesevimab. In addition, clinical worsening following bamlanivimab administration has been reported, although it is not known if these events were related to bamlanivimab use or were due to progression of COVID-19. Possible side effects of bamlanivimab and etesevimab administered together include nausea, dizziness, pruritus, and rash.
The EUA was issued to Eli Lilly and Co.
The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Groet,
5.1.2e

5.1.2e
Ministerie van Volksgezondheid, Welzijn en Sport | Programmadirectie COVID-19 |
Parnassusplein 5 | 2511 VX | Den Haag | Postbus 20350 | 2500 EJ | Den Haag
5.1.2e | 5.1.2e @minvws.nl
www.rijksoverheid.nl