Comunicato n. 695 2 August 2022

AIFA authorises the therapeutic use of the monoclonal Evusheld for the early treatment of COVID-19 in subjects at risk of progression

AIFA's Scientific Technical Committee (STC) has authorised the use of the monoclonal antibody Evusheld (tixagevimab and cilgavimab) in the early treatment of SARS-CoV-2 infected subjects at risk of a severe form of COVID-19. Until now, the medicine was only available for pre-exposure prophylaxis in high-risk subjects. With this extension of indication, AIFA makes available an intramuscular therapeutic option for subjects in whom the prescription of antiviral medicines and authorised monoclonal antibodies is considered inappropriate from a clinical and/or epidemiological point of view (in relation to the circulation of viral variants).

The AIFA's decision to authorise Evusheld for the treatment of patients with COVID-19 anticipates the EMA's assessment, which will be completed in September 2022, and is based on both the results of already published clinical trials and the interim analysis (on approximately 450 patients) of a multicentre study currently underway in Italy (Mantico-2, coordinated by prof.ssa Tacconelli, University of Verona), funded by the Agency with the aim of comparing three different alternatives (Evusheld, Paxlovid and Xevudy) in the early treatment of patients with COVID-19.

Evusheld was therefore included in the list of drugs that can be dispensed by the National Health Service under Law 648/96. For prescribing procedures, please refer to AIFA's institutional website at https://www.aifa.gov.it/registri-e-piani-terapeutici1.

The resolution is published today in the Official Journal and will take effect tomorrow, 3 August 2022.